CCGs and NHS Provider Trusts
in Norfolk and Waveney

NHS

Clinical Responsibility for Prescribing:-

Guidance and Good Practice for Shared Care

Clinical recommendations from the Therapeutics Advisory Group (TAG) and Commissioners' Decisions

Includes NICE recommended drugs
with a synopsis of NICE guidance

Updates notified via
The Prescriber Newsletter
Electronic copies available via
nww.knowledgeanglia.nhs.uk
Feeback and queries to the
TAG Lead Technician -
agem.medicines.norfolk@nhs.net

Report Date: 17 July 2023

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

IQoro euromuscular training niraevice *(Iqoro)*

TAG recommendation: Jul 2022

for use in: Hiatus hernia - improving symptoms (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: IQoro is a neuromuscular training device used for improving symptoms related to hiatus hernia by strengthening the oesophagus and diaphragm. It is initially used daily for 3 to 6 months, with follow up maintenance use dependent upon indival need.

May 2019: The TAG noted NICE MIB 176 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use is supported for this technology.

May 2019: The Norfolk and Waveney CCGs' D&TC was advised that the CCGs' Clinical Policy Development Group may have future involvement in reviewing the use of such devices. The TAG's recommendation was noted and supported by the D&TC.

June 2019: The TAG and the D&TC's recommendation was ratified by the JSCC.

July 2022 - Not commissioned. No NHS prescribing in primary or secondary care.as per PAC guidance statement (May 2022)

Acne treatment - Aknicare® products *(Aknicare® cream, lotion, Skin Roller)*

for use in: Treatment of acne (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding implementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Aknicare® cream and lotion, Aknicare® SR skin roller which stated: Not recommended for prescribing.Those who wish to try Aknicare® products should be directed to purchase them for self care. They should however be advised that benzoyl peroxide-containing OTC products are generally preferred because of the substantial clinical trial evidence to support their use.

The PRG and the TAG agreed with the PAC's recommendation and recommended a classification of Double Red (Not recommended for routine use).

September 2017:
The N&W D&TCG notd and supported the TAG's recommendation - not commissioned.

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- No BNF entry - device

ActiPatch® *(ActiPatch®)* TAG recommendation: Nov 2018

for use in: Relief of musculoskeletal pain (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2018:
The TAG supported the Prescribing Reference Group's recommendation to apply a Double Red (Not recommended for routine use) classification for this product as an interim measure, until a formal application for use is submitted via usual processes.

The TAG's recommendation was supported by the D&TC.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and the D&TC recommendations.

Aldesleukin *(Proleukin)* TAG recommendation: May 2018

for use in: Cancer - metastatic renal cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility - not routinely commissioned - as per IFR approval. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Alipogene tiparvovec *(Glybera®)* TAG recommendation: May 2018

for use in: (Gene therapy treatment for) Lipoprotein lipase deficiency - as per NHSE policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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- No BNF entry - device

Alpha-mannosidase - recombinant human *(Lamazym®)*

TAG recommendation: May 2018

for use in: Alpha Mannosidase deficiency - as per NHSE policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre use only - IFR approval required.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Antioxidant - ubiquinone aka ubidecarenone *(Co Enzyme Q10)*

TAG recommendation: Jul 2010

for use in: Any indication - as per N&W DROP List (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: GPs are advised to stop prescribing on the basis of there being no robust evidence for use. Included in the Norfolk & Waveney DROP List.

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- No BNF entry - device

Antioxidant nutritional supplements (many brands) *(Ocuvite PreserVision ICAPS MacuLEH Viteyes Vitalux)* TAG recommendation: Jul 2015

for use in: Eye health - including to prevent or slow the progression of AMD, or prevent cataracts - as per N&W DROP List - brands include Ocuvite PreserVision ICAPS

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2010:
Not recommended on the basis of being unlicensed for use in AMD and there being no robust evidence for use.

May 2015:
Revisit of previous TAG recommendation - confirmation of appropriateness of Double Red traffic light classification following review of latest available evidence.
Key Evidence Resources:
* PrescQIPP guidance on Lutein and antioxidant vitamins for prevention of AMD
* Cochrane reviews of antioxidant vitamins and supplements for preventing the development of and slowing the progression of AMD, and in the prevention of cataracts
* NTAG Appraisal Report on Multivitamins supplements for the prevention of AMD and related decision

Classified by TAG as Double Red (Not recommended for routine use) in July 2010 due to being unlicensed in AMD and lacking robust evidence to support use in the NHS.
The TAG noted the evidence against routine use of lutein and antioxidant vitamins in eye conditions as outlined in the PrescQIPP bulletin 86 and in reviews by the Cochrane collaboration.
The TAG noted and supported the PRG's recommendations to maintain the Double Red classification for these products, and to add "prevention of cataracts" to the clinical indications listed on the TAG's recommendations database.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these treatments remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Several branded products are available including Macushield Gold, Ocuvite PreserVision, ICAPS, MacuLEH, Viteyes, Vitalux

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- No BNF entry - device

Anti-Pseudomonas aeruginosa antibody *()*

TAG recommendation: May 2018

for use in: Cystic fibrosis - NHSE policy - IFR approval (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Armour Thyroid / any unlicensed thyroid products *(Armour Thyroid)*

TAG recommendation: Jan 2018

for use in: Any indication (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2018:
The TAG considered and supported PrescQIPP Guidance on Items which should not be routinely prescribed in primary care (Bulletin 203 (December 2017) v2.0 - and recommended applying a Double Red classification to this teatment for any indication related to the management of hypothyroidism.

January 2018: The Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation - Not commissioned.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TCG's recommendation.

January 2019: The TAG considered and supported RMOC guidance which recommended against NHS provision of Armour thyroid and other unlicensed thyroid extract products, plus compounded thyroid hormones, iodine-containing preparations, dietary supplementation for any indication.

Double Red - 'Not recommended for routine use / Not commissioned'

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- No BNF entry - device

Atacicept *()* TAG recommendation: May 2018

for use in: Systemic Lupus Erythematosus (SLE) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
Atacicept is a recombinant fusion protein containing the extracellular ligand-binding portion of human TACI (transmembrane activator and calcium modulator and cyclophilin-ligand interactor) receptor linked to the Fc portion of human IgG. It binds BLyS (BAFF) and APRIL (a proliferation-inducing ligand) and limits B-cell differentiation, maturation and survival.
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Autologous serum eye drops *()* TAG recommendation: May 2018

for use in: Dry eye (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
Commissioning responsibility for this treatment is uncetain.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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- No BNF entry - device

Axonics sacral neuromodulation system *(Axonics sacral neuromodulation system)* TAG recommendation: Jan 2019

for use in: Overactive bladder and faecal incontinence (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE MIB 164 (December 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for its use is supported for this technology.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Bamboo bedding (incl sheets, pillow cases) *(Symmetrikit® bamboo sheet and cushion covers)* TAG recommendation: Jul 2017

for use in: Care of very disabled patients with severe physical needs - as per N&W DROP List (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add Bamboo bedding to the Norfolk & Waveney DROP List since these should be provided through a specialist service and not on prescription, only after specialist assessment.
The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of any these products is submitted.

July 2017: Noted and supported by the D&TCG - Not commissioned

Begelomab *(Begedina®)* TAG recommendation: May 2018

for use in: Graft versus Host Disease (GvHD) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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- No BNF entry - device

Belatacept *(Nulojix®)* TAG recommendation: Nov 2017

for use in: Initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE TAs 481 & 482 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TAs 481 and 482 (Oct 17) which state that belatacept is not recommended by NICE as an initial treatment to prevent organ rejection in adults having a kidney transplant.

The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for these indications.

Belladonna adhesive plaster *()* TAG recommendation: Sep 2017

for use in: As a counter irritant for pain relief (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Belladonna adhesive plasters for pain relief and agreed to support the PRG's Double Red (Not recommended for routine use) recommendation.

September 2017:
The N&W D&TCG noted and supported the PRG and the TAG's recommendations - Not commissioned.

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- No BNF entry - device

Beta-carotene (supplements containing) *(Various)* TAG recommendation: Jul 2017

for use in: Secondary prevention of MI / reduce cardiovsacular risk post MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.2.4 Advise people not to take supplements containing beta-carotene. Do not recommend antioxidant supplements (vitamin E and/or C) or folic acid to reduce
cardiovascular risk. [2007]

Bezlotoxumab *(Zinplava®)* TAG recommendation: Nov 2019

for use in: Prevention of recurrent clostridium defficile infection (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA601 - September 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for routine use/not commissioned) for this CCG commissioning responsibility treatment.

Bimagrumab *((BYM338))* TAG recommendation: May 2018

for use in: Inclusion body myositis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility - not routinely commissioned. Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

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- No BNF entry - device

Bioidentical HRT *(Bioidentical hormone replacement therapy)* TAG recommendation: Jul 2017

for use in: Menopausal symptoms - as per N&W DROP List (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add Bioidentical HRT to the Norfolk & Waveney DROP List due to no evidence of additional benefit and not recommended by NICE NG 23 (November 2013) Menopause: diagnosis and management.
The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) for these products.

July 2017: Noted and supported by the D&TCG - Not commissioned

Blisibimod *()* TAG recommendation: May 2018

for use in: Systemic lupus erythematosus (SLE) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Braun Diveen *(Braun Diveen)* TAG recommendation: Apr 2020

for use in: Women with stress urinary incontinence (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2020 - The PRG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). There is a lack of evidence regarding effectiveness of this item. A business case would need to be submitted for review if anyone wishes to use these in future.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

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Brincidofovir *((CMX001))* TAG recommendation: May 2018

for use in: CMV infection (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Catridecacog *(NovoThirteen®)* TAG recommendation: May 2018

for use in: Congenital factor XIII A-subunit deficiency (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Cenegermin eye drops ▼ *(Oxervate ▼)* TAG recommendation: Jul 2017

for use in: Treatment of moderate or severe neurotrophic keratitis - as per NICE TA 532 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG noted a positive scientific opinion has been issued to the manufacturer, Dompe for Oxervate eye drops under the NHS England Early Access to Medicines Scheme (EAMS) and agreed to recommend a position statement of:
"CCGs will not automatically continue to fund treatment for patients initiated under the EAMS scheme upon the product becoming licensed unless a positive NICE TA is in place. It is the responsibility of initiating Trusts to ensure funding is available for the continuation of treatment once a product licence is granted until a positive NICE TA is published"
The TAG also recommended an interim traffic light classification of Double Red (Not recommended for routine use) until national guidance recommending its use is published and a local business application is submitted and supported.

July 2017: The D&TCG noted and supported the TAG's recommendation and decided to classify this treatment as Double Red (Not recommended for routine use) in the interim, until national guidance recommending its use is published and a local business application is submitted and supported.

September 2018: The TAG noted NICE TA 532 (July 2018) and reaffirmed a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

September 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

Ceralifimod *((ONO-4641))* TAG recommendation: May 2018

for use in: Multiple sclerosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. As per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Cerebrotech Visor *(Cerebrotech Visor)* TAG recommendation: Jan 2019

for use in: For detecting stroke (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE MIB 165 (December 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for its use is supported for this technology.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG recommendation.

Cerliponase *(Brineura®)* TAG recommendation: May 2018

for use in: Neuronal Ceroid Lipofuscinosis, type 2 (CLN2) from birth, also known as tripeptidyl peptidase 1 (TPP1) deficiency (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. As per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Cochlear implants *(Various)* TAG recommendation: May 2019

for use in: For children and adults with severe to profound deafness - specialist commissioned use only as per NHSE policy (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019:
The TAG noted NICE TA 566 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) since these would not be provided by local NHS Trusts. NHSE-commissioning responsibility.

May 2019:
The TAG's recommendation was noted and supported by the D&TC.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Co-enzyme Q10 *(Healthcrafts, Nature's Best, Lamb, Natrahealth etc)*

TAG recommendation: Nov 2015

for use in: All indications - as per N&W DROP List and NICE NG 71 & 181 Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: November 2015:
Use in mitochondrial disorders not recommended.
As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.44 Do not offer coenzyme Q10 or vitamin D to increase adherence to statin treatment

September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of co-enzyme Q10 as pharmacological neuroprotective therapy in Parkinson's disease - Do Not Do.

Combination analgesics with caffeine *()*

TAG recommendation: Jan 2018

for use in: Pain relief (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2018: PRG request (April 2017) that the TAG considers applying a Double Red (Not recommended for routine use use) classification to these products to formalise their classification.
The TAG agreed to support the PRG's recommendations.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Combination products - new co-drugs *(Various)*

TAG recommendation: Nov 2010

for use in: Various (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: This is general advice on combined products newly coming to market. The TAG acknowledges that there are several treatments in established use which are combined products e.g. HRT, vaccines, inhaled medication for respiratory disease. However the TAG wishes to discourage use of newer, particularly oral products offering fixed combinations of established drugs which have been marketed to extend patent life. The TAG takes the view that in general patient care is best served where medicines are titrated to individual need whilst optimising use of NHS resources.

Creams - tretinoin, hydroquinone & corticosteroid *(Tri-Luma®, Melanorm-HC, Pigmanorm®)*

TAG recommendation: Jul 2017

for use in: Melasma (Chloasma) - as per N&W DROP List (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add combination topical products for Melasma / Chloasma containing tretinoin, hydroquinone and a corticosteroid
e.g. Tri-Luma® cream containing tretinoin 0.05%, hydroquinone 4% and fluocinolone acetonide 0.01%
e.g. Melanorm-HC Cream containing tretinoin 0.05%, hydroquinone 2% and hydrocortisone 1%
e.g. Pigmanorm® Cream contains tretinoin 0.1%, hydroquinone 5%, hydrocortisone 1%
to the Norfolk & Waveney DROP List due to them having limited evidence for benefit available other than from the company and not being licensed in the UK. Other similar products also not supported.

The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of any these products is submitted.

Jul 2017: Noted and supported by the D&TCG - Not commissioned

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Cycloidal vibration accessories (Vibro-pulse) *(Vibro-pulse® accessories)* TAG recommendation: Sep 2017

for use in: Therapy for cellulitis, venous leg ulcers and lower limb oedema (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Cycloidal vibration accessories e.g. Vibro-pulse® accessories related to Therapy for cellulitis, venous leg ulcers and lower limb oedema, which are Not recommended due to there currently being insufficient evidence to recommend the use of cycloidal vibration therapy.

The PRG and the TAG recommended a Double Red classification for these items.

September 2017:
Noted and supported by the N&W D&TCG.

Darvadstrocel *(Alofisel®)* TAG recommendation: Mar 2019

for use in: Complex perianal fistulas in adults with non-active or mildly active luminal Crohn's disease - as per NICE TA 556 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE TA 556 (January 2019) which did not recommend use of this treatment.
The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) of this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Deep Brain Stimulation (DBS) *(Deep Brain Stimulation (DBS))* TAG recommendation: Sep 2015

for use in: Treatment of refractory epilepsy - as per NHS England policy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D03/P/c (D03X05) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Deep Brain Stimulation (DBS) *(Deep Brain Stimulation (DBS))* TAG recommendation: Sep 2015

for use in: Treatment of Chronic Neuropathic Pain - as per NHS England policy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D08/P/d (D08X07) (July 2015) (NHS England Commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Deodorants (stoma) *(Various)* TAG recommendation: Sep 2017

for use in: Odour management related to stoma (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of specific deodorants for odour management related to stoma.
Agreed as not recommended for prescribing on the NHS in line with current local advice in Key Message Bulletin Number 21 - http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/bulletin/kbulletin21_stoma_accessories.pdf.

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG - Not commissioned.

Diclofenac *(Flector Tissugel medicated plaster 140mg)* TAG recommendation: Jan 2019

for use in: Pain relief (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2019: The TAG supported the PRG's recommendation and agreed that the traffic light classification for NSAID plasters should be Double Red (Not recommended for routine use).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Diclofenac *(Voltarol 140mg medicated plaster)* TAG recommendation: Jan 2019

for use in: Pain relief (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2019: The TAG supported the PRG's recommendation and agreed that the traffic light classification for NSAID plasters should be Double Red (Not recommended for routine use).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Dietary supplements (non nutritional use) *(Various - see full entry below)* TAG recommendation: Jul 2010

for use in: Various non nutrition-related indications - see full entry and N&W DROP List (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG agreed to the following recommendations:
GPs are advised to stop prescribing the following:
* Ocuvite PreserVision, ICAPS, Viteyes - on the basis of being unlicensed for use in AMD and there being no robust evidence for use in cataracts
* Co Enzyme Q10 - on the basis of there being no robust evidence for use
* Glucosamine, Glucosamine & Chondroitin - on the basis of NICE CG for osteoarthritis in adults states that these products are not recommended. Available to purchase without prescription at a 10th of the cost to the NHS.
* Omega 3 fish oils including Omacor - patients should be encouraged to take healthy dietary measures to increase their intake of fish oils
* Evening Primrose Oil / gamolenic acid - Blacklisted products which should not be prescribed
* Homeopathic remedies - on the basis that the House of Commons Science & technology Committee report on Homeopathy (Feb 2010) recommended that these products should not be funded by the NHS.

Doxepin *()* TAG recommendation: Nov 2019

for use in: Antidepressant (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2019 - It was agreed to award a classification of Double Red (Not recommended for use / Not commissioned). This was supported by the D+TC and ratified by JSCC.

Doxepin *()* TAG recommendation: Nov 2019

for use in: Urticaria in dermatology (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. A traffic light classification of Double Red (Not recommended for routine use/Not commissioned).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Drisapersen *((PRO051 / GSK2402968))* TAG recommendation: May 2018

for use in: Duchenne Muscular Dystrophy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
An experimental drug that is under development for the treatment of Duchenne muscular dystrophy. The drug is a 2'-O-methyl phosphorothioate oligonucleotide that alters the splicing of the dystrophin RNA transcript, eliminating exon 51 from the mature dystrophin mRNA.

May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Edtratide *((hCDR1))* TAG recommendation: May 2018

for use in: Systemic lupus erythematosus (SLE) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Efalex *(Efalex)* TAG recommendation: Sep 1998

for use in: Dyslexia - as per N&W DROP List (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not a licensed medicine. Supplements not recommended for prescribing - included in the N&W DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Electronic cigarettes *(e-cigarettes)* TAG recommendation: Nov 2019

for use in: Tobacco dependence / smoking reduction or cessation - as per Public Health guidance (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2013.

Specific points: July 2013: The TAG and the NHS N&W D&TCG noted NICE guidelines PH45 (June 2013) Smoking: harm reduction.

Smoking cessation aids and support services are acknowledged as being the commissioning responsibility of Public Health.

March 2016:
The TAG supported the East of England Priorities Advisory Committee (PAC) guidance statement on Electronic cigarettes (e-cigarettes) for tobacco dependence. The PAC recommends that electronic cigarettes are not prescribed for tobacco-dependent patients until there is evidence to suggest that they achieve their outcome of enabling patients to stop smoking. The evidence at the moment does not appear to be promising.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) which was supported by the N&W CCGs' D&TCG.

May 2018: The TAG noted NICE NG 92 (March 2018) - Stop smoking interventions and services , which updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).

December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. The PAC interim guidance to include Voke Inhaler were noted and supported. The traffic light classification of Double Red (Not recommended for routine use/not commissioned.) to remain.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Elosulfase alpha ▼ *(Vimizim® ▼)* TAG recommendation: Sep 2015

for use in: Treatment of Mucopolysaccharidosis IV Type A (MPS IVA) (Morquio A syndrome) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted E06/P/b (E06X02) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned pending a final decision from NICE as part of its Highly Specialised Technology Appraisal process.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

January 2016:
The TAG noted NICE Highly Specialised Technology Appraisal HST2 (December 2015) which recommended use of Elosulfase alfa (Vimizim®) for treatment of mucopolysaccharidosis type Iva only if the managed patient access agreement is signed up to.

The TAG noted NICE Highly Specialised Technology Appraisal HST2 (December 2015) for this SCG-commissioning responsibility treatment and will await further commissioning information from NHS England.

January 2016:
The N&W CCG's D&TCG noted NICE Highly Specialised Technology Appraisal HST2 (December 2015) and the TAG's recommendation for this SCG-commissioning responsibility treatment.

Emricasan *()* TAG recommendation: May 2018

for use in: Non alcoholic steatohepatitis (NASH) fibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Epifix® *(Epifix®)* TAG recommendation: Mar 2018

for use in: Chronic wounds (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG considered the PRG's recommendation to apply a Double Red (Not recommended for routine use) classification to this treatment on the basis of a lack of sufficient evidence to justify the significant cost of this product:
The TAG agreed to support the PRG's recommendation.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

Epratuzumab *(Epratucyn® Epratucyn)* TAG recommendation: May 2018

for use in: Systemic lupus erythematosus (SLE) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eprodisate *(Kiacta® (formerly Fibrillex))* TAG recommendation: May 2018

for use in: Amyloidosis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Eptotermin alfa *()* TAG recommendation: May 2018

for use in: Complex spinal surgery (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eteplirsen *(Exondys 51)* TAG recommendation: May 2018

for use in: Duchenne Muscular Dystrophy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Etrolizumab *((RG7413))* TAG recommendation: May 2018

for use in: Paediatric indications (IBD) where adult TA available (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Eye compress *(Hot Eye Compress®, Meibopatch®, MGDRx Eye Bag®)* TAG recommendation: Sep 2017

for use in: Eye conditions including dry-eye syndrome, meibomian cysts, styes and blepharitis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of eye compresses such as those currently listed in the Drug Tariff:
* Hot Eye Compress®
* Meibopatch®
* MGDRx Eye Bag®

The PRG and the TAG agreed with the PAC's recommendation which stated:
Not recommended; there is no evidence of additional benefit compared to using a clean flannel and warm water as an eye compress.Those that find commercially available eye compresses more convenient to use may purchase them from a pharmacy or on-line.
The TAG therefore agreed a classification of Double Red (Not recommended for routine use) - self-care to be encouraged as per NHS Choices advice.

September 2017:
The N&W D&TCG notd and supported the TAG's recommendation - not commissioned.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Eyelid care preparations *(e.g. Blephasol, Blephaclean, Systane)*

TAG recommendation: Nov 2017

for use in: Conditions affecting the eyelids - including blepharitis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: October 2017:
The Prescribing Reference Group (A sub-group of the TAG) noted CKS advice on first-line management of blepharitis, and considered that these products are suitable for patients to purchase and follow self-care, and are not appropriate for NHS prescribing.
PRG members requested that the TAG considered applying a traffic light classification of Double Red (Not recommended for routine use).

November 2017:
The TAG noted and supported the PRG's advice and recommended a traffic light recommendation of Double Red (Not recommended for routine use) for use of these products.

November 2017:
The PRG and TAG's recommendations were noted and supported by the D&TCG.

Galaxy UNYCO *(Galaxy UNYCO)*

TAG recommendation: Jan 2019

for use in: for temporary stabilisation of lower limb fractures (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE MIB 166 (December 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use of this technology is supported.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Gamolenic Acid (Evening Primrose Oil) *(Various - Epogam (Blacklisted))*

TAG recommendation: Jul 2010

for use in: All - not for NHS prescribing (Various indications).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Blacklisted products which should not be prescribed on the NHS.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Haem iron tablets (GlobiFer) *(GlobiFer®, also Forte and Plus)* TAG recommendation: Nov 2015

for use in: Anaemia (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Expensive product with no evidence of benefit over cheaper preparations.

Heparinised saline *(Saline (heparinised))* TAG recommendation: May 2019

for use in: Central venous catheter lock in adults - as per RMOC guidance (Feb 2019) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2019:
The TAG noted that the RMOC's guidance referred to routine use of heparinised saline and that some examples of exceptional use were given. TAG Trust representatives requested that the guidance is first circulated in-Trust for a view before recommending traffic light classification.

May 2019: The TAG was advised that the NNUH had reviewed its PGDs regarding management of central venous catheters and did not see a place for use of heparinised saline. The QEH agreed that the RMOC's recommendations would not cause any issues for the Trusts.

The TAG therefore agreed to recommend a traffic light classification of Double Red (Not recommended for routine use) for use of heparinised saline for central venous catheter lock in adults, in line with the RMOC guidance.

May 2019: Noted and supported by the D&TC.
Recommended as Double Red (Not recommended for routine use) / Not Commissioned regarding use of heparinised saline for central venous catheter lock in adults, in line with the RMOC guidance.

June 2019: The JSCC ratified the above recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Herbal medicines / supplements incl St John's Wort *(Various, including St John's Wort)*

TAG recommendation: Nov 2015

for use in: All uses (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Not supported for NHS prescribing. Significant potential for interaction with prescribed medication.
Patients who choose to use them should purchase their own supplies. Advise patients to disclose any use to healthcare practitioners who may otherwise prescribe for them.

NICE CG 90 Depression in adults: recognition and management - also states:
1.4.4.2 Although there is evidence that St John's Wort may be of benefit in mild or moderate depression, practitioners should not prescribe or advise its use by people with depression because of uncertainty about appropriate doses, persistence of effect, variation in the nature of preparations and potential serious interactions with other drugs (including oral contraceptives, anticoagulants and anticonvulsants).

Homeopathy *(Various)*

TAG recommendation: May 2002

for use in: Various (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Norfolk Health Authority did not suppprt routine provision of homeopathy. A systematic review provided no research evidence to confidently recommend homepoathy on grounds of effectiveness.

July 2010: Homeopathic remedies should not be prescribed on the basis that the House of Commons Science & technology Committee report on Homeopathy (February 2010) recommended that these products should not be funded by the NHS.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Human heterologous liver cells (HHLivC) *(Heparesc®)* TAG recommendation: May 2018

for use in: Urea cycle disorders (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

HyQvia (HN Immunoglobulin & Hyalurnidase) *(HyQvia®)* TAG recommendation: May 2018

for use in: As per national Demand Management Plan (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ibuprofen *(Nurofen Joint & Muscular Pain Relief med plaster)* TAG recommendation: Jan 2019

for use in: Pain relief (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2019: The TAG supported the PRG's recommendation and agreed that the traffic light classification for NSAID plasters should be Double Red (Not recommended for routine use).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Idebenone *(Raxone®)* TAG recommendation: May 2018

for use in: Duchenne muscular dystrophy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Independence wound protection pouch - all sizes *(Rapidcare)* TAG recommendation: Nov 2019

for use in: Haemodialysis patients - protection of line when washing (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: As requested for use by renal services for home dialysis patients.
Costly product - not commissioned for prescribing in primary care.

Alternative waterproof coverings should be used instead by the patient should they wish to shower.

Double Red classification covers all sizes - Prodict codes VAP1, VAP2, VAP3 and EA1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Insert for female stress incontinence (Contiform) *(Contiform®)* TAG recommendation: Sep 2017

for use in: Female stress urinary incontinence - as per NICE CG 171 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.6.6 Do not use intravaginal and intraurethral devices for the routine management of urinary incontinence in women. Do not advise women to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise.

September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of inserts for female stress urinary incontinence, which states:

Not recommended: there is currently insufficient evidence to recommend the use of the Contiform® device, or other intravaginal or intraurethral devices for female stress incontinence. NICE do not recommend their routine use (see NICE CG 171). There is a risk of side-effects with the use of intravaginal or intraurethral devices for female stress incontinence. They include urinary tract infections, insertion trauma, vaginal irritation, haematuria, spotting, and device migration.

The TAG agreed to classify inserts for female stress incontinence as Double Red (Not recommended for routine use) - not for prescribing on the NHS, and that patienst should be generally be advised against using them.

September 2017:
The PRG and the TAG's recommendatio were noted and supported by the N&W D&TCG and stated as Not Commissioned.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Inspiratory muscle training devices *(POWERbreathe® Medic, Threshold IMT®, Ultrabreathe®)* TAG recommendation: Sep 2017

for use in: Inspiratory muscle training in COPD, non-CF bronchiectasis, upper spinal cord injuries, Cystic fibrosis, asthma (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Inspiratory muscle training devices such as those currently listed in the Drug Tariff:
* POWERbreathe® Medic
* Threshold IMT®
* Ultrabreathe®
The PAC's guidance stated:
Not recommended for routine use, but inspiratory muscle training may be considered in those with COPD, non-CF bronchiectasis and upper spinal cord injuries.
For other indications, commissioners should engage with local stakeholders including respiratory specialists to determine if there are circumstances in which the intervention will be offered. Criteria for use (e.g. trials of other treatments) and an approval process should be agreed where applicable. Inspiratory muscle training should be provided only after individual assessment by an appropriately skilled therapist.Treatment should not be initiated by GPs or other non-specialists. Some devices are promoted for fitness/sports use. In these circumstances the device should be purchased rather than prescribed.
The PRG and the TAG therefore recommended a clasification of Double Red (Not recommended for routine use) pending any local interest in use and the development of business applications.

September 2017:
The N&W D&TCG notd and supported the TAG's recommendation - not commissioned, pending any local interest in use and the development of business applications.

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Insulin safety needles

(BD-Autoshields, Mylife Clickfine, Autoprotect etc)

TAG recommendation: Nov 2015

for use in: Insulin administration (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

The product protects the administrator not the patient and should as such be purchased by the administrator or their employer. The needles can cause bruising.

The only circumstance under which use might be appropriate is for patients known to have a known blood-borne virus whose insulin is adminstered by a non health care professional.

Intrathecal pumps

(Intrathecal pumps)

TAG recommendation: Sep 2015

for use in: Treatment of severe chronic (non-cancer) pain (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D08/P/a (D08X01) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned, in accordance with the criteria outlined in the document.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Iqoro *()* TAG recommendation: May 2019

for use in: Stroke-related dysphagia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019: The TAG noted NICE MIB 175 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use is supported for this technology.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

IQoro neuromuscular training device *(Iqoro)* TAG recommendation: May 2019

for use in: Stroke-related dysphagia (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: * IQoro is a neuromuscular training device for stimulating the nerves and strengthening the muscles in the face, mouth, throat, oesophagus, and diaphragm.

May 2019: The TAG noted Medtech innovation briefing: NICE MIB 175 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use is supported for this technology.

May 2019: The Norfolk and Waveney CCGs' D&TC was advised that the CCGs' Clinical Policy Development Group may have future involvement in reviewing the use of such devices. The TAG's recommendation was noted and supported by the D&TC.

June 2019: The TAG and the D&TC's recommendation was ratified by the JSCC.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

IQoro neuromuscular training device *()* TAG recommendation: May 2019

for use in: Stroke-related dysphagia (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019: The TAG noted NICE MIB 175 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use is supported for this technology.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 1029: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Lancet (single use, safety) *(Unistik® 3)* TAG recommendation: Nov 2015

for use in: Single use safety lancet (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this product is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Limited evidence to support use.

Laquinimod *(Nerventra® (not licensed in the UK))* TAG recommendation: May 2018

for use in: Multiple sclerosis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Lesinurad ▼ (with a xanthine oxidase inhibitor *(Zurampic® ▼)*

TAG recommendation: Mar 2018

for use in: Chronic hyperuricaemia in people with gout whose serum uric acid is above the target level despite an adequate dose of a xanthine oxidase inhibitor alone (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 503 (January 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

Lixivaptan (Unlicensed drug) *((unlicensed drug))*

TAG recommendation: May 2018

for use in: Hyponatraemia and other endocrine uses - NHSE responsibility (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Lymphoedema garments *(Various)* TAG recommendation: Sep 2017

for use in: Uses other than compression in management of lymphoedema assessed by the specialist service (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of lymphoedema garments.
Agreed for use as compression in management of lymphoedema, by the specialist service only.
There is no identified funding to support prescribing by GPs.

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG.

Macimorelin *(Macrilen®)* TAG recommendation: May 2018

for use in: Growth hormone deficiency in adults (diagnostic test) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Masitinib *(Masipro®)* TAG recommendation: May 2018

for use in: Pancreatic cancer / GIST (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Melanorm-HC® *(Melanorm-HC®)* TAG recommendation: Jul 2017

for use in: Melasma / Chloasma (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add combination topical products for Melasma / Chloasma containing tretinoin, hydroquinone and a corticosteroid
e.g. Tri-Luma® cream containing tretinoin 0.05%, hydroquinone 4% and fluocinolone acetonide 0.01%
e.g. Melanorm-HC Cream containing tretinoin 0.05%, hydroquinone 2% and hydrocortisone 1%
e.g. Pigmanorm® Cream contains tretinoin 0.1%, hydroquinone 5%, hydrocortisone 1%
to the Norfolk & Waveney DROP List due to them having limited evidence for benefit available other than from the company and not being licensed in the UK. Other similar products also not supported.

The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of any these products is submitted.

Jul 2017: Noted and supported by the D&TCG - Not commissioned

Mesenchymal stem cells (Prochymal®) *(Prochymal®)* TAG recommendation: May 2018

for use in: Acute Graft vs Host Disease (GVHD) & other indications (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Metreleptin *(Myalepta®)* TAG recommendation: May 2018

for use in: Dyslipidaemia - Generalised lipodystrophy and partial lipodystrophy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Mexiletine (imported generic) unlicensed in the UK *(Unlicensed in the UK)* TAG recommendation: May 2019

for use in: NOT recommended for any indication (EXCEPT ventricular tachycardia - Hospital / Specialist use only) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2019: The TAG acknowledged the PRG's recommendation and after consideration of the wider issues agreed to apply the traffic light classification of Double Red (Not recommended for routine use / Not commissioned) for all indications other than ventricular tachycardia (including migraine and neuropathic pain for which local use has been identified).

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Mexiletine (Namuscla®) *(Namuscla®)* TAG recommendation: May 2019

for use in: NOT recommended for any indication (EXCEPT myotonia in adults with non-dystrophic myotonic disorders - as per NHSE commissioning policy - Hospital / Specialist use only) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2019: The TAG acknowledged the PRG's recommendation and after consideration of the wider issues agreed to apply the traffic light classification of Double Red (Not recommended for routine use/Not commissioned) for all indications other than myotonia in adult patients with non-dystrophic myotonic disorders (including migraine and neuropathic pain for which local use has been identified).

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Migalastat ▼ *(Galafold® ▼)* TAG recommendation: Mar 2017

for use in: Fabry disease in people over 16 years of age with an amenable mutation, and only if enzyme replacement therapy (ERT) (with agalsidase alfa or agalsidase beta) would otherwise be offered - as per NICE HST4 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2017.

Specific points: March 2017: The TAG noted Highly specialised technologies guidance [HST4] (February 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) regarding use by local acute trusts for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Minoxidil (Regaine®) *(Regaine®)* TAG recommendation: Jan 2018

for use in: Androgenetic alopecia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2018: PRG request (April 2017) that the TAG considers applying a Double Red (Not recommended for routine use use) classification to these products to formalise their classification.
The TAG agreed to support the PRG's recommendations.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

Molgramostim (rhGM-CSF) *(Molgradex®)* TAG recommendation: May 2018

for use in: Autoimmune (acquired) pulmonary alveolar proteinosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Molludab / Molutrex *(Potassium hydroxide solution 5%)* TAG recommendation: Nov 2015

for use in: Molluscum contagiosum (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Unlicensed topical treatment promoted for use in a self-limiting condition. Expensive product with limited evidence of benefit.

September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of proprietary potassium hydroxide solution for treatment of molluscum contagiosum and agreed to maintain the current Double Red classification.

September 2017:
Noted and supported by the D&TCG.

Momelotinib *()* TAG recommendation: May 2018

for use in: Cancer (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only. Not licensed in the UK.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

MooGoo Skincare emollients *(MooGoo Natural Skincare emollients)* TAG recommendation: May 2016

for use in: Emollients for dry skin conditions (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2016: The TAG and the N&W D&TCG noted and supported the PRG's recommendation that these products (which are available OTC) are added to the NHS Norfolk and Waveney 'Drugs of Low Priority' DROP List, and agreed that these products are not commissioned for NHS provision in Primary Care.

Motavizumab *(Numax®)* TAG recommendation: May 2018

for use in: Respiratory syncytial virus (RSV) prophylaxis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

NBTXR-3 *()* TAG recommendation: Dec 2021

for use in: advanced soft tissue sarcoma as per TA745 (terminated appraisal) (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of NBTXR-3 for treating advanced soft tissue sarcoma. This is because Nanobiotix does not intend to make an evidence submission for the appraisal. Nanobiotix considers that there is not enough evidence to provide an evidence submission for this appraisal.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Necitumumab ▼ *(Portrazza® ▼)* TAG recommendation: Nov 2016

for use in: Adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been treated with chemotherapy - as per NICE TA 411 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 411 (September 2016) Necitumumab (Portrazza®) (in combination with gemcitabine and cisplatin), and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Needle free injection devices *(Insujet® and Injex®)* TAG recommendation: Sep 2017

for use in: Insulin needle free injection device (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Limited evidence to support use. Associated reports of pain and bruising. Requires insulin to be drawn up into the device. Ancillary products are required to enable use.

September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Needle-free insulin delivery systems which dose not recommend routine use - inline with previously agreed advice.
Current Double Red classification maintained.

September 2017:
The N&W D&TCG noted and supported the TAG's recommendations - Not commissioned.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Nitazoxanide *(Alinia®)* TAG recommendation: May 2018

for use in: Viral Hepatitis C (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nonacog beta pegol *(Refixia®)* TAG recommendation: May 2018

for use in: Haemophilia B (congenital factor IX deficiency). (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Occlusive dressings and dry bandages *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of infected atopic eczema in children - asper NICE CG 57 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2007.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 57 - Atopic eczema in under 12s: diagnosis and management which states:

1.5.5.1 Occlusive medicated dressings and dry bandages should not be used to treat infected atopic eczema in children.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Octocog alfa *(Advate®, Kogenate Bayer®)* TAG recommendation: May 2018

for use in: Haemophilia A (congenital factor VIII deficiency) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned - as per IFR approval, Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Octreotide (Oral) Octreolin® *(Octreolin®)* TAG recommendation: May 2018

for use in: Acromegaly (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Olesoxime *()* TAG recommendation: May 2018

for use in: Spinal muscular atrophy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Organic and natural eczema skincare products *(Elena nature collection - skincare products)* TAG recommendation: Nov 2015

for use in: All dermatology conditions including eczema and psoriasis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these treatments are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Unlicensed products. No clinical studies available to suppport NHS provision. These products may be purchased by patients who prefer to use them.

Oscillating Positive Expiratory Pressure devices *(eg Acapella/Flutter/Lung flute/Pari O-PEP/RCCornet)* TAG recommendation: Mar 2021

for use in: Mucus clearance in Chronic Bronchitis, Bronchiectasis, Emphysema, Asthma, Cystic Fibrosis - as per N&W DROP List (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these devices are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

September 2017: The TAG supported the recommendation of the NHS Norfolk & Waveney CCGs' PRG to maintain the current classification of Double Red (Not commissioned) for such devices including: Acapella®, Aerobika® OPEP, Flutter®, Lungflute®, Pari O-PEP®, RC-Cornet® pending local business applications.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation

August 2020 - TAG recommended that these are discussed further at the PRG, before returning to TAG at a later date. Until then, these devices will maintain a classification of Double Red (Not recommended for routine use / Not commissioned).

Nov 2020 - existing Double Red classification to remain

March 2021 - Business case resubmitted. Double Red classification maintained as evidence remains the same

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Osilodrostat *()* TAG recommendation: May 2018

for use in: Cushing's Disease (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ostomy underwear *(Various)* TAG recommendation: Sep 2017

for use in: Any use other than for parastomal hernia assessed by a specialist (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of ostomy underwear in stoma care and agreed that specialist assessment and recommendation for use in pararstomal hernia only would be appropriate. All other uses not supported.

September 2017:The N&W D&TCG noted and supported the TAG's Green (suitable for GPs to prescribe following specialist recommendation) classification.

Pacritinib *(Enpaxiq®)* TAG recommendation: May 2018

for use in: Myelofibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Padeliporfin *(Tookad®)* TAG recommendation: Jan 2019

for use in: Untreated localised (unilateral, low-risk) prostate cancer - as per NICE TA 546 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2018.

Specific points: January 2019: The TAG noted NICE TA 546 (November 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHS England commissioning responsibility treatment

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Path Finder laser shoe attachment *(Path Finder)* TAG recommendation: May 2019

for use in: Walking aid for freezing of gait in Parkinson's disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2019.

Specific points: The Path Finder laser shoe attachment is a walking aid designed to help prevent freezing of gait in people with Parkinson's disease.

May 2019: The TAG noted NICE MIB 170 (January 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for use is supported for this technology.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk &WaveneyCCGs' JSCC supported theTAG & D&TC recommendation.

Peginterferon Lambda-1a *()* TAG recommendation: May 2018

for use in: Hepatitis C (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Pelvic floor muscle toning devices

(Incl. PelvicToner®, Kegel8®, Aquaflex®)

TAG recommendation: Sep 2017

for use in: Pelvic floor muscle training (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Pelvic toning devices for pelvic floor muscle training which stated that there is No evidence of these products offering any advantage over pelvic floor exercises alone. The PRG and the TAG recommended as Double Red (Not recommended for routine use).

September 2017:
Noted and supported by the N&W D&TCG.

May 2019:
The TAG noted NICE NG 123 (April 2019) - Urinary incontinence and pelvic organ prolapse in women: management and noted that it did not specifically recommend use of pelvic floor muscle training devices.

Pen needle and remover (Unifine Pentips Plus)

(Unifine® Pentips® Plus)

TAG recommendation: Nov 2015

for use in: Insulin administration (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this device to be added on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Not necessary as offers no benefit over currently available cheaper needles.
Please refer to local guidance on insulin needles via http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/bulletin/needle_cost_comparison.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Peptide receptor radionucleotide therapy

()

TAG recommendation: May 2018

for use in: Cancer (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pigmanorm®

(Pigmanorm®)

TAG recommendation: Jul 2017

for use in: Pigmanorm® (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add combination topical products for Melasma / Chloasma containing tretinoin, hydroquinone and a corticosteroid
e.g. Tri-Luma® cream containing tretinoin 0.05%, hydroquinone 4% and fluocinolone acetonide 0.01%
e.g. Melanorm-HC Cream containing tretinoin 0.05%, hydroquinone 2% and hydrocortisone 1%
e.g. Pigmanorm® Cream contains tretinoin 0.1%, hydroquinone 5%, hydrocortisone 1%
to the Norfolk & Waveney DROP List due to them having limited evidence for benefit available other than from the company and not being licensed in the UK. Other similar products also not supported.

The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of any these products is submitted.

Jul 2017: Noted and supported by the D&TCG - Not commissioned

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Ponesimod *()* TAG recommendation: May 2018

for use in: Multiple sclerosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

PredictSure-IBD - prognostic tool *(PredictSure-IBD)* TAG recommendation: May 2019

for use in: Prediction of prognosis in Inflammatory bowel disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019: The TAG noted NICE MIB 178 (March 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for its use is supported for this technology.

May 2019: The D&TC was advised that the CCGs' Clinical Policy Development Group may have future involvement in reviewing the use of such devices / tools.
The NHS Norfolk & Waveney CCGs' D&TC otherwise noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and the D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Probiotics *(eg VSL#3, ProDophilus, Nature's Own, Cytoplan)* TAG recommendation: Nov 2015

for use in: Any indication (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Limited evidence to support use and NHS provision.

The products listed on the DROP list include:
ProDophilusFOS VSL#3_Probiotic Food Supp Pdr Sach 4.4g, Natures own Probiotic travel Cytoplan capsules Probiotic P.B.4_Pdr, Multibionta Probiotic Multivit tabs.
This list is not exhaustive.

March 2019:
•* The CCGs' Self Care policy (October 2018) lists an exemption for use under ACBS criteria for maintenance of antibiotic induced remission of ileoanal pouchitis in adults.
* From January 2019, these products have been removed from the Drug Tariff, and are therefore unable to be prescribed or reimbursed on the NHS.

The TAG acknowledged this information and recommended that the CCGs' self-care policy to be amended in this regard.

March 2019:
The D&TC recommended that the Prescribing Reference Group be asked to revisit and revise the Self Care policy in this respect.

Progest cream *(Progest®)* TAG recommendation: Sep 1998

for use in: Hormone replacement therapy (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Prosource Jelly *(Prosource® Jelly)* TAG recommendation: Jul 2017

for use in: protein-containing food supplement for use in patients with protein energy malnutrition (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add Prosource Jelly to the Norfolk & Waveney DROP List. Prescribable under ACBS criteria only for hypoproteinaemia. The PRG noted that dietitians are requesting GP to prescribe for malnutrition.
A business case is needed describing how hypoproteinaemia will be measured. Not to be used for patients with venous leg ulcers.
The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of this product is submitted.

July 2017: Noted and supported by the D&TCG - Not commissioned

Rabbit anti-human thymocyte immunoglobulin *(Thymoglobuline®)* TAG recommendation: Nov 2017

for use in: INITIAL treatments to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE TAs 481 and 482 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TAs 481 and 482 (Oct 17) which state that Rabbit anti-human thymocyte immunoglobulin, prolonged-release tacrolimus, mycophenolate sodium, sirolimus, everolimus and belatacept are not recommended by NICE as initial treatments to prevent organ rejection in adults, children and young people having a kidney transplant.
The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for these treatments for this indication.

Noted by the D&TCG.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Reagent Pad (Neuropad) *(Neuropad)* TAG recommendation: Nov 2015

for use in: Diagnostic test for peripheral neuropathy (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this product is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Expensive - no advantage over clinical examination.

RESPeRATE® *(RESPeRATE®)* TAG recommendation: Nov 2015

for use in: Device used to lower BP by changing breathing rates (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Expensive product. Poor evidence to support use.

Reveglucosidase alfa *()* TAG recommendation: May 2018

for use in: Pompe Disease (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Rigosertib *(Estybon®)* TAG recommendation: May 2018

for use in: Refractory myelodysplastic syndromes (MDS), high-risk / Pancreatic cancer (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Roxadustat *()* TAG recommendation: May 2018

for use in: Dialysis induced anaemia (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

RT300 (functional electrical stimulation system) *(RT300)* TAG recommendation: Mar 2019

for use in: Spinal cord injury rehabilitation - as per MIB 169 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE MIB 169 (January 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) until a local business application for its use is supported for this technology.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Safety needles (insulin) *(BD-Autoshields, Mylife Clickfine Autoprotect etc)* TAG recommendation: Nov 2015

for use in: Insulin administration (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

The product protects the administrator not the patient and should as such be purchased by the administrator or their employer. The needles can cause bruising.

The only circumstance under which use might be appropriate is for patients known to have a known blood-borne virus whose insulin is adminstered by a non health care professional.

Sargramostim (GM-CSF) *(Leukine® (import))* TAG recommendation: May 2018

for use in: Antibody-positive pulmonary alveolar proteinosis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Sialic acid *()* TAG recommendation: May 2018

for use in: Myopathy - as per NHSE policy (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Silicone gel sheet dressing *(Cica-Care®)* TAG recommendation: Sep 2002

for use in: Reduce and prevent hypertrophic and keloid scarring (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Costly dressing ((£12 to £23 per sheet).
TAG referred to Dr Sassoon for opinion on preferred indication for use in the light of poor evidence but no response forthcoming. In occasional use at the JPH.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment remain on to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Silk garments *(Various)* TAG recommendation: Sep 2017

for use in: Dermatology (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of silk garments in dermatology care and considered that specialist recommendation following assessment might be appropriate.

September 2017:
The D&TCG was advised of a recent review of use of silk garments in children moderate to severe eczema which questioned the clinical and economic benefit of providing silk garments in addition to standard care.
The D&TCG therefore decided not to support the TAG's recommendation for the time being.
Classified as Double Red/ Not recommended for routine use) in line with the EoE PAC recommendations - insufficient evidence to support routine use.

October 2017:
The Prescribing Reference Group (which is a sub-group of the TAG) noted a new RCT of silk garments for children with moderate to severe eczema versus best care, with the conclusion that silk garments gave no additional benefits to standard care.
Link to key reference - http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002280
The PRG therefore made a revised recommendation to the TAG to apply a classification of Double Red (Not recommended for routine use).

November 2017:
The TAG noted and supported the PRG's recommendations and confirmed the revised traffic light recommendation of Double Red (Not recommended for routine use).

November 2017:
Noted and supported by the D&TCG.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Sipuleucel-T *(Provenge®)* TAG recommendation: Mar 2015

for use in: Treatment of adults with asymptomatic or minimally symptomatic metastatic hormone relapsed prostate cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2015.

Specific points: March 2015: The TAG acknowledged the NICE TA332 which does not recommend use of this treatment, and recommended a classification of Double Red (Not recommended for routine use) for this NHS England SCG-commissioned drug.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Smart One (portable spirometer) *(Smart One (portable spirometer))* TAG recommendation: Mar 2017

for use in: Measuring lung function (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2017.

Specific points: Smart One is a portable spirometer used for measuring lung function which transmits measurements wirelessly to a smartphone (or tablet) and records results in a diary app which can be shared electronically with a healthcare professional.

The TAG acknowledged NICE Medtech innovation briefing [MIB96] (February 2017) and recommended a traffic light classifications of Double Red (Not recommended for routine use).

March 2017:
The N&W Drugs & Therapeutics Commissioning Group noted and supported the TAG recommendation - Not commissioned for provision on the NHS.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Smartinhaler *(Smartinhaler)* TAG recommendation: Mar 2017

for use in: Asthma (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2017.

Specific points: Smartinhaler is a technology that monitors the activation of a person's asthma inhaler and uploads data to a mobile or cloud-based application.

The TAG acknowledged NICE Medtech Innovation Briefing [MIB90] (January 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use).

March 2017:
The N&W Drugs & Therapeutics Commissioning Group noted and supported the TAG recommendation - Not commissioned for provision on the NHS.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Sodium chloride nasal appliance *(Sterimar isotonic & hypertonic, Aqua maris)*

TAG recommendation: Nov 2015

for use in: Nasal congestion and sinusitis (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Used as nasal irrigation. Patients can buy normal saline OTC as an alternative.

September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Nasal products - such as saline nasal sprays, e.g. Sterimar®, Aqua maris® for nasal congestion and sinusitis and agreed to maintain the previous Double Red classification.

September 2017:
Noted and supported by the N&W D&TCG - not commissioned.

November 2017:
The TAG acknowledged NICE NG 79 - Sinusitis (acute): antimicrobial prescribing (October 2017) and noted the differences in recommended antibiotic choices for acute sinusitis compared with the locally agreed antibiotic formularies. The TAG was advised that NG 79 would be taken into consideration as part of the on-going review of the formularies.

Noted by the D&TCG.

Spatone *(Spatone Iron-Plus sachets / products)*

TAG recommendation: Nov 2015

for use in: Iron supplement (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Very poor evidence base - do not prescribe on the NHS.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

St Mark's solution (ready made) *(Ready made sachets from unlicensed specials)* TAG recommendation: Nov 2015

for use in: Oral rehydration solution (ORS) which is used in the management of Short Bowel Syndrome (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this product is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Expensive and variable costs of sachets. Can be made up cheaply at home from readily available ingredients which may also be purchased. See article in The Prescriber newsletter (April 2014 - under Cost-effective Prescribing Tips (2)) for further guidance - https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=SU3_MiD5P28%3d&tabid=878&portalid=1&mid=1891

Strimvelis *(Strimvelis)* TAG recommendation: May 2018

for use in: Adenosine deaminase deficiency - severe combined immunodeficiency (ADA-SCID) - as per NICE HST 7 (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2018.

Specific points: May 2018: The TAG noted NICE HST 7 (February 2018) and although recommended as an option by NICE, decided to classify this NHSE-commissioning responsibility treatment as Double Red (Not recommended for routine use) in order to avoid local clinicians being given the impression that it is available for use locally by the NHS

May 2018: The NHS Norfolk & Waveney CCGs D&TC noted the TAG recommendation.

Tabalumab *()* TAG recommendation: May 2018

for use in: Systemic Lupus Erythematosus (SLE) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Tafamidis *(Vyndaqel®)* TAG recommendation: May 2018

for use in: Amylodosis - Treatment of transthyretin familial amyloid polyneuropathy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Teduglutide *(Revestive®)* TAG recommendation: May 2018

for use in: Short bowel syndrome (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Tri-Luma® *(Tri-Luma®)* TAG recommendation: Jul 2017

for use in: Melasma (Chloasma) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the Prescribing Reference Group's recommendation to add combination topical products for Melasma / Chloasma containing tretinoin, hydroquinone and a corticosteroid
e.g. Tri-Luma® cream containing tretinoin 0.05%, hydroquinone 4% and fluocinolone acetonide 0.01%
e.g. Melanorm-HC Cream containing tretinoin 0.05%, hydroquinone 2% and hydrocortisone 1%
e.g. Pigmanorm® Cream contains tretinoin 0.1%, hydroquinone 5%, hydrocortisone 1%
to the Norfolk & Waveney DROP List due to them having limited evidence for benefit available other than from the company and not being licensed in the UK. Other similar products also not supported.

The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of any these products is submitted.

Jul 2017: Noted and supported by the D&TCG - Not commissioned

Unloading knee braces *()* TAG recommendation: Nov 2020

for use in: Support for knee joint (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use) pending the submission of a business case. Supported by TAG and D+TC. Ratified by CCG Governing Body

Uroshield catheter device *()* TAG recommendation: Nov 2020

for use in: preventing catheter-related urinary infections (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use) The evidence is not strong enough to support use locally. Suoorted by TAG and D+TC. Ratified by CCG Governing Body

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Vacuum dressings *(Vacuum Assisted Closure (VAC dressings).)* TAG recommendation: May 2008

for use in: Healing of chronic wounds (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2008:
The TAG agreed that no new patients should be started on vacuum dressings for the time being due to poor cost-effectiveness compared standard care. The TAG also recommended that an economic analysis should be commissioned to examine cost implications and that a tightly defined patient target group should be agreed.
Vacuum dressings (topical negative pressure wound therapy using vacuum-assisted closure) for use in wound care are therefore classified as Double Red (Not recommended for routine use).
Prescriber's Rating of 5. "Judgement reserved. The TAG postpones its judgement until better data and a more thorough evaluation of the therapy are available."

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment will remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Vadadustat *()* TAG recommendation: May 2018

for use in: Anaemia in chronic kidney disease in dialysis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. as per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Virulite electronic cold sore device *(Virulite)*

TAG recommendation: Nov 2015

for use in: Electronic cold sore device (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Expensive product with poor evidence for use.

Vitamin / Multivitamin products *(Various - OTC products)*

TAG recommendation: Nov 2015

for use in: Vitamin supplementation for a variety of indications (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these OTC products to be added on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Vitamin supplements showed not be provided on the NHS and are available for purchase OTC.

Yohimbine *(eg Prowess, Aphrodyne, Dayto Himbin, Yocon,Yohimes)*

TAG recommendation: Nov 2015

for use in: Erectile dysfunction (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

No evidence over licensed treatments for erectile dysfunction.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

- No BNF entry - device

Ziconotide *(Prialt®)* TAG recommendation: May 2018

for use in: Intrathecal analgesia for severe chronic pain - as per NHS England Policy 16011/P (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16011/P. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

0 - - No BNF entry - device

SQ HDM SLIT *()* TAG recommendation: Nov 2022

for use in: allergic rhinitis and allergic asthma caused by house dust mites as per TA834 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

1.1.1 - Antacids and simeticone

Antacids - various *(Various)* TAG recommendation: Jul 2017

for use in: Long term frequent use in functional dyspepsia - as per NICE CG 184 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2004.

Specific points: uly 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 184 Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management (last update November 2014) included these recommendations:
1.8.7 (Regarding functional dyspepsia) Avoid long-term, frequent dose, continuous antacid therapy (it only relieves symptoms in the short term rather than preventing them). [2004, amended 2014]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

1.2 - Antispasmodics & other drugs altering gut motility

Dicycloverine *(Generics available)* TAG recommendation: Sep 2017

for use in: GI indications (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017: The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) for all uses of dicycloverine to prevent use in any new cases and also to encourage the review of current long-standing cases.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Glycopyrronium *(N/A)* TAG recommendation: May 2022

for use in: Hyperhidrosis (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2022 -Blue - No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing for hypersalivation. No prescribing in primary care.
Majority of these prescriptions will come from paediatricians so any new prescriptions should be Red/Hospital until there is a pathway

1.3.5 - Proton pump inhibitors

Esomeprazole *(Nexium®, Emozul®, Generic available)* TAG recommendation: Nov 2015

for use in: First line PPI option for licensed indications - as per N&W DROP List (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these treatments are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Esomeprazole is an isomer of omeprazole which is now off patent. If a PPI is required use a low cost alternative such as omeprazole, lansoprazole or pantoprazole.

Use may only be appropriate under gastroenterologist recommendation if a patient has not responded to other PPIs or for Barrett's oesophagus. Prescribe generically if must be rused.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

1.4.2 - Antimotility drugs

Teduglutide *()* TAG recommendation: May 2021

for use in: short bowel syndrome as per TA690 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2021.

Specific points: Terminated appraisal - Double Red (Not recommended for routine use / Not commissioned)

1.5.3 - Drugs affecting the immune response

Vedolizumab *(Entyvio®)* TAG recommendation: Oct 2022

for use in: chronic refractory pouchitis after surgery for ulcerative colitis as per TA826 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2022.

Specific points: NICE is unable to make a recommendation about the use in the NHS of vedolizumab for treating chronic refractory pouchitis after surgery for ulcerative colitis. This is because Takeda did not provide an evidence submission. Takeda has confirmed that the technology will not be launched in the UK for this indication.

Not commissioned. No NHS prescribing in primary or secondary care

1.6.6 - Peripheral opioid-receptor antagonists

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

1.6.6 - Peripheral opioid-receptor antagonists

Methylnaltrexone bromide ▼ *(Relistor® ▼)* TAG recommendation: Sep 2017

for use in: Opioid-induced bowel dysfunction in palliative care - as per NICE TA 468 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2017.

Specific points: The TAG noted NICE TA 277 (March 2013) (terminated appraisal - due to no evidence submission received form the manufacturer who is seeking a permanent owner in Europe for the marketing authorisation for this treatment).

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) decision - Not commissioned

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment remains on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

September 2017: The TAG acknowledged NICE TA 468 (August 2017) (terminated appraisal) and re-affirmed a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Naldemedine *(Rizmoic)* TAG recommendation: Oct 2020

for use in: treating opioid-induced constipation as per TA651 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case and pathway. This was supported by the D+TC

2.1.1 - Cardiac glycosides

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.1.1 - Cardiac glycosides

Digoxin *(Generics available)* TAG recommendation: Jul 2017

for use in: Cor pulmonale (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 101 (July 2010) for COPD included these recommendations:
The following are not recommended for the treatment of cor pulmonale:
* angiotensin-converting enzyme inhibitors
* calcium channel blockers
* alpha-blockers
* digoxin (unless there is atrial fibrillation). [2004]

2.2.3 - Aldosterone antagonists

Finerenone *(Kerendia®)* TAG recommendation: Jun 2023

for use in: chronic kidney disease in type 2 diabetes TA877 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

2.3.2 - Supraventricular arrhythmias

Vernakalant *()* TAG recommendation: Mar 2021

for use in: rapid conversion of recent onset atrial fibrillation to sinus rhythm (TA675 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - NICE is unable to make a recommendation about the use in the NHS of vernakalant for the rapid conversion of recent onset atrial fibrillation (7 days or less) to sinus rhythm in adults who have not because Correvio Ltd did not provide an evidence submission for the appraisal.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.4 - Beta-adrenoceptor blocking drugs

Pindolol *(Visken®)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

2.5 - Alpha-adrenoceptor blocking drugs

Alpha blockers - various *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of cor pulmonale - as per NICE CG 101 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 101 (July 2010) for COPD included these recommendations:
The following are not recommended for the treatment of cor pulmonale:
* angiotensin-converting enzyme inhibitors
* calcium channel blockers
* alpha-blockers
* digoxin (unless there is atrial fibrillation). [2004]

2.5.1 - Vasodilator antihypertensive drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.1 - Vasodilator antihypertensive drugs

Macitentan *(Opsumit®)* TAG recommendation: May 2018

for use in: Pulmonary Arterial Hypertension (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Selexipag *(Uptravi®)* TAG recommendation: May 2018

for use in: Pulmonary arterial hypertension - as per NHSE policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.1 - Vasodilator antihypertensive drugs

Treprostinil *(Tyvaso (EU), Remodulin (U.S))* TAG recommendation: Nov 2011

for use in: Peripheral Arterial Hypertension (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.
These are:
Hammersmith Hospital, Royal Brompton Hospital and the
Royal Free Hospital in London.
Papworth Hospital near Cambridge.
Royal Hallamshire Hospital , Sheffield.
Great Ormond Street Hospital provides PAH services for children.

The TAG noted the SCG policy which states that use of treprostinil is not commisioned.

On 17th November 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered and agreed with the TAG's recommendation.

November 2013: Still not available in the UK Refn: http://www.ukmi.nhs.uk/applications/ndo/record_view.asp?newDrugID=3065

Treprostinil diethanolamine *(Orenitram (US))* TAG recommendation: May 2018

for use in: Pulmonary Arterial Hypertension (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.1 - Vasodilator antihypertensive drugs

Treprostinil sodium *(Trevyent®)* TAG recommendation: May 2018

for use in: Pulmonary Arterial Hypertension - as per NHS England policy A11/P/c (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval for new patients - NHS England Policy A11/P/c. Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

2.5.4 - Alpha-adrenoceptor blocking drugs

Doxazosin MR *(Cardura® XL)* TAG recommendation: Nov 2015

for use in: Hypertension; benign prostatic hyperplasia - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

No evidence of increased benefit over immediate-release formulation. The elimination half-life of both formulations is 22hours.

2.5.5 - Drugs affecting the renin-angiotensin system

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5 - Drugs affecting the renin-angiotensin system

Aliskiren ▼ *(Rasilez® ▼)* TAG recommendation: Mar 2008

for use in: Treatment of essential hypertension - as per NICE CG 127 and N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not recommended in view of the current lack of outcome and long term safety data related to this drug, which has black triangle status ▼.

May 2009 - the TAG considered a new submission for aliskiren as a treatment option for patients with refractory hypertension or those patients who have developed unacceptable side-effects from current antihypertensive medication and fail to achieve NICE guidelines. On reviewing the data presented it was found that there was no evidence of effectiveness for refractory hypertension, as the trials had been conducted in mild to moderate hypertension. Given the very limited evidence of effectiveness and its higher cost compared to existing treatments it was decided to maintain aliskiren as Double Red (not recommended for routine use).

September 2011: The TAG noted NICE Clinical Guideline 127 - Clinical management of primary hypertension in adults (replaces CG 34) - http://guidance.nice.org.uk/CG127 - which does not mention use of renin inhibitors.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment to remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Perindopril arginine *(Coversyl® Arginine tablets)* TAG recommendation: Nov 2015

for use in: All indications (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

No advantage over perindopril erbumine. Risk of confusion over dfferent strengths.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5 - Drugs affecting the renin-angiotensin system

Vericiguat *()* TAG recommendation: Oct 2021

for use in: chronic heart failure with reduced ejection fraction as per TA731 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of vericiguat for treating chronic heart failure with reduced ejection fraction. This is because Bayer did not provide an evidence submission for the appraisal and will not be launching the technology in the UK.

2.5.5.1 - Angiotensin-converting enzyme inhibitors

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5.1 - Angiotensin-converting enzyme inhibitors

ACE inhibitors *(Various)* TAG recommendation: Jan 2009

for use in: with Angiontensin-II Receptor Antagonists (ARBs) - NICE Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: November 2001:
ACE inhibitors are not recommended for routine use with Angiotensin-II-Receptor Antagonists (AIIRAs). Spironolactone is worth considering as an addition to ACE Inhibitors, but care is required with respect to renal function and potassium levels.

September 2006:
Continued interest in combined use of ACEIs + ARBs, particularly from renal consultants for patients with chronic renal disease. However the TAG did not feel that there was sufficient evidence to support Routine Use of the combination. It was acknowledged that renal consultants may wish to discuss possible benefits for individual patients with GPs.

January 2009:
The TAG agreed that this combination is still not recommended for routine use. However the TAG acknowledges that NNUH renal physicians might recommend an ACEI+ARB in the following circumstances:
1. Diabetic nephropathy, particularly where proteinuria has not been significantly reduced by single agent alone and/or blood pressure target is not achieved.
2. Any form of glomerulonephritis with proteinuria, particularly when hypertension target is not achieved.
3. Nephrotic syndrome failing to respond to primary treatment, with or without renal impairment.
Co-use of ACEI + ARB would generally be avoided in patients with overt widespread vascular disease, including renal disease. In extreme circumstances, it might be used with extreme caution with Renal Consultant follow up.
A useful review of the evidence can be found at http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/What-is-the-rationale-and-evidence-for-combining-angiotensin-converting-enzyme-inhibitors-with-angiotensin-II-receptor-antagonists/

NB only candesartan is currently licensed for combined use with an ACEI, for treatment of heart failure.

September 2011: The TAG noted NICE Clinical Guideline 127 Clinical management of primary hypertension in adults (replaces CG 34) - http://guidance.nice.org.uk/CG127

September 2014: The TAG acknowledged NICE CG 182 (July 2014) which updates and replaces CG 73. The guideline affirms the previous TAG classification of Double Red (not recommended for routine use) regarding combined use of drugs affecting the renin-angiotensin system.

January 2017:
The TAG acknowledged CG 127 (updated November 2016) - Hypertension in adults: Diagnosis and management.
Recommendation 1.6.7 states:
Do not combine an ACE inhibitor with an ARB to treat hypertension.

November 2018: The TAG acknowledged NG 106 - Chronic heart failure in adults: diagnosis and management which includes recommendations on treating heart failure with these drug options but does not specifically mention their combined use.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5.1 - Angiotensin-converting enzyme inhibitors

ACE Inhibitors - various *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of cor pulmonale - as per NICE CG 101 - NICE Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 101 (July 2010) for COPD included these recommendations:
The following are not recommended for the treatment of cor pulmonale:
* angiotensin-converting enzyme inhibitors
* calcium channel blockers
* alpha-blockers
* digoxin (unless there is atrial fibrillation). [2004]

2.5.5.2 - Angiotensin-II receptor antagonists

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5.2 - Angiotensin-II receptor antagonists

Angiotensin-II receptor antagonists *(Various)* TAG recommendation: Sep 2006

for use in: with ACE inhibitors (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: November 2001:
ACE inhibitors are not recommended for use with Angiotensin-II-Receptor Antagonists (AIIRAs). Good theory, not well proven in practice.
Spironolactone is worth considering as an addition to ACE Inhibitors, but care is required with renal function and potassium levels.
MeReC Bulletin 2003 Vol 13 No. 6 reviews the place of AIIRAs.

September 2006:
The TAG revisited the above decision because of continued interest in combined use of ACEIs + ARBs, particularly from renal consultants for patients with chronic renal disease. However despite an overview of meta-analyses that have been published since November 2001, TAG members did not believe that there is sufficient evidnece available to support Routine Use of this drug combination. However it was acknowledged that consultants may wish to discuss possible benefits for individual patients with GPs.

NB only candesartan is currently licensed for combined use with an ACEI, for treatment of heart failure.

September 2011: The TAG noted NICE Clinical Guideline 127 Clinical management of primary hypertension in adults (replaces CG 34) - http://guidance.nice.org.uk/CG127

September 2014: The TAG acknowledged NICE CG 182 (July 2014) which updates and replaces CG 73. The guideline affirms the previous TAG classification of Double Red (not recommended for routine use) regarding combined use of drugs affecting the renin-angiotensin system.

January 2017:
The TAG acknowledged CG 127 (updated November 2016) - Hypertension in adults: Diagnosis and management.
Recommendation 1.6.7 states:
Do not combine an ACE inhibitor with an ARB to treat hypertension.

November 2018: The TAG acknowledged NG 106 - Chronic heart failure in adults: diagnosis and management which includes recommendations on treating heart failure with these drug options but does not specifically mention their combined use.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.5.5.2 - Angiotensin-II receptor antagonists

Azilsartan *(Edarbi®)* TAG recommendation: Nov 2015

for use in: Essential hypertension - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Limted evidence to support use, lack of safety data. High cost, black triangle drug.

2.6.2 - Calcium-channel blockers

Calcium channel blockers - various *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of cor pulmonale - as per NICE CG 101 - NICE Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 101 (July 2010) for COPD included these recommendations:
The following are not recommended for the treatment of cor pulmonale:
* angiotensin-converting enzyme inhibitors
* calcium channel blockers
* alpha-blockers
* digoxin (unless there is atrial fibrillation). [2004]

Trimetazidine *()* TAG recommendation: Oct 2022

for use in: refractory angina (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Formulary application will be required. Unlicensed import

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.6.2 - Calcium-channel blockers

Valsartan / Amlodipine *(Exforge®)* TAG recommendation: Nov 2015

for use in: Hypertension (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Combination products not supported and valsartan no tfirst choice ARB.

2.6.4 - Peripheral vasodilators and related drugs

Cilostazol *(Pletal®)* TAG recommendation: Jul 2011

for use in: Treatment of intermittent claudication in people with peripheral arterial disease - as per NICE TA 223 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 223 which recommeded the following:
1.1 Naftidrofuryl oxalate is recommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered appropriate after taking into account other treatment options. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation.
1.2 Cilostazol, pentoxifylline and inositol nicotinate are not recommended for the treatment of intermittent claudication in people with peripheral arterial disease.
1.3 People currently receiving cilostazol, pentoxifylline and inositol nicotinate should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

September 2012: September 2012: The TAG noted NICE CG 147 (August 2012 http://guidance.nice.org.uk/CG147) - Lower limb peripheral arterial disease.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.6.4 - Peripheral vasodilators and related drugs

Inositol nicotinate *(Hexopal®)* TAG recommendation: Jul 2011

for use in: Treatment of intermittent claudication in people with peripheral arterial disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 223 which recommeded the following:
1.1 Naftidrofuryl oxalate is recommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered appropriate after taking into account other treatment options. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation.
1.2 Cilostazol, pentoxifylline and inositol nicotinate are not recommended for the treatment of intermittent claudication in people with peripheral arterial disease.
1.3 People currently receiving cilostazol, pentoxifylline and inositol nicotinate should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

September 2012: The TAG noted NICE CG 147 (August 2012 http://guidance.nice.org.uk/CG147) - Lower limb peripheral arterial disease.

Pentoxifylline (Oxpentifylline) *(Trental®)* TAG recommendation: Jul 2011

for use in: Treatment of intermittent claudication in people with peripheral arterial disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 223 which recommeded the following:
1.1 Naftidrofuryl oxalate is recommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered appropriate after taking into account other treatment options. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation.
1.2 Cilostazol, pentoxifylline and inositol nicotinate are not recommended for the treatment of intermittent claudication in people with peripheral arterial disease.
1.3 People currently receiving cilostazol, pentoxifylline and inositol nicotinate should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

September 2012: The TAG noted NICE CG 147 (August 2012 http://guidance.nice.org.uk/CG147) - Lower limb peripheral arterial disease.

2.7.2 - Vasoconstrictor sympathomimetics

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.7.2 - Vasoconstrictor sympathomimetics

Angiotensin II *(Giapreza®)* TAG recommendation: Mar 2023

for use in: vasosuppressor-resistant hypotension caused by septic or distributive shock (terminated appraisal) TA859 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care
NICE is unable to make a recommendation about the use in the NHS of angiotensin II for treating vasosuppressor-resistant hypotension caused by septic or distributive shock. This is because Paion AG has confirmed that it does not intend to make an evidence submission for the appraisal. Paion AG considers that there are likely low numbers of people who would be eligible for treatment because of the likely positioning in the treatment pathway for this condition

2.8.1 - Parenteral anticoagulants

Epoprostenol *(Flolan®)* TAG recommendation: May 1999

for use in: Acute respiratory distress syndrome (ARDS) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Some other indications supported.

Fondaparinux sodium *(Arixtra®)* TAG recommendation: Nov 2002

for use in: Prophylaxis of venous thromboembolism in those undergoing major orthopaedic surgery of the legs - as per NICE DoNotDo recommendation (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2010.

Specific points: November 2002: TAG agreed to await submission from local consultants.

March 2010: NICE CG 92 states "Fondaparinux sodium is not recommended for use preoperatively for patients undergoing hip fracture surgery. If it has been used preoperatively it should be stopped 24 hours before surgery and restarted 6 hours after surgical closure, provided haemostasis has been established and there is no risk of bleeding (for example, active bleeding and acquired bleeding disorders such as acute liver failure)."

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.8.1 - Parenteral anticoagulants

Heparin - Low molecular weight (LMWH) *(Various)* TAG recommendation: May 2001

for use in: Prevention of DVT during flights (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use Enter period.

NICE has not issued any guidance.

Specific points: (Dalteparin, Enoxaparin, Tinzaparin)

Insufficient evidence to support provision on the NHS for this indication.

Not commissioned (May 2001).

2.8.2 - Oral anticoagulants

Apixaban *(Eliquis®)* TAG recommendation: Jul 2017

for use in: Combined use with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.3.28 Do not add a new oral anticoagulant (rivaroxaban, apixaban or dabigatran) in combination with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI. [new 2013]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.8.2 - Oral anticoagulants

Dabigatran *(Pradaxa®)* TAG recommendation: Jul 2017

for use in: Combined use with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.3.28 Do not add a new oral anticoagulant (rivaroxaban, apixaban or dabigatran) in combination with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI. [new 2013]

Edoxaban ▼ *(Lixiana® ▼)* TAG recommendation: Jul 2017

for use in: Combined use with with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.3.28 Do not add a new oral anticoagulant (rivaroxaban, apixaban or dabigatran) in combination with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI. [new 2013]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.8.2 - Oral anticoagulants

Rivaroxaban *(Xarelto®)* TAG recommendation: Jul 2017

for use in: Combined use with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.3.28 Do not add a new oral anticoagulant (rivaroxaban, apixaban or dabigatran) in combination with dual antiplatelet therapy in people who otherwise need anticoagulation, who have had an MI. [new 2013]

Warfarin *(Generics available)* TAG recommendation: Jul 2017

for use in: Routine use in combination with prasugrel or ticagrelor to people who need anticoagulation who have had an MI - as per NICE CG 172 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.3.26 Do not routinely offer warfarin in combination with prasugrel or ticagrelor to people who need anticoagulation who have had an MI. [new 2013]

2.8.3 - Anticoagulation reversal agents

Andexanet alfa *()* TAG recommendation: Apr 2022

for use in: reversing anticoagulation for edoxaban patients (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not commissioned for use in edoxaban patients

2.9 - Antiplatelet drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.9 - Antiplatelet drugs

Aspirin *()* TAG recommendation: May 2018

for use in: Primary prevention of CVD in T1 or T2 Diabetes - as per NG17 and NG 28 Do Not Do's (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2017.

Specific points: May 2018:

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Cangrelor ▼ *(Kengrexal® ▼)* TAG recommendation: Sep 2015

for use in: Treatment for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti platelet therapy - as per NICE TA 351 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2015.

Specific points: September 2015: The TAG noted NICE TA 351 (July 2015) (terminated appraisal) for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti platelet therapy and recommended a traffic light classification of Double Red (Not recommended for routine use) for this treatment.

NICE was unable to make a recommendation about the use of this treatment in the NHS because no evidence submission was received from the manufacturer.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

Clopidogrel *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: May 2018

for use in: Primary prevention of CVD in T1 or T2 Diabetes - as per NG17 and NG 28 Do Not Do's (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2017.

Specific points: May 2018:

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.9 - Antiplatelet drugs

Prasugrel *(Efient®)* TAG recommendation: Sep 2010

for use in: Targeted use in diabetics: In combination with aspirin, prevention of atherothrombotic events in patients with acute coronary syndrome (ACS) undergoing primary or delayed percutaneous coronary intervention (PCI) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: November 2009:
NICE TA 182 October 2009 recommends prasugrel, in combination with aspirin, as an option for preventing atherothrombotic events in people with acute coronary syndromes having PCI.

The TAG debated interpretation of NICE guidance against its previous concerns regarding prasugrel i.e. beneficial in high risk groups but more risky in patients who are higher risk of a bleed.

September 2010: The TAG considered a revised proposal for use of prasugrel from the NNUH and made the following recommendation regarding targeting use of prasugrel in diabetics which was approved by the NHS Norfolk Drug & Therapeutics Commissioning Programme Board in September 2010:

Targeted use in diabetics presenting with ACS who undergo coronary intervention is Double Red (Not recommended for routine use) on the basis of uncertainty about risks verses benefits, and major concerns about the cost-effectiveness of prasugrel compared with generic clopidogrel.

See separate entry for approved uses of prasugrel.

2.11 - Antifibrinolytic drugs and haemostatics

Etamsylate *(Dicynene®)* TAG recommendation: Jul 2017

for use in: Heavy menstrual bleeding - as per NICE CG 44 and the BNF (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 44 - Heavy menstrual bleeding: assessment and management which states:

1.5.16 Etamsylate should not be used for the treatment of HMB. [2007]

May 2018: The TAG acknowledged NG 88 (March 2018) - Heavy menstrual bleeding: assessment and management, which updates and replaces NICE guideline CG44 (January 2007).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.11 - Antifibrinolytic drugs and haemostatics

Fostamatinib *(Tavlesse®)* TAG recommendation: Mar 2022

for use in: refractory chronic immune thrombocytopenia as per TA759 - Jan 2022 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2022.

Specific points: Not commissionied for use in primary or secondary care. Not recommended by NICE

GlycoPEGylated Factor IX *(Rebinyn®)* TAG recommendation: May 2018

for use in: Haemophilia B (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Susoctocog alfa *(Obizur®)* TAG recommendation: May 2018

for use in: Antihaemorrhagics, blood coagulation factor VIII (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.11 - Antifibrinolytic drugs and haemostatics

Trenonacog alpha *(IXinity®)* TAG recommendation: May 2018

for use in: Haemophilia B (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Von Willebrand factor, recombinant - Factor VIII *(Von Willebrand factor (recombinant))* TAG recommendation: May 2018

for use in: Von Willebrand's disease / factor VIII deficiency (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

2.12 - Lipid-regulating drugs - Fibrates

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Bezafibrate *(Bezalip; Fibrazate)* TAG recommendation: Jul 2017

for use in: Prevention of CVD - as per NICE CG 181 "Do Not Do" (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.45 Do not routinely offer fibrates for the prevention of CVD to any of the following:
* people who are being treated for primary prevention
* people who are being treated for secondary prevention
* people with CKD
* people with type 1 diabetes
* people with type 2 diabetes. [new 2014]

Cholestyramine *(Questran®)* TAG recommendation: Jul 2017

for use in: Prevention of CVD, alone or added to a statin - as per NICE CG 181 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.47 Do not offer a bile acid sequestrant (anion exchange resin) for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes.

1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Ciprofibrate *(Generics are available)* TAG recommendation: Jul 2017

for use in: Prevention of CVD - as per NICE CG 181 "Do Not Do" (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.45 Do not routinely offer fibrates for the prevention of CVD to any of the following:
* people who are being treated for primary prevention
* people who are being treated for secondary prevention
* people with CKD
* people with type 1 diabetes
* people with type 2 diabetes. [new 2014]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Colesevelam HCl ▼ *(Cholestagel® ▼)* TAG recommendation: May 2008

for use in: Hypercholesterolaemia - as per N&W DROP List and NICE CG 181 Do Not Do (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: May 2008: The TAG agreed that colesevelam is classified as Double Red (Not recommended for routine use) in view of the lack of outcome data to support use over other evidence-based lipid-lowering therapies. The TAG also noted that this product is significantly more expensive than other lipid-lowering agents and that the recommended dosage regimen may cause compliance issues for many patients.

Colesevelam (Cholestagel) is a Black triangle ▼ drug which requires monitoring and reporting of any suspected adverse drug reactions Prescriber's Rating of 6. "Nothing New - the product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available."

March 2009: Following feedback from Dr Steve Absalom, Consultant Chemical Pathologist (JPUH), the TAG revisited its recommendation but maintained the Double Red classification. However it was agreed that individual cases could be considered where all other treatment options were inappropriate. GPs should contact their PCT Prescribing Adviser for advice.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.47 Do not offer a bile acid sequestrant (anion exchange resin) for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Colesevelam hydrochloride *(Cholestagel®)* TAG recommendation: Jul 2017

for use in: Prevention of CVD, alone or added to a statin - as per NICE CG 181 - Do Not Do (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.47 Do not offer a bile acid sequestrant (anion exchange resin) for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes.

1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.

Colestipol hydrochloride *(Colestid®)* TAG recommendation: Jul 2017

for use in: Prevention of CVD, alone or added to a statin - as per NICE CG 181 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.47 Do not offer a bile acid sequestrant (anion exchange resin) for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes.

1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Fenofibrate *(Lipantil®; Supralip®; Cholib®)* TAG recommendation: Jul 2017

for use in: Prevention of CVD - as per NICE CG 181 "Do Not Do" (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.45 Do not routinely offer fibrates for the prevention of CVD to any of the following:
* people who are being treated for primary prevention
* people who are being treated for secondary prevention
* people with CKD
* people with type 1 diabetes
* people with type 2 diabetes. [new 2014]

Fish oils (omega-3 fatty acids) *(Various - e.g. Equazen®, Omacor®, Maxepa®)* TAG recommendation: Sep 2004

for use in: Treatment of attention deficit hyperactivity disorder (ADHD) - as per N&W DROP List (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2000.

Specific points: September 2004:
TAG members agreed that, due to a lack of supportive evidence, use of omega-3 fatty acids (fish oils) for ADHD is not recommended for routine use (Double Red). This recommendation would be reviewed in the light of further information becoming available to supports use and an appropriate change in clinical practice.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Fish oils (omega-3 fatty acids) *(e.g. Omacor®, Maxepa®, Equazen®)* TAG recommendation: Jul 2017

for use in: Prevention of CVD, alone or added to a statin - as per NICE CG 181 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.48 Do not offer omega-3 fatty acid compounds for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes. [new 2014]

1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.

Gemfibrozil *(Lopid®)* TAG recommendation: Jul 2017

for use in: Prevention CVD - as per NICE CG 181 "Do Not Do" (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.45 Do not routinely offer fibrates for the prevention of CVD to any of the following:
* people who are being treated for primary prevention
* people who are being treated for secondary prevention
* people with CKD
* people with type 1 diabetes
* people with type 2 diabetes. [new 2014]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Lomitapide *(Lojuxta®)* TAG recommendation: May 2018

for use in: Homozygous familial hypercholesterolemia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nicotinic acid (niacin) and derivatives *(Various)* TAG recommendation: Jul 2017

for use in: All indications including prevention in CVD, alone or added to a statin - as per NICE CG 181 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.46 Do not offer nicotinic acid (niacin) for the prevention of CVD to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with CKD people with type 1 diabetes, people with type 2 diabetes.

1.3.50 Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

2.12 - Lipid-regulating drugs - Fibrates

Omega-3-acid ethyl esters *(Omacor®)* TAG recommendation: Sep 2007

for use in: Adjunct in lowering triglycerides in secondary prevention of coronary heart disease / ADHD (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2007.

Specific points: May 2004: Until further supporting evidence is available the TAG does not support widespread use of omega-3 fatty acid preparations as part of standard drug management in secondary prevention of CHD.
Advice regarding appropriate diet stands.

September 2007: Following publication of NICE Clinical Guideline No. 48 (May 2007) MI - Secondary Prevention, the TAG revisited the evidence for use of omega-3 fish oil products as part of routine treatment post MI. The TAG agreed that patients should be guided to increase their intake via healthy dietary measures and did not support routine provision of omega-3 fish oil products.
There should be no recommendation from secondary care specialists for these products to be prescribed in primary care.

July 2008: The TAG noted NICE Clinical Guideline No.66 May 2008 - Type 2 diabetes which refers to use of omega-3 fish oils for management of hypertriglyceridaemia but agreed to maintain its previous recommendation until more evidence becomes available.

July 2010: The TAG agreed to support the recommendation from the NHS Norfolk Prescribing Reference Group that regarding use of Omega 3 fish oils including Omacor, patients should be encouraged to take healthy dietary measures to increase their intake of fish oils.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment remains on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Poor evidence of benefit in ADHD. Not supported post MI.

2.14 - Cardiovascular system - miscellaneous

Tafamidis *(Vyndaqel®)* TAG recommendation: Jun 2021

for use in: transthyretin amyloidosis with cardiomyopathy as per TA696 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2021.

Specific points: Tafamidis is not recommended, within its marketing authorisation, for treating wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM) in adults

3.1.1 - Adrenoceptor agonists

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.1.1 - Adrenoceptor agonists

Epinephrine (Adrenaline) inhaler (Primatene Mist®) *(Primatene Mist®)* TAG recommendation: Nov 2015

for use in: Asthma - reliever therapy - as per N&W DROP List (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Unlicensed product previously available OTC.

Poor supporting data. Expensive product. Not recommended in national asthma guidelines.

3.2 - Sedating antihistamines

Alimemazine (Trimeprazine) *(Generics)* TAG recommendation: Mar 2018

for use in: Sedative in children / general antihistamine (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2018: PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment on the basis of a lack of sufficient evidence to justify the significant cost of this product over other available alternatives.
The TAG agreed to support the PRG's recommendation.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.2 - Sedating antihistamines

Inhaled corticosteroids *(Various)* TAG recommendation: Mar 2002

for use in: Children who wheeze with a cold (viral wheeze / bronchiolitis) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2007.

Specific points: No supporting evidence for the common practice of using inhaled steroids in children who wheeze only with a cold. Instead use a short course of oral steroids and multi-dosing of a bronchodilator. Consider anti-cholinergics in younger children.

January 2008: The TAG noted NICE Technology Appraisal Guidance 131 - Inhaled corticosteroids for the treatment of chronic asthma in children under the age of 12 years.

July 2015: The TAG and the D&TCG noted and acknowledged (NICE) NG 9 (May 2015) - Bronchiolitis in Children. NG 9 recommends that the following treatments should NOT be used to treat this condition in children:
* antibiotics
* hypertonic saline
* adrenaline (nebulised)
* salbutamol
* montelukast
* ipratropium bromide
* systemic or inhaled corticosteroids
* a combination of systemic corticosteroids and nebulised adrenaline.

July 2015: The D&TCG acknowledged NG 9 and agreed that the supporting evidence for this guidance would be considered further by the group.

3.4.1 - Antihistamines

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.4.1 - Antihistamines

Antihistamines (oral) *(Various)* TAG recommendation: Jul 2017

for use in: (Routine use) for Atopic eczema in children - as per NICE CG 57 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 57 - Atopic eczema in under 12s: diagnosis and management which states:

1.5.6.1 Oral antihistamines should not be used routinely in the management of atopic eczema in children.

1.5.6.2 Healthcare professionals should offer a 1-month trial of a non-sedating antihistamine to children with severe atopic eczema or children with mild or moderate atopic eczema where there is severe itching or urticaria. Treatment can be continued, if successful, while symptoms persist, and should be reviewed every 3 months.

1.5.6.3 Healthcare professionals should offer a 7-14 day trial of an age-appropriate sedating antihistamine to children aged 6 months or over during an acute flare of atopic eczema if sleep disturbance has a significant impact on the child or parents or carers. This treatment can be repeated during subsequent flares if successful.

Desloratadine *(Generics are available)* TAG recommendation: May 2018

for use in: Allergy (not for NHS provision - self care recommended) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is CCG commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.4.1 - Antihistamines

Doxylamine succinate + Pyridoxine *(Xonvea®)* TAG recommendation: Sep 2019

for use in: (with pyridoxine hydrochloride 10mg in a delayed-release formulation) for the treatment of nausea and vomiting in pregnancy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2019: The TAG noted that Xonvea® is the sole licensed option in the UK for this indication.
The TAG also acknowledged that there is long term experience of using other medicines off-label for this condition.
The TAG deferred making any recommendation for this product until the East of England Priorities Advisory Committee (PAC) issues its final interim guidance.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendations and decided to apply an interim traffic light classification of Double Red (Not recommended for routine use) / Not commissioned for use of Doxylamine succinate 10mg plus pyridoxine hydrochloride 10mg delayed-release (Xonvea®) for the treatment of nausea and vomiting in pregnancy.

May 2019: The TAG was advised that Local (NNUH) specialists have commented on the draft version 6. citing varying support for use on the licensed product. Draft v7 since circulated for final support
The latest draft PAC guidance indicates possible use in secondary care but not primary care.

Final PAC guidance not yet available (at the time of writing the TAG's agenda)
- further feedback from the PAC to be returned to the TAG in July 2019.

May 2019: The D&TC confirmed that the current interim traffic light classification of Double Red (Not recommended for routine use) / Not commissioned is maintained.

October 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of September 2019. The interim classification of Double Red (Not recommended for routine use) / Not commissioned to be made permanent.

Levocetirizine *(Xyzal®)* TAG recommendation: Nov 2015

for use in: Symptomatic relief of allergy such as hay fever, urticaria (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Isomer of cetirizine (which is now off-patent). No evidence of advantages over cetirizine other than for patients who have not tolerated or not responded to adequate trials of other less expensive antihistamines.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.4.1 - Antihistamines

Rupatadine *(Generic)* TAG recommendation: Sep 2018

for use in: Symptomatic relief of allergic rhinitis and urticaria (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2018: PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment due to a lack of evidence of sufficient additional benefit over standard care with other antihistamines to justify its additional cost.
The TAG agreed to support the PRG's recommendation.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

3.4.2 - Allergen immunotherapy

Grass pollen allergen extract *(Grazax®)* TAG recommendation: Sep 2013

for use in: Seasonal allergic hay fever due to grass pollen (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2007: Use not supported by the TAG due to lack of supporting evidence.

September 2013: Submission of JPUH re-application for use. The TAG considered that insufficient evidence was presented to say that the most severely affected group of patients would benefit significantly from the treatment, and that it would be clinically and cost effective.
The TAG felt unable to recommend a different classification on the basis of the evidence presented. Double Red (Not recommended for routine use / Not commissioned should be maintained for the time being.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) supported the TAG recommendation - treatment was not commissioned.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.4.2 - Allergen immunotherapy

Mepolizumab () TAG recommendation: Jan 2023

for use in: eosinophilic granulomatosis with polyangiitis (terminated appraisal) TA845 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Mepolizumab () TAG recommendation: Jan 2023

for use in: severe chronic rhinosinusitis with nasal polyps (terminated appraisal) TA847 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Mepolizumab () TAG recommendation: Jan 2023

for use in: severe hypereosinophilic syndrome (terminated appraisal) TA846 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Omalizumab () TAG recommendation: Mar 2021

for use in: chronic rhinosinusitis with nasal polyps (terminated appraisal) as per TA678 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - NICE is unable to make a recommendation about the use in the NHS of omalizumab for treating chronic rhinosinusitis with nasal polyps because Novartis Pharmaceuticals did not provide an evidence submission

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.4.2 - Allergen immunotherapy

Tralokinumab *()* TAG recommendation: May 2018

for use in: Asthma (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

3.4.3 - Allergic emergencies (not listed in BNF)

Avoralstat *()* TAG recommendation: May 2018

for use in: Hereditary angioedema (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ecallantide *(Kalbitor®)* TAG recommendation: May 2018

for use in: Hereditary angiodema - acute treatment only (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

3.7 - Mucolytics

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.7 - Mucolytics

Dornase alfa *(Pulmozyme®)* TAG recommendation: May 2018

for use in: Primary Ciliary Dyskinesia (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned - Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Lumacaftor-ivacaftor ▼ *(Orkambi® ▼)* TAG recommendation: Sep 2016

for use in: For treating cystic fibrosis in people 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2016.

Specific points: September 2016: The TAG acknowledged NICE TA 398 (July 2016) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.
The TAG was also advised that the manufacturer is offering free supplies of the treatment via a compassionate access scheme until a revised costing model is returned to NICE.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.7 - Mucolytics

N-acetylcysteine *()* TAG recommendation: May 2018

for use in: Idiopathic pulmonary fibrosis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2010.

Specific points: May 2018:
This treatment is CCG commissioning responsibility.

NICE CG 101 (June 2010) describes the management of chronic obstructive pulmonary disease and the place of mucolytics - https://www.nice.org.uk/guidance/CG101/chapter/1-Guidance#managing-stable-copd

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

Sodium Chloride (Hypertonic 3-7%) as a mucolytic *(Various including MucoClear®, Nebusal®)* TAG recommendation: Jul 2017

for use in: Prevent exacerbations in people with stable chronic obstructive pulmonary disease (COPD) - as per NICE CG 101 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 101 - COPD (update) which states:

1.2.3.9 Do not routinely use mucolytic drugs to prevent exacerbations in people with stable chronic obstructive pulmonary disease (COPD).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

3.7 - Mucolytics

Tezacaftor *(Symkevi® (with ivacaftor))* TAG recommendation: May 2018

for use in: Cystic Fibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

4 - Cough and congestion

Cough and cold remedies *((OTC products))* TAG recommendation: Nov 2015

for use in: Cough and cold (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG these treatments are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Generally aplies to any OTC remedy. There is limited evidence to suppport provision on the NHS. Most are not prescribable on FP10. These products may be purchased by patients who prefer to use them.

4.1.1 - Hypnotics

Clomethiazole *(Heminevrin®)* TAG recommendation: Jul 2017

for use in: Community-based assisted alcohol withdrawal - as per NICE CG 115 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 115 - Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence which states:
1.3.5.7 Do not offer clomethiazole for community-based assisted withdrawal because of the risk of overdose and misuse.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.1.1 - Hypnotics

Melatonin (all preparations) *(Colonis®, Ceyesto®, Syncrodin®)* TAG recommendation: Sep 2019

for use in: Jet lag (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: October 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG, D&TC & PRG recommendations and agreed a traffic light classification of Double Red (Not recommended for routine use/Not commissioned).

May 2020 - This recommendation includes the Colonis® brand melatonin 1mg/ml oral solution as this is not licenced for children under 18

Melatonin (SLENYTO®) *(SLENYTO®)* TAG recommendation: Mar 2020

for use in: Management of sleep disorders (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG concluded that they cannot support the use of Slenyto®, based on inability to assess cost effectiveness against present formulations and concerns that the population in which it is intended to be used is different than the present one that it is used. Therefore, a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) is advised for this branded medication. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for the Norfolk and Waveney CCG

Melatonin liquid preparations *()* TAG recommendation: Mar 2022

for use in: All indications (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Liquid preparations are not commissioned for local use. No prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.1.1 - Hypnotics

Melatonin prolonged release tablets (CIRCADIN) *(Circadin®)* TAG recommendation: Dec 2020

for use in: Management of sleep disorders in adults aged 18-55 (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Dec 2020 - The TAG and D+TC supported this recommendation. Ratified by CCG Governing Body

Melatonin prolonged-release tablets ▼ (Circadin) ▼ *(Circadin® ▼)* TAG recommendation: Sep 2008

for use in: Short term treatment of primary insomnia in adults aged 55 years and over (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG noted the main points from an independent review of Circadin:
* Evidence for use in primary insomnia is limited and indicates small effect
* The numbers of patients studied in the trials were very small
* There are no active comparator trials for use in primary insomnia (the licensed indication)
* Circadin is taken 1 to 2 hours before bedtime.
* The TAG did not support off-licence use of Circadin for other indications e.g. secondary insomnia which accounts for most cases of insomnia
* Sleep hygiene and stimulus control advice should be given before starting any pharmacological intervention in treating insomnia.
* Circardin is significantly more expensive than other hypnotics - NICE guidance states that the drug with the lowest acquisition cost should be prescribed following initial advice and management.

The TAG agreed a Prescriber's Rating of 7. "Not acceptable: the Product is without evident benefit but potential or real disadvantages."
The TAG did not amend its previous recommendation regarding use of immediate-release melatonin for use in sleep disorders (Red (Hospital Only)), but noted that MHRA restrictions on the import of unlicensed melatonin products do not apply to products which are manufactured to GMP standards in the UK.

4.1.2 - Benzodiazepines

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.1.2 - Benzodiazepines

Benzodiazepines *(Various)* TAG recommendation: Jul 2017

for use in: Generalised Anxiety Disorder (long term use) - as per NICE CG 113 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 113 - Generalised anxiety disorder and panic disorder in adults: management which states:

1.2.25 Do not offer a benzodiazepine for the treatment of GAD in primary or secondary care except as a short-term measure during crises. Follow the advice in the 'British national formulary' on the use of a benzodiazepine in this context. [new 2011]

Benzodiazepines *(Various)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.1.2 - Benzodiazepines

Benzodiazepines *(Various)* TAG recommendation: Jul 2017

for use in: Ongoing treatment of alcohol dependence - as per NICE CG 115 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 115 - Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence which states:
1.3.6.15 Benzodiazepines should only be used for managing alcohol withdrawal and not as on-going treatment for alcohol dependence.

Benzodiazepines *(Various)* TAG recommendation: Jul 2017

for use in: Panic disorder - as per NICE CG 113 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 113 - Generalised anxiety disorder and panic disorder in adults: management which states:

1.4.7 Benzodiazepines are associated with a less good outcome in the long term and should not be prescribed for the treatment of individuals with panic disorder.
[2004]

Buspirone *(Generics are available)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.2.1 - Antipsychotics

Antipsychotics *(Various)* TAG recommendation: Jul 2017

for use in: Borderline personality disorder (medium to long term treatment) - as per NICE CG 78 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 78 - Borderline personality disorder: recognition and management which states:

1.3.5.2 Antipsychotic drugs should not be used for the medium- and long-term treatment of borderline personality disorder.

Antipsychotics *(Various)* TAG recommendation: Jul 2017

for use in: Combined use (except for short periods) - as per NICE CG 178 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2014.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 178 - Psychosis and schizophrenia in adults: prevention and management which states:
1.3.6.10 Do not initiate regular combined antipsychotic medication, except for short periods (for example, when changing medication). [2009]

Antipsychotics *(Various)* TAG recommendation: Sep 2017

for use in: Loading doses of antipsychotic medication (aka 'rapid neuroleptisation') (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2014.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 178 - Psychosis and schizophrenia in adults: prevention and management which states:
1.3.6.9 Do not use a loading dose of antipsychotic medication (often referred to as 'rapid neuroleptisation'). [2009]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.2.1 - Antipsychotics

Antipsychotics *(Various)* TAG recommendation: Jul 2017

for use in: Generalised Anxiety Disorder - as per NICE CG 113 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 113 - Generalised anxiety disorder and panic disorder in adults: management which states:

1.2.26 Do not offer an antipsychotic for the treatment of GAD in primary care. [new 2011]

Antipsychotics *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of ADHD in children, young people and adults - as per NICE CG 72 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 72 -Attention deficit hyperactivity disorder: diagnosis and management which states:

1.5.5.7 Antipsychotics are not recommended for the treatment of ADHD in children and young people. [2008]
and
1.7.1.12 Antipsychotics are not recommended for the treatment of ADHD in adults. [2008]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.2.1 - Antipsychotics

Butyrophenones (benperidol and haloperidol) *(Various)*

TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Use in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of butyrophenones (and phenothiazines) in Parkinson's disease since they worsen the motor features of the condition.

The butyrophenones are:
benperidol and haloperidol, which resemble the group 3 phenothiazines in their clinical properties (i.e. generally characterised by fewer sedative and antimuscarinic effects, but more pronounced extrapyramidal side-effects than other phenothiazines).

Loxapine inhalation *(Adusave®)*

TAG recommendation: Jul 2013

for use in: Acute agitation and disturbed behaviours associated with schizophrenia and bipolar disorder (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2013.

Specific points: NICE TA 286 (May 2013) (terminated appraisal) states that NICE is unable to recommend the use in the NHS of loxapine inhalation for treating acute agitation and disturbed behaviours associated with schizophrenia and bipolar disorder because no evidence submission was received from the manufacturer of the technology.

July 2013: Noted by the Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) and comfirmed as Not Commissioned.

Lurasidone *(Latuda®)*

TAG recommendation: Nov 2020

for use in: •Off-label use of lurasidone to manage hallucinations/aggression relating to dementia (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use). Supported by TAG and D+TC. Ratified by CCG Governing Body

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.2.1 - Antipsychotics

Olanzapine *(Zalasta®, Zyprexa®, ZypAdhera® IM)* TAG recommendation: Sep 2017

for use in: For hallucinations and delusions in Parkinson's disease, where no cognitive impairment (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of olanzapine for hallucinations and delusions in Parkinson's disease.
The manufacturer's SPC states:
The use of olanzapine in the treatment of dopamine agonist associated psychosis in patients with Parkinson's disease is not recommended. In clinical trials, worsening of Parkinsonian symptomatology and hallucinations were reported very commonly and more frequently than with placebo, and olanzapine was not more effective than placebo in the treatment of psychotic symptoms.

Phenothiazines (see list of drugs in TAG Guidance) *(Various)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Use in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of phenothiazines (and butyrophenones) in Parkinson's disease since they worsen the motor features of the condition.

The phenothiazines are:
Group 1:
chlorpromazine, levomepromazine, and promazine, generally characterised by pronounced sedative effects and moderate antimuscarinic and extrapyramidal side-effects.
Group 2:
pericyazine, generally characterised by moderate sedative effects, but fewer extrapyramidal side-effects than groups 1 or 3.
Group 3:
fluphenazine, perphenazine, prochlorperazine, and trifluoperazine, generally characterised by fewer sedative and antimuscarinic effects, but more pronounced extrapyramidal side-effects than groups 1 and 2.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.2.1 - Antipsychotics

Quetiapine *(Seroquel)* TAG recommendation: Jan 2013

for use in: Generalised anxiety disorder (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2013:
Not commissioned by NHS Norfolk & Waveney. NICE guidance suspended. The manufacturer had withdrawn their licensing application for this indication.

4.2.3 - Drugs used for mania and hypomania

Carbamazepine *(Tegretol®, Carbagen®)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

4.3 - Antidepressant drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.3 - Antidepressant drugs

Antidepressants (including SSRIs) *(Various)* TAG recommendation: Jul 2017

for use in: (Routine use) for the treatment of alcohol misuse alone - as per NICE CG 115 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2011.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 115 - Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence which states:
1.3.6.13 Do not use antidepressants (including selective serotonin reuptake inhibitors [SSRIs]) routinely for the treatment of alcohol misuse alone.

4.3.1 - Tricyclic and related antidepressant drugs

Dosulepin hydrochloride *(Prothiaden®)* TAG recommendation: Jul 2017

for use in: Depression - as per NICE CG 90 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.5.2.4 When prescribing drugs other than serotonin reuptake inhibitors (SSRIs), dosulepin should not be prescribed.
and
1.8.1.3 Do not switch to, or start, dosulepin because evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.3.1 - Tricyclic and related antidepressant drugs

Trimipramine *(Generics available)* TAG recommendation: Sep 2017

for use in: Treatment of depressive illness, especially where sleep disturbance, anxiety or agitation are presenting symptoms (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017: The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) for all uses of trimipramine to prevent use in any new cases and also to encourage the review of current long-standing cases. Recommended to be added to the Norfolk & Waveney DROP List.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

4.3.2 - Monoamine-oxidase inhibitors

Monoamine oxidase inhibitors (MAOIs) *(Various)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

4.3.3 - Selective Serotonin RE-uptake Inhibitors

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.3.3 - Selective Serotonin RE-uptake Inhibitors

Paroxetine *(Generics available)* TAG recommendation: May 2018

for use in: Depression in children and young people - as per NICE CG 28 "Do Not Do" (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
Paroxetine (and also Venlafaxine) is not supported for use in children and young people - as per section 1.6.4.13 in NICE CG 28 - Depression in children and young people: identification and management (last updated September 2017).

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

4.3.4 - Other antidepressant drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.3.4 - Other antidepressant drugs

Agomelatine *(Valdoxan®)* TAG recommendation: Mar 2013

for use in: 4th line use in depression where other treatments have failed or not been tolerated (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2011.

Specific points: September 2011: NICE TA 231 (terminated appraisal) (http://guidance.nice.org.uk/TA231) was noted by the TAG. NICE was unable to recommend use of agomelatine in severe depression due to lack of submission.

January 2013: Listed as not commissioned by NHS Norfolk & Waveney (PCT).

March 2013:
The TAG revised its previous "Red" classification to "Double Red" in line with the current local commissioning position. The committee noted that the treatment is being provided within the Norfolk & Suffolk NHS FT at their own financial and clinical risk. GPs should NOT be approached to prescribe this treatment in Primary Care in Norfolk and Waveney.

January 2015:
The TAG noted the MHRA Drug Safety Update bulletin (Nov 2014) which included further warnings of the risk of liver toxicity caused by agomelatine:

Advice for healthcare professionals:
* Perform baseline liver function tests in every patient before starting treatment with agomelatine.
* Do not start treatment if serum transaminases exceed three times the upper limit of normal.
* Monitor liver function at 3, 6, 12, and 24 weeks after starting treatment and regularly thereafter when clinically indicated.
* Stop treatment immediately if serum transaminases exceed three times the upper limit of normal, or if patients have symptoms or signs of suspected liver injury.
* Tell patients to watch out for the symptoms and signs of liver injury (eg, jaundice, dark urine, bruising).
* Explain the importance of regular liver function monitoring.
* Advise patients to stop taking agomelatine and to get medical help immediately if they have any signs or symptoms of liver injury.
* Report any suspected cases of liver toxicity or other side effects via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard)

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.3.4 - Other antidepressant drugs

Esketamine *(Spravato®)* TAG recommendation: Jan 2023

for use in: treatment-resistant depression TA854 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care. Esketamine nasal spray with a selective serotonin reuptake inhibitor (SSRI) or a serotonin-norepinephrine reuptake inhibitor (SNRI) is not recommended, within its marketing authorisation, for treatment-resistant depression that has not responded to at least 2 different antidepressants in the current moderate to severe depressive episode in adults.

Esketamine *(Spravato®)* TAG recommendation: Jul 2023

for use in: major depressive disorder in adults at imminent risk of suicide (terminated appraisal) TA899 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Venlafaxine *(Generics / Various)* TAG recommendation: May 2018

for use in: Depression in children and young people - as per NICE CG 28 "Do Not Do" (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2017.

Specific points: May 2018:
Venlafaxine (and also paroxetine) is not supported for use in children and young people - as per section 1.6.4.13 in NICE CG 28 - Depression in children and young people: identification and management (last updated September 2017).

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

4.4 - CNS stimulants and drugs used for ADHD

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.4 - CNS stimulants and drugs used for ADHD

ADHD drugs - various *(Various)* TAG recommendation: Jul 2017

for use in: Use in pre-school children - as per NICE CG 72 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2016.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 72 (last updated February 2016) for Attention Deficit Hyperactivity Disorder included these recommendations:
Drug treatment is not recommended for pre-school children with ADHD. [2008]

ADHD drugs - various *(Various)* TAG recommendation: Jul 2017

for use in: First-line use in children and adolescents with ADHD - as per NICE CG 72 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2016.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations:

NICE CG 72 (last updated February 2016) for Attention Deficit Hyperactivity Disorder included these recommendations:
Drug treatment is not indicated as the first-line treatment for all school-age children and young people with ADHD. It should be reserved for those with severe symptoms and impairment or for those with moderate levels of impairment who have refused non-drug interventions, or whose symptoms have not responded sufficiently to parent-training/education programmes or group psychological treatment. [2008]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.4 - CNS stimulants and drugs used for ADHD

Dexamfetamine sulphate ▼ *(Generics are available)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.4 - CNS stimulants and drugs used for ADHD

Methylphenidate Hydrochloride *(Various)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.4 - CNS stimulants and drugs used for ADHD

Modafinil *(Provigil®)* TAG recommendation: Sep 2010

for use in: All unlicensed indications, including excess sleepiness in MS, Parkinson's Disease, obstructive sleep apnoea, or chronic shift work sleep disorder. (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2014.

Specific points: September 2010:
The TAG noted that the August 2010 MHRA Drug Safety bulletin included updated advice on use of modafinil. The TAG agreed to revise its previous recommendation regarding off-label use of modafinil to state:

Modafinil (Provigil®) is classified as Double Red (Not recommended for routine use) for all unlicensed indications, including excessive sleepiness associated with Multiple Sclerosis and Parkinson's Disease, obstructive sleep apnoea, or chronic shift work sleep disorder.

See separate "Green" entry for use in narcolepsy.

January 2015:
The TAG noted and supported NICE CG 186 regarding the following drug treatment recommendations under Section 1.5 - MS symptom management and rehabilitation:
For spasticity:
First- line: Use baclofen or gabapentin. If not tolerated consider switching to the other drug. Consider combining baclofen and gabapentin if individual drugs do not provide adequate relief, or side effects from individual drugs prevent the dose being increased.
Second-line: Consider tizanidine or dantrolene.
Third-line: Consider benzodiazepines; be aware of their potential benefit in treating nocturnal spasms. DO NOT offer Sativex® for spasticity in MS.
For oscillopsia:
First-line: Gabapentin.
Second-line: Consider memantine. Refer for specialist advice if there is no improvement after treatment with gabapentin and memantine, or side effects prevent continued use.
Lack of mobility in MS:
DO NOT use fampridine as it is not cost-effective.
Fatigue in MS:
Offer amantadine. DO NOT use vitamin B12 injections for fatigue.
Relapse and exacerbation: Offer oral methylprednisolone 0.5 g daily for 5 days. Do not use lower doses, nor provide a rescue course to treat next relapse.

The TAG also noted that the full NICE Clinical Guideline 186 also states that "modafanil should not be used to treat fatigue in MS."

Other treatments:
Consider amitriptyline to treat emotional lability.
DO NOT offer vitamin D solely for MS.
DO NOT offer omega-3 or -6 fatty acids.
Although the TAG decided not to assign new "Traffic Light" recommendations to any of the above-listed treatments, it was agreed that previous

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.4 - CNS stimulants and drugs used for ADHD

Double Red (Not recommended for routine use) recommendations for Sativex® for spasticity and for fampridine for reduced mobility were in line with NICE CG 186 and should be maintained.

January 2015:
The D&TCG noted and supported the TAG's recommendations regarding NICE CG 186 with particular reference to the treatments which are not recommended which will be drawn to the attention of local prescribers.

Pitolisant hydrochloride *(Ozawade®)* TAG recommendation: Apr 2022

for use in: excessive daytime sleepiness caused by obstructive sleep apnoea as per TA776 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2022.

Specific points: Not commissioned. Pitolisant hydrochloride is not recommended, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy such as continuous positive airway pressure (CPAP), or who cannot tolerate it.

Solriamfetol *(Sunosi®)* TAG recommendation: Apr 2022

for use in: excessive daytime sleepiness caused by obstructive sleep apnoea as per TA777 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2022.

Specific points: Not commissioned. Solriamfetol is not recommended, within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness in adults with obstructive sleep apnoea whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy, such as continuous positive airway pressure (CPAP).

Solriamfetol *(Sunosi®)* TAG recommendation: Mar 2022

for use in: excessive daytime sleepiness caused by narcolepsy as per TA758 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2022.

Specific points: Formulary application required

4.5 - Obesity

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.5 - Obesity

Naltrexone and Bupropion (Mysimba®)▼ *(Mysimba® ▼)* TAG recommendation: Jan 2018

for use in: Treatment of obesity (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2017.

Specific points: September 2016: The TAG acknowledged the PAC Full Evidence Review (Oct-Dec15) Naltrexone and Bupropion (Mysimba®) for treatment of obesity and recommended a classification of Double Red (Not recommended for routine use) as an interim position pending the UK launch of this treatment.
The TAG also requested that the PAC be asked to consider the place of this treatment for patients on mental health treatments which have led to weight gain.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation and agreed that Naltrexone and Bupropion (Mysimba®) for treatment of obesity is Double Red (Not recommended for routine use) / Not commissioned as an interim position, pending the UK launch of this treatment and local applications proposing its use.

January 2018: The TAG acknowledged NICE TA 494 (Dec 17) which does not recommend use of naltrexone-bupropion for managing overweight and obesity in adults and reaffirmed a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

4.5.1 - Anti-obesity drugs

Semaglutide *(Wegovy®)* TAG recommendation: Jun 2023

for use in: managing overweight and obesity TA875 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

Not yet available in UK.

4.6 - Drugs used in muscle spasm

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.6 - Drugs used in muscle spasm

Diazepam *(Generic)* TAG recommendation: Mar 2019

for use in: Chronic use for spasticity in adults with cerebral palsy - NICE Do Not Do as per NG 119 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2019.

Specific points: March 2019:
The TAG noted NICE NG 119 (January 2019) and acknowledged the Do Not Do's as follows:
*Regarding Drug therapy see:
1.3.9 Do not offer diazepam for spasticity in adults with cerebral palsy, except in an acute situation when spasticity is causing severe pain or anxiety.
1.3.10 Do not rapidly withdraw muscle relaxant drugs, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually to avoid withdrawal symptoms.
1.3.20 Do not prescribe levodopa to manage dystonia in adults with cerebral palsy, except in the rare situation when it is used as a therapeutic trial to identify dopa-responsive dystonia.
1.3.21 Do not rapidly withdraw enteral drugs for treating dystonia, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually to avoid withdrawal symptoms

Nabilone *(Nabilone®)* TAG recommendation: May 1998

for use in: Pain and spasticity in Multiple Sclerosis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Supported for this indication in trials only. Trials of cannabinoids underway at James Paget Hospital.

4.7.1 - Non-opiod analgesics & compound analgesic preps

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.7.1 - Non-opiod analgesics & compound analgesic preps

Co-proxamol *(Distalgesic)* TAG recommendation: Nov 2015

for use in: Pain - as per N&W DROP List (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Rationale for inclusion on the DROP list:
Markedly more toxic in overdose than paracetamol. No robust evidence of superiority over paracetamol alone (acute or chronic use).
Now a "special" and an extremely expensive product.

Tramadol & paracetamol combination *(Tramacet®)* TAG recommendation: Nov 2015

for use in: Moderate to severe pain (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Fixed dose combination of 37.5mg tramadol plus 325mg paracetamol per tablet. No more effective than established analgesics in acute or chronic pain. The combination ir more expensive than the individual components.

Only foreseen circimstances in which use migh be appropriate is specialist initiation in exceptional circumstances by pain physicians.

4.7.2 - Opioid analgesics

Dipipanone10mg / cyclizine 30mg *(Diconal®)* TAG recommendation: Jan 2022

for use in: treatment of acute pain (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: No NHS prescribing in primary or secondary care. Used for pain relief, legacy drug, drive to get patients to stop this treatment

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

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4.7.2 - Opioid analgesics

Fentanyl I-R - buccal tabs, loz, nasal sprays *(Effentora®, Actiq®, Instanyl®, PecFent®)* TAG recommendation: Dec 2021

for use in: (Acute) breakthrough pain in cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG agreed to recommend that Abstral® (sublingual tablets) is the immediate-release (I-R) fentanyl formulation of choice. Other immediate-release fentanyl preparations including buccal tablets, lozenges/lollipops, and intranasal sprays, are not recommended for routine use (Double Red).
Sublingual fentanyl tablets are for use only in breakthrough pain in cancer as a third-line treatment option.
The maximum recommended number of daily doses must not be exceeded. Background analgesia must be adjusted if more than 4 episodes of breakthrough pain are experienced a day.
Use of Abstral® is recommended only under an approved shared care agreement with Palliative Care specialists i.e. Amber (option for shared care with a written agreement).
Abstral® is currently recommended as Red (Hospital Only) until a written shared care agreement is agreed by local Palliative Care consultants and approved by the TAG.
Prescriber's Rating of 4. Possibly helpful - the product has minimal additional value, and should not change prescribing habits except in rare circumstances.
Abstral® is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the CHM and MHRA Yellow Card scheme.

July 2012: The TAG noted NICE CG 140 Opioids in Palliative Care.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

September 2016:
The TAG acknowledged NICE CG 140 (August 2016) - update includes recommendations on:
* communication
* starting strong opioids and titrating the dose
* first-line maintenance treatment
* first-line treatment using transdermal patches or subcutaneous delivery, if oral opioids are not suitable
* first-line treatment for breakthrough pain in patients who can take oral opioids *managing constipation, nausea and drowsiness

Dec 2021 - Regarding Abstral, TAG felt a shared care agreement was not
appropriate under these circumstances. Statement to be published on Netformulary. Under very rare/emergency circumstances (related to inability of consultant generated prescriptions being able to arrive with the patient in sufficient time to receive ongoing supplies) it is considered that a direct request from a
consultant to a GP to issue a very short-term limited emergency supply would be acceptable with no expectation of ongoing GP prescription responsibility

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.7.2 - Opioid analgesics

Oxycodone / Naloxone (Targinact®) ▼ *(Targinact® ▼)* TAG recommendation: Jul 2009

for use in: Pain / opioid-induced constipation (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG agreed that there was no information to indicate that Targinact offers an advantage over standard treatment. Prescriber's Reference 5. Judgement Reserved - the committee will revisit its judgement when better data and a more thorough evaluation of the drug are available.
* Targinact® is a combination of a modified-release oxycodone with the opioid antagonist naloxone, which although shown to reduce constipation but has not been compared with standard treatment with laxatives.
* The TAG noted that the Scottish Medicines Consortium (SMC) does not recommend use of Targinact® due a lack of a robust economic case being made.
* The TAG was also concerned about cost-effectiveness compared with standard care and pain control with modified-release morphine sulphate.
* The TAG did not support use of a fixed-combination where treatment could not be adjusted to individual need.

July 2012: The TAG noted NICE CG 140 Opioids in Palliative Care.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment remains on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Uncertain clinical benefit. Poor cost effectiveness. Rejected by the Scottish Medicines Consortium (SMC).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.7.2 - Opioid analgesics

Prolonged release oxycodone (Onexila XL) *(Onexila® XL)* TAG recommendation: May 2018

for use in: Analgesia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April to May 2018:
PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment on the basis of a risk of inappropriate prescribing if confused with 12 hour BD MR preps i.e. Longtec, Oxycontin.
Prescribing by brand to avoid confusion between different formulations is also recommended.

The TAG agreed to support the PRG's recommendation.

May 2018: Noted and supported by the D&TC as Double Red (Not recommended for routine use)
- Not recommended for commissioning.

June 2018:
The TAG and the D&TC's recommendaions were supported by the Norfolk and Waveney CCGs' JSCC.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.7.2 - Opioid analgesics

Tapentadol (immediate-release) *(Palexia® ▼)* TAG recommendation: May 2012

for use in: Management of moderate to severe pain in adults, where opioid analgesia is necessary (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG used a Decision-Making Framework to assess use of immediate-release tapentadol. The majority of the assessment criteria were rated as medium grade regarding clinical effectiveness and safety, and low grade regarding cost and priorities. There was no clear indication for its use. No specific patient groups were identified where the treatment would be beneficial.

Prescriber's Rating:
Nothing new - the product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available.

17th May 2012: NHS Norfolk & Waveney Drug & Therapeutics Commissioning Group decided that use of tapentadol immediate-release tablets for any indication was not supported and is not commissioned for NHS prescribing in NHS Norfolk and Waveney.

July 2012: The TAG noted NICE CG 140 Opioids in Palliative Care.

The TAG also supported a Shared Care Agreement for tapentadol SR (see separate entry under Amber section) to be used in conjunction with an Initiation Checklist when transferring prescribing responsibility to GPs.
The Shared Care document is available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2016:
The TAG acknowledged NICE CG 140 (August 2016) - update includes recommendations on:
* communication
* starting strong opioids and titrating the dose
* first-line maintenance treatment
* first-line treatment using transdermal patches or subcutaneous delivery, if oral opioids are not suitable
* first-line treatment for breakthrough pain in patients who can take oral opioids *managing constipation, nausea and drowsiness

4.7.4.1 - Treatment of acute migraine

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.7.4.1 - Treatment of acute migraine

Sumatriptan (as Imigran RADIS®) *(Imigran RADIS®)* TAG recommendation: Nov 2015

for use in: Acute migraine; cluster headaches (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

New forumulation of a drug which is off-patent. This is considerably more expensive than generic sumatriptan.

4.7.4.2 - Prophylaxis of migraine

Erenumab *(Aimovig®)* TAG recommendation: Apr 2021

for use in: preventing migraine as per TA682 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2021.

Specific points: April 2021 - awaiting submission of business case

Rimegepant *(Vydura)* TAG recommendation: Jul 2023

for use in: preventing migraine TA906 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

4.8.1 - Control of epilepsy

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.8.1 - Control of epilepsy

Brivaracetam *(Briviact®)* TAG recommendation: Mar 2022

for use in: epilepsy as alternative to levetiracetam (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Formulary application required

Eslicarbazepine *(Zebinix®)* TAG recommendation: Nov 2020

for use in: Epilepsy (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use) pending the submission of a business case. Supported by TAG and D+TC. Ratified by CCG Governing Body

Eslicarbazepine *(Zebinix®)* TAG recommendation: Nov 2020

for use in: trigeminal neuralgia (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use) pending the submission of a business case. Supported by TAG and D+TC. Ratified by CCG Governing Body

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.8.1 - Control of epilepsy

Lamotrigine *(Lamictal®; Generics are available)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.8.1 - Control of epilepsy

Retigabine ▼ (discontinued June 2017) *(Trobalt® ▼)* TAG recommendation: Jul 2015

for use in: Adjunctive treatment for partial onset seizures +/- secondary generalization (A licensed indication).

Prescribing responsibility: Not recommended for routine use at least one month & stable.

NICE issued Guidance in: July 2011.

Specific points: NICE TA 232 states: Retigabine is recommended (by NICE) as an option for the adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and older with epilepsy, only when previous treatment with carbamazepine, clobazam, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, sodium valproate and topiramate has not provided an adequate response, or has not been tolerated.
Recommended by the TAG as Red (Hospital Only).

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided NOT to commission or fund retigabine as adjunctive treatment for partial onset seizures in epilepsy as per NICE TA 232 (July 2011) until there is agreement on a local treatment pathway and a business case for use is approved.
November 2011: The TAG considered a business case from the NNUH regarding use of retigabine as per NICE (http://guidance.nice.org.uk/TA232) i.e. 9th line use, awaiting the submission of a Shared Care Agreement.

17th November 2011: The NHS Norfolk and Waveney Drugs & Therapeutics Commissioning Group agreed to support the TAG's recommendation.

January 2012: The TAG approved a Shared Care proposal from the NNUH for use of retigabine, 9th line after other treatments have been ineffective or not tolerated, as per NICE TA 232.
The TAG recommended that the traffic light classification was revised from Red (Hopsital Only) to Amber (option for Primary Care prescribing under an approved shared care agreement).
Noted and supported by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (January 2012).
The Shared Care Agreement for use of retigabine is available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2013: Dr J Cochius (Consultant Neurologist NNUH) has confirmed that following recent MHRA safety warnings regarding adverse effects on skin, nails and eyes related to use of retigabine, he will not initiate treatment in any new patients. Current patients will have appropriate ophthalmic examinations organised via the NNUHFT.

July 2015: ePACT data indicates that there are only two local patients in Norfolk still on retigabine. TAG agreed that the current shared care prescribing document should be revised to Prescribing Guidance specifically for the GPs of the remaining two patients in primary care and retigabine to be re-classified as Double Red (Not for routine use/not commissioned).

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.8.1 - Control of epilepsy

Sodium valproate ▼/ semisodium ▼ *(Epilim®, Episenta®, Depakote®)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2017.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

Stiripentol *(Diacomit®)* TAG recommendation: Sep 2018

for use in: For SCN1A related and Severe Myoclonic Epilepsies in Infancy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2018: The TAG agreed that for the time being stiripentol should be classified as Double Red (Not recommended for routine use) with any requests for funding to be made via the IFR-Drugs Panel.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

4.8.2 - Drugs used in status epilepticus

Fosphenytoin sodium *(Pro-Epanutin®)* TAG recommendation: Apr 2000

for use in: Status epilepticus, seizures with head injury,etc. (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Phenytoin preferred. Prescribe by brand to ensure continuity of care.

4.9.1 - Dopamine-receptor agonists

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.1 - Dopamine-receptor agonists

Bromocriptine *()* TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

Cabergoline *()* TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

Levodopa *(Generic / various)* TAG recommendation: Mar 2019

for use in: Management of dystonia in adults with cerebral palsy - as per NG 119 - NICE Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2019.

Specific points: March 2019:
The TAG noted NICE NG 119 (January 2019) and acknowledged the Do Not Do's as follows:
*Regarding Drug therapy see:
1.3.9 Do not offer diazepam for spasticity in adults with cerebral palsy, except in an acute situation when spasticity is causing severe pain or anxiety.
1.3.10 Do not rapidly withdraw muscle relaxant drugs, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually to avoid withdrawal symptoms.
1.3.20 Do not prescribe levodopa to manage dystonia in adults with cerebral palsy, except in the rare situation when it is used as a therapeutic trial to identify dopa-responsive dystonia.
1.3.21 Do not rapidly withdraw enteral drugs for treating dystonia, particularly if adults with cerebral palsy have taken them for more than 2 months or at a high dosage. Reduce the dosage gradually to avoid withdrawal symptoms

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.1 - Dopamine-receptor agonists

Pergolide () TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

Pramipexole () TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.1 - Dopamine-receptor agonists

Pramipexole - Prolonged Release *(Mirapexin® Prolonged Release)* TAG recommendation: Jul 2017

for use in: Idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa - Not commissioned from mid March 2011 onwards (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2011:
Please also see separate "Green" entries relating to immediate-release pramipexole and for prolonged release pramipexole for patients initiated on treatment prior to mid March 2011.

March 2011:
The TAG considered the comparative costs of generic IR pramipexole and branded PR pramipexole. PR pramipexole was not judged to offer cost-effective treatment at present, prior to agreement on the patient group and treatment pathway.
The TAG's recommendations were noted and approved by NHS Norfolk's D&TCG on 17th March 2011.

January 2012: Work on agreeing a treatment pathway is in progress.

June 2013: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group considered concerns raised by the NNUH regarding on-going prescribing responsibility for patients maintained on pramipexole MR whose treatment had been initiated prior to the decision not to commission use.

The D&TCG agreed the following:
* There should be no new episodes of treatment with Mirapexin MR started whilst it remains Not Commissioned.
* The Acute Trusts should ensure that all neurology / MFE specialists (including nurses) are aware of the current commissioning position and that there must be no new initiations of treatment.
* GPs can continue to prescribe Mirapexin MR for current patients only i.e. those patients started on treatment prior to mid March 2011.
* However there should be active attempts at specialist clinic appointments to review and transfer their treatment to immediate-release pramipexole or other suitable and cost-effective treatment options.

May 2017:
TheTAG reiterated its position regarding use of pramipexole prolonged-release and confirmed that only immediate-release formulations are supported for use.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.1 - Dopamine-receptor agonists

Rasagiline *(Generics available)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Pharmacological neuroprotective therapy in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of MAO-B inhibitors as pharmacological neuroprotective therapy in Parkinson's disease.

Ropinirole *()* TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

Rotigotine *()* TAG recommendation: Mar 2022

for use in: restless legs syndrome (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Safinamide ▼ *(Xadago® ▼)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Pharmacological neuroprotective therapy in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of MAO-B inhibitors as pharmacological neuroprotective therapy in Parkinson's disease.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.1 - Dopamine-receptor agonists

Selegiline *(Eldepryl®, Zelapar®)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Pharmacological neuroprotective therapy in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of MAO-B inhibitors as pharmacological neuroprotective therapy in Parkinson's disease.

4.9.2 - Antimuscarinic drugs used in parkinsonism

Orphenadrine *(Generics available)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Dyskinesia and/or motor fluctuations in Parkinson's disease - as per NG 71 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of anticholinergics for Parkinson's dyskinesia and/or motor fluctuations.

Procyclidine *(Kemadrin®)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Dyskinesia and/or motor fluctuations in Parkinson's disease - as per NG 71 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of anticholinergics for Parkinson's dyskinesia and/or motor fluctuations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.9.2 - Antimuscarinic drugs used in parkinsonism

Trihexyphenidyl hydrochloride *(Generics available)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Dyskinesia and/or motor fluctuations in Parkinson's disease - as per NG 71 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson’s disease in adults which recommended against use of anticholinergics for Parkinson’s dyskinesia and/or motor fluctuations.

4.9.91 - Dopamine-receptor agonists

Rotigotine *()* TAG recommendation: Sep 2017

for use in: Pharmacological neuroprotective therapy in Parkinson's disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson’s disease in adults which recommended against use of dopamine agonists as pharmacological neuroprotective therapy in Parkinson's disease.

4.10 - Drugs used in substance dependence

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.10 - Drugs used in substance dependence

Naltrexone - low dose *(Several low strength options available)* TAG recommendation: May 2004

for use in: Use of a Low Dose in Multiple Sclerosis (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Low-strength doses (1mg to 5mg oral doses, obtained from imported low strength tablets and capsules) have been used to control symptoms of MS. However such use is unlicensed in the UK and clinical trial evidence to support its use (on the NHS) is lacking. The TAG did not support its use nor would encourage provision via private prescription.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this treatment will remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Note: Naltrexone HCl Caps are available in 1.5mg, 1mg, 2mg, 2.5mg, 3mg, 3.5mg, 4mg, 4.5mg and 5mg strengths - all are classified as Double Red (Not recommended for routine use)

4.10.1 - Drugs used in alcohol dependence

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.10.1 - Drugs used in alcohol dependence

Nalmefene *(Selincro®)* TAG recommendation: Mar 2013

for use in: Reduction of alcohol consumption in those aged ≥18 years with alcohol dependence that have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification. (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2014.

Specific points: March 2013:
Nalmefene is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the MHRA Yellow Card scheme.

Recommended by the TAG as Double Red (Not recommended for routine use).
Prescriber's Rating: "Judgement reserved (#5)" until further information becomes available.

Not commissioned by NHS Norfolk & Waveney for the time being.

July 2013: The TAG noted the NHS East of England - Priorities Advisory Committee (PAC) Draft Policy which states that:
At present GPs should not be asked to prescribe Nalmefene unless there is a local arrangement.
Commissioning responsibility sits with DAAT.
Points to be considered by DAAT:
* To establish a place for Nalmefene as part of the pathway in the management of alcohol dependence
* The prescribing must not be a repeat process but with supervision to ensure that it is used for treating alcohol dependence and not to support a chosen life style.
* Nalmefene should be initiated under specialist recommendation and supervision.
* Not suitable for initiation in primary care.

Noted by the Norfolk & Waveney Drugs & Therapeutics Commissioning Group.

November 2014: The TAG noted the positive NICE Final Appraisal Determination (ID 660) and agreed to reconsider nalmefene after publication of the final NICE TA guidance in November 2014, alongside a possible application from the NSFT. Commissioning responsibility rests with Public Health.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG's recommendation.

January 2015: The TAG acknowledged NICE TA 325 but was unable to recommend a revised classification due to an application and proposed pathway from local specialists for its use not having been considered yet by the NSFT D&TC and service leads.

January 2015: Noted by the NHS Norfolk & Waveney CCGs' D&TCG and recommended as "Not for prescribing in Primary Care" until the commissioning position and associated supportive services related to this treatment are finalised by the responsible commissioner.

March 2015: In the absence of confirmation regarding the commissioning of this treatment and its related support services by Public Health, the TAG agreed that the classification of Double Red (Not recommended for routine use) should remain in the interim in order to guide GPs against prescribing nalmefene outside a locally commissioned service with secure funding arrangements.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

4.10.1 - Drugs used in alcohol dependence

March 2015: The TAG's recommendation to maintain the classification of Double Red (Not recommended for routine use) was noted and supported by the NHS Norfolk & Waveney CCGs' D&TCG.

July 2015: The TAG and the D&TCG were advised on Public Health Norfolk's intention to commission a specialist service to support provision of this treatment and would await further progress on this matter.

July 2016: The TAG was advised that Public Health (Norfolk) has decided not to commission a service to support the use of nalmefene. In view of there being a 6.8% reduction in spending, year on year for the next 5 years, the decision not to commission this treatment is therefore unlikely to be changed.

July 2016: The D&TCG noted Public Health Norfolk's commissioning decision regarding this treatment and reiterated the position that GPs in Norfolk & Waveney should not prescribe nalmefene.

4.10.3 - Opioid substitution therapy

Buprenorphine long-acting injection *(Buvidal®)* TAG recommendation: May 2021

for use in: opioid substitution treatment (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case as per RMOC guidance

5.1 - Aminoglycoside antibacterials

Amikacin - liposomal for inhalation *(Arikace®)* TAG recommendation: May 2018

for use in: Gram-negative bacterial infection in Cystic Fibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre use only - IFR approval required.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.1 - Aminoglycoside antibacterials

Amikacin (for inhalation) *(Amikin®)* TAG recommendation: May 2018

for use in: Gram-negative bacterial infection in Cystic Fibrosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre use only - IFR approval required.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Antibiotic prophylaxis *(Various)* TAG recommendation: Jul 2017

for use in: Infective endocarditis and interventional procedure (dental/non dental) - as per NICE CG 64 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2016.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 64 - Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures which states:

Prophylaxis against infective endocarditis:
1.1.3 Antibiotic prophylaxis against infective endocarditis is not recommended routinely[1]:
* for people undergoing dental procedures
* for people undergoing non-dental procedures at the following sites:
  - upper and lower gastrointestinal tract
  - genitourinary tract; this includes urological, gynaecological and obstetric procedures, and childbirth
  - upper and lower respiratory tract; this includes ear, nose and throat procedures and bronchoscopy. [2015]

1.1.4 Chlorhexidine mouthwash should not be offered as prophylaxis against infective endocarditis to people at risk of infective endocarditis undergoing dental procedures. [2015]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.1 - Aminoglycoside antibacterials

Antibiotics (oral for children)) *(Various)* TAG recommendation: Sep 2017

for use in: Fever in children without apparent source - as per NICE CG 160 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2017.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 160 - Fever in under 5s: assessment and initial management which states:
1.4.4.1 Do not prescribe oral antibiotics to children with fever without apparent source. [2007]

5.1.7 - Some other antibacterials

Rifaximin *((Targaxan® / Xifaxanta®))* TAG recommendation: Jul 2017

for use in: Chronic diarrhoea in G-I disorders (including Crohn's disease, Ulcerative Colitis, Diverticular disease, IBS, recurrent C. diff infection, small intestinal bacterial ovegrowth (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG acknowledged the guidance from the East of England Priorities Advisory Committee (PAC) (July 2016) and agreed to recommend a classification of Double Red (Not recommended for routine use) for the management of chronic diarrhoea associated with gastro-intestinal disorders (including Crohn's disease (CD), Ulcerative Colitis (UC), Diverticular disease (DD), Irritable bowel syndrome (IBS), recurrent Clostridium difficile infection and small intestinal bacterial overgrowth (SIBO)).

July 2017: The Norfolk & Waveney CCGs' D&TCG noted and supported the PAC and the TAG recommendations and decided to classify this treatment as Double Red (Not recommended for routine use) for the additional specified indications.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.1.7 - Some other antibacterials

Rifaximin *(Xifaxanta®)* TAG recommendation: May 2015

for use in: For treatment of traveller's diarrhoea (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2015: Use of rifaximin for this indication not supported by the nhs Norfolk & Waveney CCGs' PRG and recommended for addition to the N&W DROP List
The TAG noted and supported the PRG's recommendations.
The TAG therefore recommended a classification of Double Red (Not recommended for routine use) for this product for this licensed indication.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

5.1.9 - Antituberculosis drugs - Antimycobacterials

(Para-)aminosalicylic acid *()* TAG recommendation: May 2018

for use in: Tuberculosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.1.9 - Antituberculosis drugs - Antimycobacterials

Pretomanid *()* TAG recommendation: May 2018

for use in: Multi drug resistant tuberculosis (TB) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.1.12 - Quinolones

Ciprofloxacin (inhalation) *()* TAG recommendation: May 2018

for use in: Cystic Fibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ciprofloxacin liposomal (inhaled) *()* TAG recommendation: May 2018

for use in: Cystic Fibrosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.2 - Antifungal drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.2 - Antifungal drugs

Fluconazole (Oral) *(Generics available)* TAG recommendation: May 2018

for use in: Vaginal candidiasis in pregnancy - as per NICE CG 62 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2017.

Specific points: May 2018:
NICE CG 62 states:
1.4.6.3 The effectiveness and safety of oral treatments for vaginal candidiasis in pregnancy are uncertain and these treatments should not be offered.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.2.4 - Echinocandin antifungals

Micafungin *(Mycamine®)* TAG recommendation: Mar 2011

for use in: Systemic fungal infections (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The Chronic Pulmonary Aspergillosis Service was designated and nationally commissioned from April 2009. It is a single centre service provided at the University Hospital of South Manchester NHS Foundation Trust.
All anti-fungal therapies for the treatment of CPA are to be commissioned nationally.
There should be no local prescribing of anti-fungal therapies for the treatment of CPA.

Following a review of the evidence, in conjunction with the service provider, the following treatments are recommended:
* Short course IV amphotericin B for in-patient treatment to induce disease control in severely ill patients before transfer to oral itraconazole.
* Antifungal therapy limited to oral itraconazole (1st line) with oral voriconazole available only for those who are intolerant or resistant to itraconazole.
* Patients intolerant or resistant to voriconazole will receive either (i) supportive care or non-pharmaceutical intervention (subject to further presentation of evidence) or (ii) additional anti-fungal therapy offered only as part of a robust clinical trial commissioned and funded outside the NCG contract. Therefore, the use of posaconazole, long-term IV amphotericin B, IV micafungin or IV gamma interferon (the latter solely as a treatment for chronic pulmonary aspergillosis) should not be routinely commissioned because of the lack of evidence to support their use.
* Individual funding requests for patients considered to be exceptional to this policy will be submitted (subject to clarification of this process) and, where appropriate, funded by NCG.

November 2103: Policy adopted by NHS England Commissioning Board - http://www.england.nhs.uk/wp-content/uploads/2013/06/a14-chron-pulm-asper-ad.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3 - Antiviral drugs

Antivirals *(Various)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

Filibuvir *()* TAG recommendation: May 2018

for use in: Viral Hepatitis (B&C) and Respiratory Syncytial Virus (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3 - Antiviral drugs

Lonafarnib *(Sarasar®)* TAG recommendation: May 2018

for use in: Hepatitis D infection (with ritonavir) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Anglia Cancer Network Commissioned Therapies. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Taribavirin (viramidine) *()* TAG recommendation: May 2018

for use in: Viral Hepatitis C (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.3.1 - HIV Infection - not a licensed product

Doravirine *()* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR Approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3.1 - HIV Infection - not a licensed product

Elvucitabine *()* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Fostemsavir *()* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ibalizumab *(Trogarzo®)* TAG recommendation: May 2018

for use in: HIV in combination with other anti-retroviral drugs (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3.1 - HIV Infection - not a licensed product

Tenofovir alafenamide fumarate ▼ *(Vemlidy® ▼)* TAG recommendation: May 2017

for use in: Chronic Hepatitis B (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 434 (March 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017: The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group noted the TAG's recommendation.

5.3.3 - Not listed in BNF - cylcophilin inhibitor

Alisporivir *((aka Debio 025 / DEB025 / UNIL-025))* TAG recommendation: May 2018

for use in: Viral Hepatitis C - as per NHSE policy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre use only - IFR approval required.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Beclabuvir *()* TAG recommendation: May 2018

for use in: Hepatitis C (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3.3 - Not listed in BNF - cylcophilin inhibitor

Dasabuvir *(Exviera®)* TAG recommendation: May 2018

for use in: Viral Hepatitis C (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR Approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Setrobuvir *()* TAG recommendation: May 2018

for use in: Viral Hepatitis C - as per NHSE policy (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Telbivudine *(Sebivo®)* TAG recommendation: Sep 2008

for use in: Chronic hepatitis B (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2008.

Specific points: NICE Technology Appraisal No. 154 states that telbivudine is not recommended for treatment of chronic hepatitis B.

November 2013: Commissioning responsibility for chronic hepatitis B transferred to NHS England SCG from April 2013.

5.3.3.2 - Not listed in BNF

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3.3.2 - Not listed in BNF

Asunaprevir (with Daclatasvir) *()* TAG recommendation: May 2018

for use in: Viral Hepatitis (B&C) and Respiratory Syncytial Virus (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Simeprevir *(Olysio®)* TAG recommendation: Nov 2015

for use in: For treating genotype 1 or 4 chronic hepatitis C in combination with sofosbuvir (Sovaldi®) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2015.

Specific points: November 2015: The TAG noted NICE TA 361 (October 2015) (terminated appraisal) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

5.3.4 - Influenza

Amantadine Hydrochloride *(Lysovir®)* TAG recommendation: Nov 2008

for use in: Prophylaxis of influenza (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2008.

Amantadine Hydrochloride *(Lysovir®)* TAG recommendation: Nov 2003

for use in: Treatment of influenza (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2009.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

5.3.4 - Influenza

Baloxavir marboxil *()* TAG recommendation: Nov 2022

for use in: acute uncomplicated influenza as per TA732 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2022.

Specific points: No NHS prescribing in primary or secondary care. NICE is unable to make a recommendation about the use in the NHS of baloxavir marboxil for treating acute uncomplicated influenza. This is because Roche has confirmed that it does not intend to make an evidence submission for the appraisal at this time

5.4.1 - Antimalarials

Malaria prophylaxis *(Choroquine Malarone® Mefloquine Primaquine Proguan)* TAG recommendation: Nov 2015

for use in: Malaria chemoprophylaxis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Not reimbursible under NHS (guidance FHSL(95)7).

May be provided to registered patients using private prescriptions.

6 - Vitamins and trace elements - B group

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6 - Vitamins and trace elements - B group

Aminobenzoic acid (capsules and powder) *(Potaba®)*

TAG recommendation: Jan 2018

for use in: Peyronie's disease, Scleroderma (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2018: PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment:
The TAG agreed to support the PRG's recommendation

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation

Potassium aminobenzoate (capsules and powder) *(Potaba®)*

TAG recommendation: Jan 2018

for use in: Peyronie's disease, Scleroderma (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2018: PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment:
The TAG agreed to support the PRG's recommendation

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

6.1.1.1 - Rapid-acting insulins

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.1.1 - Rapid-acting insulins

Insulin analogues (rapid acting) *(Various)* TAG recommendation: Sep 2015

for use in: Routine use after meals in T1 Diabetes - NICE Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2015.

Specific points: NG 17 - Diabetes mellitus states:
Rapid-acting insulin
1.7.7 Offer rapid-acting insulin analogues injected before meals, rather than rapid-acting soluble human or animal insulins, for mealtime insulin replacement for adults with type 1 diabetes. [new 2015]
1.7.8 Do not advise routine use of rapid-acting insulin analogues after meals for adults with type 1 diabetes. [new 2015]
1.7.9 If an adult with type 1 diabetes has a strong preference for an alternative mealtime insulin, respect their wishes and offer the preferred insulin. [new 2015]

6.1.1.2 - Intermediate and long-acting insulins

Insulin - Non-basal-bolus regimens *(Various)* TAG recommendation: Sep 2015

for use in: Newly diagnosed Type 1 diabetes - NICE Do Not Do (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2015.

Specific points: NG 17 - Diabetes mellitus states:
1.7 Insulin therapy
Insulin regimens
1.7.1 Offer multiple daily injection basal-bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin injection regimen of choice for all adults with type 1 diabetes. Provide the person with guidance on using multiple daily injection basal-bolus insulin regimens. [new 2015]

1.7.2 DO NOT offer adults newly diagnosed with type 1 diabetes non-basal-bolus insulin regimens (that is, twice-daily mixed, basal only or bolus only). [new 2015]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.1.2 - Intermediate and long-acting insulins

Insulin degludec *(Tresiba®)* TAG recommendation: May 2018

for use in: ROUTINE use in Type 1 and Type 2 diabetes mellitus - see separate entry regarding RESTRICTED USE (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2015.

Specific points: March 2017:
The TAG noted the East of England Priorities Committee (PAC) recommendations for restricted use of insulin degludec in adults and children with type 1 diabetes, and recommended against routine use in type 1 diabetes and any case of type 2 diabetes.
The TAG supported the guidance and recommended a classification of Double Red (Not recommended for routine use).

May 2018: The TAG considered the PAC's revised guidance, which states:
1. Insulin degludec is not recommended for routine use in adults or children with either type 1 or type 2 diabetes.
See separate "Green" entry for advice on RESTRICTED use of insulin degludec.

The TAG agreed to accept the PAC's recommendations as stated above, to revise the Double Red (Not recommended for routine use) classification for routine use in Type 1 and Type 2 diabetes mellitus, and to extend the classification as Green (GP prescribable following specialist recommendation) for restricted use where the initial dose titration and monitoring is closely supervised by the initiating specialist for the first three months or until stable, as per the above-listed criteria for use, including use in Type 2 diabetes.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted that the extended criteria now also relate to T-2 diabetes.
The D&TC supported that PAC's criteria, with the TAG's recommendations.

June 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG and the D&TC's recommendations.

March 2019: The TAG noted that the PAC had amended the wording in their guidance regarding use in patients with disabling hypoglycaemia, which now state:
"Patients with disabling hypoglycaemia (defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life), despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE, DESMOND), and optimisation of basal insulin/multiple daily injections."

The TAG supported continued use of the PAC's revised guidance document with the proviso that the previous local agreement was maintained which related to wording on use for severe insulin resistance, which had been amended to facilitate use of insulin degludec by local acute trust consultant diabetologists for this indication, to avoid the need for unnecessary referral to tertiary centre specialists.

March 2019: The revised wording and the TAG's recommendations were noted and supported by the N&W CCGs' D&TC.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.1.2 - Intermediate and long-acting insulins

Insulin degludec / liraglutide combi (Xultophy®) *(Xultophy®)* TAG recommendation: May 2018

for use in: Diabetes mellitus (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April to May 2018:
PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification to this treatment on the basis that combination products are not generally supported and also that this is an expensive product compared with other treatment options. The TAG agreed to support the PRG's recommendation.

May 2018:
Noted and supported by the D&TC as Double Red (Not recommended for routine use).
Not recommended for commissioning.

June 2018:
The TAG and the D&TC's recommendaions were supported by the Norfolk and Waveney CCGs' JSCC.

Insulin Glargine and Lixisenatide solution *(Suliqua®)* TAG recommendation: Sep 2019

for use in: Diabetes mellitus (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: October 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC, TAG & PRG recommendations of September 2019 for the application of a traffic light classification of Double Red (Not recommended for routine use/Not commissioned).

6.1.2 - Oral antidiabetic drugs

Chlorpropamide *()* TAG recommendation: Sep 2000

for use in: Type 2 diabetes mellitus (A licensed indication).
Prescribing responsibility: Not recommended for routine use Enter period.

NICE has not issued any guidance.

Specific points: Safer alternatives are available.
BNF lists as a drug considered to be less suitable for prescribing.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.2 - Oral antidiabetic drugs

Glibenclamide *(Various eg Daonil®, Euglucon®)* TAG recommendation: Sep 2000

for use in: Type 2 diabetes mellitus (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Safer alternatives are available.

6.1.2.1 - Antidiabetic drugs - sulfonylureas

Gliclazide modified release *(Diamicron® MR)*

for use in: Type 2 diabetes mellitus (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Similar effects on blood glucose control as the standard-release formulation. Risk of confusion in overdose.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

6.1.2.3 - Other antidiabetic drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.2.3 - Other antidiabetic drugs

Dapagliflozin *(Forxiga®)* TAG recommendation: Dec 2021

for use in: With insulin for treating type 1 diabetes (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendations from November 2019. NICE TA597 was noted and afforded a traffic light classification of Double Red (Not recommended for routine use/not commissioned) for this CCG commissioning responsibility treatment pending the provision of a business case

Dec 2021 - In November 2021 NICE withdrew this guidance because dapagliflozin (Forxiga) with insulin is no longer licensed for treating type 1 diabetes. .

Dapagliflozin *(Forxiga®)* TAG recommendation: Jul 2023

for use in: chronic heart failure with preserved or mildly reduced ejection fraction TA902 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

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Liraglutide *()* TAG recommendation: Jan 2022

for use in: managing obesity in people aged 12 to 17 years as per TA749 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of liraglutide for managing obesity in people aged 12 to 17 years. This is because Novo Nordisk does not intend to provide an evidence submission for the appraisal. Novo Nordisk considers that there is not enough evidence to provide an evidence submission for this appraisal

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.2.3 - Other antidiabetic drugs

Liraglutide *(Victoza®)* TAG recommendation: Nov 2010

for use in: 1.8 mg dose for Type 2 diabetes mellitus - currently under review (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2010.

Specific points: November 2010: The TAG noted NICE TA 203 does not recommend use of liraglutide 1.8mg.
Please refer to the "Amber - Option for Shared Care prescribing" section regarding liraglutide 1.2mg.

September 2016:
The TAG acknowledged NG 28 (July 2016) - Type 2 diabetes in adults: management, which updates and replaces NICE TA 203. This includes recommendations on:
* Individualised care
* Managing blood glucose levels:
  HbA1c measurement and targets
  Self-monitoring of blood glucose
  Drug treatment
* Antiplatelet therapy
* Managing complications

Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Sotagliflozin *()* TAG recommendation: Mar 2020

for use in: type 1 diabetes as per NICE TA622 - Feb 2020 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2020.

Specific points: March 2020 - The TAG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned)
Sotagliflozin is not yet available in the NHS, but the company anticipates that it will be available to the NHS in England and Wales within 12 months of guidance publication. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by Governing Body for Norfolk and Waveney CCG

6.1.6 - Blood glucose monitoring

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.1.6 - Blood glucose monitoring

i-Port Advance *()* TAG recommendation: Jul 2020

for use in: Blood glucose monitoring as per PAC guidance - March 2020 (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2020 - The PAC guidance does not support the use of this product. The TAG acknowledged this and recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC

6.2.1 - Thyroid Hormones

Liothyronine / L-triiodothyronine sodium (T3) *()* TAG recommendation: Mar 2020

for use in: ROUTINE use of liothyronine as monotherapy or in combination with levothyroxine for treatment of hypothyroidism (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2019.

Specific points: March 2020 - Consensus decision was to confirm agreement with NICE guidance and award a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) for monotherapy or combination therapy. Therefore, there should be no ROUTINE use of liothyronine as monotherapy or in combination with levothyroxine. TAG however acknowledges that RMOC's decision making process allows for differing commissioning views for practical management of present use .

This recommendation was supported by the D+TC.The committee agreed that in cases of non-routine use, the previously agreed pathway would be followed.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.2.1 - Thyroid Hormones

Thyroxine (Levothyroxine sodium) *(Generics are available)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

Thyroxine (Levothyroxine sodium) / Liothyronine *(Generics)* TAG recommendation: Sep 2017

for use in: Augmentation of an antidepressant - as per NICE CG 90 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2009.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 90 - Depression in adults: recognition and management which states:

1.8.1.9 Augmentation of an antidepressant with pindolol, buspirone, carbamazepine, lamotrigine, valproate or thyroid hormones should not be used (routinely) as there is inconsistent evidence of effectiveness.
Augmentation of an antidepressant with a benzodiazepine for more than 2 weeks is not recommended as there is a risk of dependence.

6.2.2 - Thyroid hormones

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.2.2 - Thyroid hormones

Liothyronine/L-tri-iodothyronine sodium (T3) *(Cytomel, Triostat (US))* TAG recommendation: Jan 2019

for use in: Resistant depression - as per RMOC guidance (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2019: The TAG considered guidance from RMOC (November 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) pending an evidence-based business and costed application for use.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.2.2 - Thyroid hormones

ronine / L-tri-iodothyronine sodium (T3) *(Cytomel, Triostat (U.S.))* TAG recommendation: May 2018

for use in: ROUTINE use for long term for treatment of Hypothyroidism (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2016: The TAG agreed to support the advice in the PrescQIPP DROP-List support bulletin 21 and recommended a traffic light classification of Double Red (Not recommended for routine use) for the long-term use of liothyronine in hypothyroidism, due the lack of evidence to justify long-term use of this expensive treatment option.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed that long-term use of liothyronine in hypothyroidism is Double Red (Not recommended for routine use / Not commissioned) and no new patients should be started on liothyronine for the following reasons:
* Liothyronine has a short half-life; steady-state levels cannot be maintained with once-daily dosing.
* The combination of levothyroxine and liothyronine has not consistently been shown to be more beneficial than levothyroxine alone with respect to cognitive function, social functioning and wellbeing.
* The variation in hormonal content and large amounts of liothyronine may lead to increased serum concentrations of L-T3 and subsequent thyrotoxic symptoms, such as palpitations and tremor.
* There is currently insufficient evidence of clinical and cost-effectiveness to support the use of liothyronine (either alone or in combination) for treatment of hypothyroidism.
* Patients currently taking liothyronine long-term should be reviewed as transferred to thyroxine where possible, with support from the initiating specialist where necessary.

May 2018:
The TAG considered new recommendations from the East of England Priorities Advisory Committee (PAC) regarding use of liothyronine (T3) which were as follows:
1. Levothyroxine monotherapy is the treatment of choice for hypothyroidism. There is no consistent evidence to support the routine use of liothyronine in the management of hypothyroidism, either alone or in combination with levothyroxine.
2. Liothyronine for treatment of hypothyroidism is NOT recommended for routine funding unless one of the following criteria applies:
a. Post thyroidectomy thyroid cancer patients. Patients who need to receive radioactive iodine treatment (Radioiodine Remnant Ablation RRA) after their surgery will initially be started on liothyronine due to its shorter half-life and therefore faster onset of action than levothyroxine. These patients will remain on liothyronine until the oncologist is confident that they will not need any more radioactive iodine at which point they are switched over to levothyroxine. Prescribing in these circumstances must remain with the secondary care specialist and GPs should not accept prescribing responsibility for these patients - see separate "Red" entry
b. In rare cases of levothyroxine induced liver injury, long term liothyronine prescribing may be supported but only after initiation and stabilisation by a secondary care specialist. Arrangements for individual prior approval, prescribing and supply should be agreed locally, ensuring that appropriate patient monitoring is in place.
3. Initiation and prescribing of liothyronine for patients on levothyroxine who continue to suffer with symptoms despite adequate biochemical correction should remain in secondary care under the supervision of an accredited endocrinologist - see separate "Red" entry.
4. Funding of unlicensed medicines e.g. Armour Thyroid for the treatment of hypothyroidism is not supported - see separate "Double Red" entry.
5. Prescribers in primary care should not initiate or accept clinical responsibility for on-going prescribing of liothyronine for any new patient, including patients who are currently self-funding and obtaining supplies via private prescription or previously prescribed by a secondary care consultant, unless the criteria stated above are met and they have agreed to accept clinical responsibility for prescribing.
6. CCGs should give consideration to providing guidance for GPs to switch existing patients to levothyroxine where clinically appropriate, with

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.2.2 - Thyroid hormones

support from a consultant NHS endocrinologist where necessary or agree arrangements for appropriate review by a consultant NHS endocrinologist
These recommendations will be reviewed (by the PAC) in the light of new evidence of clinical and cost effectiveness.

The TAG supported the PAC's recommendations which were broadly in line with previous local commissioning decisions. New recommendations 2b and 3 above which were recommended to be classified as Red (Hospital/Specialist use only).

May 2018: The The Norfolk and Waveney CCGs' D&TC noted and supported the PAC's, and the TAG's related, recommendations regarding criteria for use of liothyronine.

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations.

January 2019: The TAG considered guidance from the RMOC (November 2018) which confirmed previous recommendations which did not support the use of liothyronine for routine maintenance treatment of hypothyroidism.

6.3.1 - Mineralocorticoids (such as fludrocortisone)

Mineralocorticoids (such as fludrocortisone) *(Generic s are available)* TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

6.3.2 - Glucocorticoids

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.3.2 - Glucocorticoids

Glucocorticoids (inc hydrocortisone, prednisolone) *(Generics are available)*

TAG recommendation: Jul 2017

for use in: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) - as per NICE CG 53 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2007.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 53 - Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management which states:

1.4.6.1 The following drugs should not be used for the treatment of CFS/ME:
monoamine oxidase inhibitors
glucocorticoids (such as hydrocortisone)
mineralocorticoids (such as fludrocortisone)
dexamphetamine
methylphenidate
thyroxine
antiviral agents.

Hydrocortisone MR *(Plenadren® MR tablets)*

TAG recommendation: Nov 2015

for use in: Treatment of adrenal insufficiency in adults (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Expensive and no evidence of benefit over cheaper plain tablets.

Hydrocortisone MR hard capsules *(Efmody)*

TAG recommendation: Mar 2022

for use in: congenital adrenal hyperplasia (CAH) in patients 12 years old and above. (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not commissioned. No prescribing in primary or secondary care.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.3.2 - Glucocorticoids

Prednisone MR *(Lodotra® MR tablets)* TAG recommendation: Nov 2015

for use in: Moderate to severe RA (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Expensive and no evidence of benefit over cheaper generic prednisolone preparations.

6.4.1 - Female sex hormones

Raloxifene *(Evista®)* TAG recommendation: Jan 2009

for use in: Primary prevention of osteoporotic fragility fractures in postmenopausal women (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2008.

Specific points: NICE Technoogy Appraisal Guidance No.160 October 2008: Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women, which relates only to treatments for the primary prevention of fragility fractures in postmenopausal women who have osteoporosis.

Osteoporosis is defined by a T-score of −2.5 standard deviations (SD) or below on dual-energy X-ray absorptiometry (DXA) scanning. However, the diagnosis may be assumed in women aged 75 years or older if the responsible clinician considers a DXA scan to be clinically inappropriate or unfeasible.
This guidance assumes that women who receive treatment have an adequate calcium intake and are vitamin D replete. Unless clinicians are confident that women who receive treatment meet these criteria, calcium and/or vitamin D supplementation should be considered.

The above NICE guidance states that raloxifene is not recommended as a treatment option for the primary prevention of osteoporotic fragility fractures in postmenopausal women.

The guidance also states that women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2013: NICE CG 164 (June 2013)
(p34 Section 1.7 Treatment strategies) noted by the TAG.

6.4.1.1 - Oestrogens and HRT

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.4.1.1 - Oestrogens and HRT

Hormone Replacement Therapy (HRT) - systemic *(Various)* TAG recommendation: Jul 2017

for use in: Treatment of urinary incontinence - as per NICE CG 171 - NICE Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.20 Do not offer systemic hormone replacement therapy for the treatment of urinary incontinence.

Ospemifene *(Senshio®)* TAG recommendation: Jul 2019

for use in: Moderate to Severe Symptomatic Vulvar And Vaginal Atrophy (VVA) In Post-Menopausal Women Who Are Not Candidates For Local Vaginal Oestrogen Therapy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2019: The TAG noted the PRG recommendation and recommended a traffic light classification of Double Red (Not recommended for routine use/not commissioned)

July 2019: The NHS Norfolk & Waveney CCGs; D&TC noted and supported the TAG recommendation.

August 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

6.4.1.2 - Progestogens and progesterone receptor modulators

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.4.1.2 - Progestogens and progesterone receptor modulators

Progestogens (oral) *(Various)* TAG recommendation: Jul 2017

for use in: (given during the luteal phase only) for treatment of Heavy Menstrual Bleeding - as per NICE CG 44 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 44 - Heavy menstrual bleeding: assessment and management which states:

1.5.15 Oral progestogens given during the luteal phase only should not be used for the treatment of HMB. [2007]

May 2018: The TAG acknowledged NG 88 (March 2018) - Heavy menstrual bleeding: assessment and management, which updates and replaces NICE guideline CG44 (January 2007).

6.4.2 - Male sex hormones and antagonists

Testosterone - transdermal patches *()* TAG recommendation: Nov 2015

for use in: Hormone replacement in androgen deficiency (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG testosterone transdermal patches to be added on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Regarding transdermal testosterone patches, these are currently only available as an expensive unlicensed special. Other more cost-effective options are available.

6.5.1 - Hypothalamic & anterior pituitary hormones

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.5.1 - Hypothalamic & anterior pituitary hormones

Albutropin *()* TAG recommendation: May 2018

for use in: Adult onset growth hormone deficiency (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Discontinued for further development by manufacturer - https://www.sps.nhs.uk/medicines/albutropin/

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

HGH - Saizen®, Zomacton®, Nordiflex®, Nutropin® Aq *(Saizen®, Zomacton®, Nordiflex®, Nutropin Aq)* TAG recommendation: May 2018

for use in: Growth hormone deficiency (GHD) - as per East of England PAC policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
These treatments are CCG commissioning responsibility but are not recommended on cost grounds as per the East of England Prioriies Sdvisory Committee policy which has been adopted by local CCGs.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

6.6.1 - Calcitonin and

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.1 - Calcitonin and

Abaloparatide *(Eladynos®)* TAG recommendation: May 2018

for use in: Male and juvenile osteoporosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only, as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human parathyroid hormone-related protein analogue *()* TAG recommendation: May 2018

for use in: Male and juvenile osteoporosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Parathyroid Hormone (recombinant) *()* TAG recommendation: Apr 2020

for use in: hypoparathyroidism as per NICE TA625 March 2020 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2020.

Specific points: April 2020 - Discussed at D+TC as TAG cancelled due to covid. NICE is unable to make a recommendation about the use in the NHS of recombinant human parathyroid hormone for treating hypoparathyroidism because Shire Pharmaceuticals (now part of Takeda) did not provide an evidence submission. The recommendation of Double Red (Not recommended for routine use / Not commissioned) was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.1 - Calcitonin and

Teriparatide *(Forsteo®)* TAG recommendation: May 2018

for use in: Male and juvenile osteoporosis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Teriparatide *(Forsteo®)* TAG recommendation: May 2018

for use in: Osteogenesis imperfecta - as per NHS England Policy 16002/P (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

6.6.2 - Bisphosphonates & other drugs affecting bone metab

Alendronate / Vitamin D3 combination *(Fosavance®)* TAG recommendation: Nov 2015

for use in: Treatment of post menopausal osteoporosis in women at risk of vitamin D deficiency - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.2 - Bisphosphonates & other drugs affecting bone metab

Denosumab *(XGEVA®)* TAG recommendation: Jan 2019

for use in: Preventing skeletal-related events in multiple myeloma - as per NICE TA 549 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 549 (December 2018) (terminated appraisal), which stated that NICE is unable to make a recommendation about this treatment because no evidence submission was received from Amgen. The company has confirmed that it does not intend to make a submission because denosumab is unlikely to be used at this point in the treatment pathway. The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for this treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Denosumab *(Prolia®)* TAG recommendation: Sep 2010

for use in: Treatment of therapy-induced bone loss in non-metastatic prostate cancer - as per NICE TA 194 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2014.

Specific points: The TAG noted NICE TA Guidance 194: Denosumab for the treatment of therapy-induced bone loss in non-metastatic prostate cancer (terminated appraisal).

March 2014: The TAG acknowledged NICE Clinical Guideline 175 (January 2014) - Prostate cancer, which supersedes NICE TA 194.

The TAG noted that denosumab was recommended by the NICE CG although for osteoporosis and not for skeletal related events. The TAG agreed that this use of denosumab may need to be considered in the future and a business case would need to be submitted at that time.

Romosozumab *(EVENITY®)* TAG recommendation: Jun 2022

for use in: treating severe osteoporosis as per TA791 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.2 - Bisphosphonates & other drugs affecting bone metab

Strontium ranelate ▼ *(Protelos® ▼)* TAG recommendation: Sep 2017

for use in: Secondary prevention of osteoporotic fragility fractures in postmenopausal women (last line option) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.161 October 2008: Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

Strontium ranelate (and raloxifene) are recommended as alternative treatment options for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to comply with the special instructions for the administration of alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (see below) and
* who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see below) as specified in the full guidance (www.nice.org.uk/nicemedia/pdf/TA161guidanceword.doc).

If a woman aged 75 years or older who has one or more independent clinical risk factors for fracture or indicators of low BMD has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

NICE Guidance defines Indicators of low BMD as:
* low body mass index (defined as less than 22 kg/m2)
* medical conditions such as ankylosing spondylitis, Crohn's disease
* conditions that result in prolonged immobility
* untreated premature menopause

NICE Guidance defines Independent Clinical Risk Factors for fracture are:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis

NICE Guidance defines Intolerance of alendronate, risedronate or etidronate as:
* persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment,
and
* that occurs even though the instructions for administration have been followed correctly.

Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

May 2014:
The TAG noted the MHRA safety warning and advice regarding strontium ranelate as follows:
Advice for healthcare professionals:
* Strontium ranelate is now restricted to the treatment of severe osteoporosis in postmenopausal women and adult men at high risk of fracture who cannot use other osteoporosis treatments due to, for example, contraindications or intolerance

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.2 - Bisphosphonates & other drugs affecting bone metab

* Treatment should only be started by a physician with experience in the treatment of osteoporosis
* The risk of developing cardiovascular disease should be assessed before starting treatment. Treatment should not be started in people who have or have had:
  ischaemic heart disease
  peripheral arterial disease
  cerebrovascular disease
  uncontrolled hypertension

* Cardiovascular risk should be monitored every 6-12 months
* Treatment should be stopped if the individual develops ischaemic heart disease, peripheral arterial disease, or cerebrovascular disease, or if hypertension is uncontrolled

September 2017:
The TAG acknowledged that strontium ranelate (Protelos) has been discontinued from the end of August 2017. Servier Laboratories Ltd, the manufacturer of strontium ranelate (Protelos®), has confirmed that they will cease worldwide marketing and distribution of their product permanently in August 2017. This worldwide and strategic decision is taken for commercial reasons based on the following grounds:
* The restricted indication/limited use of Protelos®
* The continuous decrease of patients treated with Protelos®

Protelos® is indicated in the treatment of severe osteoporosis in postmenopausal women and in adult men at high risk of fracture, for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example, contraindications or intolerance.
In March 2014 new restricted and monitoring recommendations for the use of strontium ranelate were imposed following a European Medicines Agency evaluation of the benefits and risks of strontium ranelate. This led to a general decline in the use of the treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.2 - Bisphosphonates & other drugs affecting bone metab

Strontium ranelate ▼ (discontinued August 2017) *(Protelos® ▼)* TAG recommendation: Sep 2017

for use in: Primary prevention of osteoporotic fragility fractures in postmenopausal women (last line option) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.160 October 2008: Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women.

Strontium ranelate is recommended as an alternative treatment option for the primary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to comply with the special instructions for the administration of alendronate and either risedronate or etidronate
or
* have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (see below)
and
* who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see below) as specified in the full NICE guidance (http://www.nice.org.uk/nicemedia/pdf/TA160guidance.doc).

NICE defines Independent Clinical Risk Factors for fracture as:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis

NICE defines Indicators of Low BMD as:
* Low body mass index (defined as less than 22 kg/m2)
* Medical conditions such as ankylosing spondylitis, Crohn's disease
* Conditions that result in prolonged immobility
* Untreated premature menopause

NICE guidance defines intolerance of alendronate, risedronate or etidronate as:
* persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.

The guidance also states that women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

May 2014:
The TAG noted the MHRA safety warning and advice regarding strontium ranelate as follows:
Advice for healthcare professionals:
* Strontium ranelate is now restricted to the treatment of severe osteoporosis in postmenopausal women and adult men at high risk of fracture who cannot use other osteoporosis treatments due to, for example, contraindications or intolerance

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.6.2 - Bisphosphonates & other drugs affecting bone metab

* Treatment should only be started by a physician with experience in the treatment of osteoporosis
* The risk of developing cardiovascular disease should be assessed before starting treatment. Treatment should not be started in people who have or have had:
  ischaemic heart disease
  peripheral arterial disease
  cerebrovascular disease
  uncontrolled hypertension

* Cardiovascular risk should be monitored every 6-12 months
* Treatment should be stopped if the individual develops ischaemic heart disease, peripheral arterial disease, or cerebrovascular disease, or if hypertension is uncontrolled.

September 2017:
The TAG acknowledged that strontium ranelate (Protelos) has been discontinued from the end of August 2017. Servier Laboratories Ltd, the manufacturer of strontium ranelate (Protelos®), has confirmed that they will cease worldwide marketing and distribution of their product permanently in August 2017. This worldwide and strategic decision is taken for commercial reasons based on the following grounds:
* The restricted indication/limited use of Protelos®
* The continuous decrease of patients treated with Protelos®

Protelos® is indicated in the treatment of severe osteoporosis in postmenopausal women and in adult men at high risk of fracture, for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example, contraindications or intolerance.
In March 2014 new restricted and monitoring recommendations for the use of strontium ranelate were imposed following a European Medicines Agency evaluation of the benefits and risks of strontium ranelate. This led to a general decline in the use of the treatment.

6.7.1 - Ergot-derived dopamine agonists

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.7.1 - Ergot-derived dopamine agonists

Bromocriptine mesilate *(Parlodel®)* TAG recommendation: Sep 2017

for use in: First-line use in Parkinson's disease - as per NICE NG 17 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against first-line use of ergot-derived dopamine agonists in Parkinson's disease due to the risk of fibrotic reactions if used long-term.
This is based on Medicines and Healthcare Products Regulatory Agency guidance (Drug safety update: volume 1, issue 12 2008) which recommended warnings and contraindications for ergot-derived dopamine agonists as a result of the risk of fibrosis, particularly cardiac fibrosis, associated with chronic use.
The risk of cardiac fibrosis is higher with cabergoline and pergolide than with the other ergot-derived dopamine agonists. Ergot-derived dopamine agonists should not be given to people who have had fibrosis in the heart, lungs or abdomen. Cabergoline, pergolide and bromocriptine are contraindicated for people with evidence of valve problems, and cabergoline and pergolide are restricted to second-line use in Parkinson's disease. Absence of cardiac fibrosis should be verified before treatment is started, and people must be monitored for signs of fibrosis on echocardiography before treatment is started, and then regularly during treatment.

Cabergoline *(Cabaser®)* TAG recommendation: Sep 2017

for use in: First-line use in Parkinson's disease - as per NICE NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against first-line use of ergot-derived dopamine agonists in Parkinson's disease due to the risk of fibrotic reactions if used long-term.
This is based on Medicines and Healthcare Products Regulatory Agency guidance (Drug safety update: volume 1, issue 12 2008) which recommended warnings and contraindications for ergot-derived dopamine agonists as a result of the risk of fibrosis, particularly cardiac fibrosis, associated with chronic use.
The risk of cardiac fibrosis is higher with cabergoline and pergolide than with the other ergot-derived dopamine agonists. Ergot-derived dopamine agonists should not be given to people who have had fibrosis in the heart, lungs or abdomen. Cabergoline, pergolide and bromocriptine are contraindicated for people with evidence of valve problems, and cabergoline and pergolide are restricted to second-line use in Parkinson's disease. Absence of cardiac fibrosis should be verified before treatment is started, and people must be monitored for signs of fibrosis on echocardiography before treatment is started, and then regularly during treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

6.7.1 - Ergot-derived dopamine agonists

Pergolide *()* TAG recommendation: Sep 2017

for use in: First-line use in Parkinson's disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against first-line use of ergot-derived dopamine agonists in Parkinson's disease due to the risk of fibrotic reactions if used long-term.
This is based on Medicines and Healthcare Products Regulatory Agency guidance (Drug safety update: volume 1, issue 12 2008) which recommended warnings and contraindications for ergot-derived dopamine agonists as a result of the risk of fibrosis, particularly cardiac fibrosis, associated with chronic use.
The risk of cardiac fibrosis is higher with cabergoline and pergolide than with the other ergot-derived dopamine agonists. Ergot-derived dopamine agonists should not be given to people who have had fibrosis in the heart, lungs or abdomen. Cabergoline, pergolide and bromocriptine are contraindicated for people with evidence of valve problems, and cabergoline and pergolide are restricted to second-line use in Parkinson's disease. Absence of cardiac fibrosis should be verified before treatment is started, and people must be monitored for signs of fibrosis on echocardiography before treatment is started, and then regularly during treatment.

6.7.2 - Drugs affecting gonadotrophins

Danazol *(Danol®)* TAG recommendation: Jul 2017

for use in: Heavy menstrual bleeding - as per NICE CG 44 - Do Not Do (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 44 - Heavy menstrual bleeding: assessment and management which states:

1.5.14 Danazol should not be used routinely for the treatment of HMB. [2007]

May 2018: The TAG acknowledged NG 88 (March 2018) - Heavy menstrual bleeding: assessment and management, which updates and replaces NICE guideline CG44 (January 2007).

7.2.1 - Preparations for vaginal and vulval changes

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.2.1 - Preparations for vaginal and vulval changes

Prasterone *(INTRAROSA®)* TAG recommendation: Apr 2020

for use in: Vulvar and vaginal atrophy (in post-menopausal women with moderate to severe symptoms) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2020 - The PRG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). This would provide an interim commissioned position pending the submission of an evidence-based and costed business application to propose its place in a locally agreed treatment pathway.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

7.3.1 - Combined hormonal contraceptives

Estradiol / Dienogest *(Qlaira®)* TAG recommendation: Nov 2015

for use in: Contraception - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

No evidence of clinicaly significant benefit over alternatives.

Yasmin *(Yasmin®)* TAG recommendation: May 2002

for use in: Contraception (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment to remain on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

No evidence of clinically significant benefit over more cost-effective alternatives.

7.4.2 - Drugs for urinary incontinence

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.4.2 - Drugs for urinary incontinence

Flavoxate hydrochloride *(Urispas®)* TAG recommendation: Jul 2017

for use in: Overactive bladder and unrinary incontinence in women - as per NICE CG 171 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.5 Do not use flavoxate, propantheline and imipramine for the treatment of urinary incontinence or overactive bladder syndrome in women.

Imipramine *(Generics available)* TAG recommendation: Jul 2017

for use in: Overactive bladder and urinary incontinence in women - as per NICE CG 171 - NICE Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.5 Do not use flavoxate, propantheline and imipramine for the treatment of urinary incontinence or overactive bladder syndrome in women.

Oxybutynin (immediate release) *(Generics are available)* TAG recommendation: Jul 2017

for use in: Use in frail elderly women - as per NICE CG 171 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.6 Do not offer oxybutynin (immediate release) to frail older women.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.4.2 - Drugs for urinary incontinence

Propantheline *(Pro-Banthine®)* TAG recommendation: Jul 2017

for use in: Overactive bladder and urinary incontinence in women - as per NICE CG 171 - NICE Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2015.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.5 Do not use flavoxate, propantheline and imipramine for the treatment of urinary incontinence or overactive bladder syndrome in women.

7.4.4 - Maintenance of indwelling urinary catheters

Farco-fill Protect *()* TAG recommendation: Apr 2021

for use in: indwelling urinary catheterisation (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2021 - awaiting submission of business case

7.4.5 - Drugs for erectile dysfunction

Avanafil ▼ *(Spedra® ▼)* TAG recommendation: Sep 2014

for use in: Use of regular, daily doses for penile rehabilitation in prostate cancer/post radical prostatectomy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2014: The TAG considered the evidence provided in an EAMIS overview of the use of ED drugs (June 14) and also noted an Anglian Cancer Network draft policy on Prostate Cancer which includes proposed guidelines on the use of PDEIs for this indication, notably recommending daily use of tadalafil. It was noted that there is no robust evidence (no comparative/head to head studies) to suggest that the daily use of PDEIs as opposed to on demand use has been tested for this indication.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation and the regular, daily use of these drugs is not commissioned for this clinical indication.

Please also see entry under Erectile Dysfunction Drugs.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.4.5 - Drugs for erectile dysfunction

Etilefrine *()* TAG recommendation: Nov 2020

for use in: Priapism in sickle cell crisis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Nov 2020 - The PRG recommended Double Red (Not recommended for routine use) pending the submission of a business case. Supported by TAG and D+TC. Ratified by CCG Governing Body

Sildenafil *(Generic)* TAG recommendation: Sep 2014

for use in: Use of regular, daily doses for penile rehabilitation in prostate cancer/post radical prostatectomy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2014: The TAG considered the evidence provided in an EAMIS overview of the use of ED drugs (June 14) and also noted an Anglian Cancer Network draft policy on Prostate Cancer which includes proposed guidelines on the use of PDEIs for this indication, notably recommending daily use of tadalafil. It was noted that there is no robust evidence (no comparative/head to head studies) to suggest that the daily use of PDEIs as opposed to on demand use has been tested for this indication.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation and the regular, daily use of these drugs is not commissioned for this clinical indication.

Please see entry under Erectile Dysfunction Drugs.

Tadalafil (Cialis) *(Cialis®)* TAG recommendation: Mar 2013

for use in: Treatment of symptoms associated with benign prostatic hyperplasia (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2013.

Specific points: NICE TA 273 (January 2013 http://guidance.nice.org.uk/TA273) -
Terminated appraisal

Not commissioned by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (March 2012).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.4.5 - Drugs for erectile dysfunction

Tadalafil (Cialis) *(Cialis®)* TAG recommendation: Sep 2014

for use in: Use of regular, daily doses for penile rehabilitation in prostate cancer/post radical prostatectomy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2014: The TAG considered the evidence provided in an EAMIS overview of the use of ED drugs (June 14) and also noted an Anglian Cancer Network draft policy on Prostate Cancer which includes proposed guidelines on the use of PDEIs for this indication, notably recommending daily use of tadalafil. It was noted that there is no robust evidence (no comparative/head to head studies) to suggest that the daily use of PDEIs as opposed to on demand use has been tested for this indication.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation and the regular, daily use of these drugs is not commissioned for this clinical indication.

Please see entry under Erectile Dysfunction Drugs.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment remains on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

This is not a cost-effective option compared with intermittent dosing formulations.

July 2021 - review - current Double Red (Not recommended for routine use) position will not change following loss of patent and reduction in price. Lack of evidence remains.

Tadalafil taken once every day *(Cialis®)* TAG recommendation: Nov 2015

for use in: Erectile dysfunction/penile rehabilitation (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment remains on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

This is not a cost-effective option compared with intermittent dosing formulations.

July 2021 - classification review. current Double Red (Not recommended for routine use) position will not change following loss of patent and reduction in price. Lack of evidence remains.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.4.5 - Drugs for erectile dysfunction

Vardenafil *(Levitra®)* TAG recommendation: Sep 2014

for use in: Use of regular, daily doses for penile rehabilitation in prostate cancer/post radical prostatectomy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2014: The TAG considered the evidence provided in an EAMIS overview of the use of ED drugs (June 14) and also noted an Anglian Cancer Network draft policy on Prostate Cancer which includes proposed guidelines on the use of PDEIs for this indication, notably recommending daily use of tadalafil. It was noted that there is no robust evidence (no comparative/head to head studies) to suggest that the daily use of PDEIs as opposed to on demand use has been tested for this indication.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation and the regular, daily use of these drugs is not commissioned for this clinical indication.

Please see entry under Erectile Dysfunction Drugs.

7.4.6 - Drugs for premature ejaculation

Dapoxetine *(Priligy®)* TAG recommendation: Nov 2013

for use in: For diagnosed premature ejaculation (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2013: The TAG considered the UKMI evidence review available for this treatment for diagnosed premature ejaculation. The TAG noted that there is some risk of harm with the treatment and that relative cost over benefit does not currently justify the drug being routinely provided by the NHS. A classification of Double Red was recommended.
Prescriber's rating 7 - not acceptable.

November 2013: TAG recommendation supported. Not commissioned.

7.6.1 - Not listed

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

7.6.1 - Not listed

Gluten-free foods *(Various)* TAG recommendation: Jul 2010

for use in: Gluten sensitive enteropathies in adults (all CCGs) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2010:
Diagnosis of celiac disease should be by serology and biopsy as per NICE CG 86 - Coeliac Disease. G-F products should not be prescribed for patients unless diagnosis in line with the guidance.
NHS Norfolk supported provision of BASIC FOODSTUFF only (bread (not fresh UNLESS the patient agrees to immediate collection and freezer storage of loaves), pasta, bread and pastry mixes).
Order quantities are as per the units recommended by age and gender.

July to December 2015: CCGs in central Norfolk have decided to no longer support routine NHS provision of any gluten-free foods.

West Norfolk CCG still offers provision of G-F bread and flour for children.

Great Yarmouth & Waveney CCG has a separate policy which covers limited NHS provision of G-F bread and flour only - http://nww.knowledgeanglia.nhs.uk/prescribing_gyw/gluten_free_prescribing_policy_delivery_contacts.pdf

November 2015:
The TAG and the D&TCG noted NICE NG 20 (September 2015) - Coeliac disease: recognition, assessment and management
Includes recommendations on:
* Referral of people with suspected coeliac disease
* Information and support
* Advice on dietary management
* Non-responsive and refractory coeliac disease
* Monitoring and review in people with coeliac disease

March 2016:
Great Yarmouth and Waveney CCG revised their previous policy to no prescribing of any G-F products on FP10 for adults or children.

http://www.greatyarmouthandwaveneyccg.nhs.uk/news_item.asp?fldID=776

8.1 - Cytotoxic drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1 - Cytotoxic drugs

Alpelisib *(Piqray®)* TAG recommendation: Nov 2020

for use in: with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer (terminated appraisal) TA652 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2020.

Specific points: Nov 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). Supported by D+TC and ratified by CCG Governing Body

Bazedoxifene plus conjugated oestrogens *(Duavive®)* TAG recommendation: Nov 2016

for use in: Management of oestrogen deficiency symptoms in postmenopausal women with a uterus for whom treatment with progestin-containing therapy is not appropriate (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG noted the PAC Full Evidence Review update(Oct16)
and recommended a traffic light classification of Double Red (Not recommended for routine use) for Bazedoxifene + conjugated oestrogens (Duavive®) for post menopausal symptoms.

November 2016:
The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation. Not commissioned.

Olaparib *(Lynparza®)* TAG recommendation: Nov 2022

for use in: previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer as per TA831 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1 - Cytotoxic drugs

Pembrolizumab *()* TAG recommendation: Mar 2021

for use in: untreated PD-L1-positive, locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (terminated appraisal) as per TA674 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - NICE is unable to make a recommendation about the use in the NHS of pembrolizumab for untreated PD-L1-positive, locally advanced or metastatic urothelial cancer when cisplatin is unsuitable. Merck Sharp & Dohme does not intend to make a complete evidence submission for the appraisal

Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2018

for use in: Relapsed or refractory classical Hodgkin lymphoma in adults who have had autologous stem cell transplant and brentuximab vedotin - as per NICE TA 540 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2018.

Specific points: November 2018: The TAG noted NICE TA 540 (Recommended for treating relapsed or refractory classical Hodgkin lymphoma in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant, only if pembrolizumab is stopped after 2 years of treatment or earlier if the person has a stem cell transplant or the disease progresses)
and recommended a traffic light classification of Double Red (Not recommended for routine use) in adults who have had autologous stem cell transplant and brentuximab vedotin, and Red (Hospital / Specialist use only) in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant as per criteria specified by NICE, for this NHSE-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1 - Cytotoxic drugs

Pembrolizumab *(Keytruda®)* TAG recommendation: May 2019

for use in: For treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy - as per NICE TA 570 (terminated appraisal) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019:
NICE is unable to make a recommendation about the use in the NHS of this treatment because no evidence submission was received from Merck Sharp & Dohme.

The TAG noted NICE TA 559 (January 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE-commissioning responsibility treatment.

May 2019: Noted by the D&TC.

Pembrolizumab *(Keytruda)* TAG recommendation: Oct 2020

for use in: with axitinib for untreated advanced renal cell carcinoma as per TA650 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This was supported by the D+TC

Pembrolizumab *(Keytruda®)* TAG recommendation: May 2021

for use in: locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy as per TA692 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2021.

Specific points: Double Red (Not recommended for routine use / Not commissioned) - not recommended by NICE

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1 - Cytotoxic drugs

Ramucirumab *(Cyramza®)* TAG recommendation: Jan 2020

for use in: Unresectable hepatocellular carcinoma after sorafenib (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2019.

Specific points: January 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Double Red (Not recommended for routine use/Not commissioned) was afforded for this NHS England commissioning responsibility treatment.

Ramucirumab (with erlotinib) *()* TAG recommendation: Jul 2020

for use in: untreated EGFR-positive metastatic non-small-cell lung cancer as per TA635 (June 2020 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC

Ramucirumab ▼ *(Cyramza® ▼)* TAG recommendation: Mar 2016

for use in: Advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy. (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG noted NICE TA 378 (January 2016) and recommended a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1 - Cytotoxic drugs

Ramucirumab ▼ in combination with doxetaxel *(Cyramza® ▼)* TAG recommendation: Sep 2016

for use in: Locally advanced or metastatic non-small-cell lung cancer in adults whose disease has progressed after platinum-based chemotherapy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2016.

Specific points: September 2016: The TAG acknowledged NICE TA 403 (August 2016) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Tagraxofusp *()* TAG recommendation: Apr 2022

for use in: blastic plasmacytoid dendritic cell neoplasm as oer TA782 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2022.

Specific points: Terminated - NICE is unable to make a recommendation about the use in the NHS of tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm. This is because Stemline Therapeutics has confirmed that it does not intend to make an evidence submission for the appraisal. The company considers that there is not enough evidence to provide a submission for this appraisal

8.1.1 - Alkylating drugs

Carmustine implants *(Gliadel®)* TAG recommendation: Jul 2008

for use in: Treatment of recurrent glioblastoma multiforme - as per NICE TA 149 and NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2008.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No.149 June 2008 - terminated appraisal

NHS England SCG commissioning responsibility from April 2013. Not listed on Sept 2013 Cancer Drug Fund List: http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.1 - Alkylating drugs

Melphalan *(Alkeran®)* TAG recommendation: Oct 2022

for use in: for haematological diseases before allogeneic haematopoietic stem cell transplant as per TA822 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2022.

Specific points: NICE is unable to make a recommendation about the use in the NHS of melphalan for treating haematological diseases before allogeneic haematopoietic stem cell transplant. This is because ADIENNE has confirmed that it does not intend to make an evidence submission for the appraisal because it does not represent a commercially viable option for them to pursue.

Not commissioned. No NHS prescribing in primary or secondary care

8.1.3 - Antimetabolites

Azacitidine *(Vidaza®)* TAG recommendation: Sep 2016

for use in: Acute myeloid leukaemia with more than 30% bone marrow blasts in people of 65 years or older who are not eligible for haematopoietic stem cell transplant - as per NICE TA 399 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2016.

Specific points: September 2016: The TAG acknowledged NICE TA 399 (July 2016) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recomnendation

Cladribine *(Mavenclad®; Leustat®; Litak®)* TAG recommendation: May 2018

for use in: Pulmonary Langerhans histiocytosis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.3 - Antimetabolites

Decitabine *(Dacogen®)* TAG recommendation: Jan 2019

for use in: Untreated acute myeloid leukaemia - as per NICE TA 548 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 548 (December 2018) (Terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG commissioning responsibility treatment

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Decitabine *(Dacogen®)* TAG recommendation: Jan 2013

for use in: Acute Myeloid Leukaemia - as per NICE TA 270 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2013.

Specific points: The TAG noted NICE TA 270 (December 2012 http://guidance.nice.org.uk/TA270) (terminated appraisal) - no NICE recommendation since no evidence submitted.

January 2013: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

NHS England commissioning responsibility from April 2013. Not on Sept 2013 Cancer Drug Fund List: http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf
Not commissioned.

Fludarabine *(Fludara®)* TAG recommendation: May 2007

for use in: B-cell Chronic Lymphocytic Leukaemia - 1st line treatment - as per NICE TA 119 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2007.

Specific points: May 2007: the TAG noted NICE Technology Appraisal Guidance 119 - Fludarabine monotherapy, within its licensed indication, is NOT recommended for the first-line treatment of chronic lymphocytic leukaemia.
Fludarabine is not licensed for use in combination with other drugs.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.3 - Antimetabolites

Gemcitabine *()* TAG recommendation: May 2016

for use in: Treatment of the first recurrence of platinum sensitive ovarian cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2016.

Specific points: May 2016: The TAG noted NICE TA 389 (April 2016) review of TA91 & TA 222 (ID468) Topotecan (Hycamtin®), pegylated liposomal doxorubicin hydrochloride (Caelyx®), paclitaxel, trabectedin (Yondelis®) and gemcitabine for advanced recurrent ovarian cancer:
* Paclitaxel in combination with platinum or as monotherapy is recommended as an option.
* Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended as an option.
* PLDH in combination with platinum is recommended as an option.
The following are not recommended for treating the first recurrence of platinum sensitive ovarian cancer:
* gemcitabine in combination with carboplatin
* trabectedin in combination with PLDH
* topotecan
The appraisal committee was unable to recommend use of these technologies to treat platinum sensitive ovarian cancer beyond the first recurrence.
*Topotecan is not recommended for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

The TAG recommended a classification of Red (Hospital/Specialist only) for the treatments recommended by NICEand Double Red (Not recommended for routine use/Not commissioned) for those treatments not recommended by NICE.
It was noted that these are SCG-commissioning responsibility treatments.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendations.

Raltitrexed *(Tomudex®)* TAG recommendation: Jan 2012

for use in: Advanced colorectal cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2005.

Specific points: NICE TA 93 (August 2005) recommended that use is confined to clinical studies only.

NICE CG 131 (November 11) recommends that: "faltitrexed is considered only for patients with advanced colorectal cancer who are intolerant to 5-fluorouracil and folinic acid, or for whom these drugs are not suitable (for example, patients who develop cardiotoxicity). The risks and benefits of raltitrexed should be fully discussed with the patient.
Prospectively collect data on quality of life, toxicity, response rate, progression-free survival, and overall survival for all patients taking raltitrexed."

January 2013: Not commissioned by NHS Norfolk & Waveney.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.4 - Vinca alkaloids and etoposide

Glasdegib *()* TAG recommendation: Oct 2020

for use in: with chemotherapy for untreated acute myeloid leukaemia as per TA646 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This was supported by the D+TC

Vinflunine *(Javlor® ▼)* TAG recommendation: Mar 2013

for use in: Treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract - as per NICE TA 272 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2013.

Specific points: NICE TA 272 (January 2013 http://guidance.nice.org.uk/TA272) -
Not recommended by NICE.

Not commissioned by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (March 2012).

8.1.5 - Protein Kinase Inhibitors

Afatinib ▼ *(Giotrif® ▼)* TAG recommendation: Jul 2017

for use in: Advanced squamous non-small-cell lung cancer after platinum-based chemotherapy - as per NICE TA 444 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 444 (May 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Aflibercept *(Zaltrap®)* TAG recommendation: May 2014

for use in: Treatment of metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy (along with irinotecan and fluorouracil-based therapy) - as per NICE TA 307 - NICE Do Not Do (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2014.

Specific points: March 2014: NICE TA 307 states that aflibercept in combination with irinotecan and fluorouracil-based therapy is not recommended within its marketing authorisation for treating metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen.

This treatment is the commissioning responsibility of NHS England SCG.

Alectinib ▼ *(Alecensa® ▼)* TAG recommendation: May 2017

for use in: Previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer - as per NICE TA 438 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2017.

Specific points: May 2017:
The TAG acknowledged NICE TA 438 (March 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group noted the TAG's recommendation.

Amivantamab *(Rybrevant®)* TAG recommendation: Jan 2023

for use in: EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy TA850 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care
Amivantamab is not recommended, within its marketing authorisation, for treating locally advanced or metastatic non-small-cell lung cancer (NSCLC) after platinum-based chemotherapy in adults whose tumours have epidermal growth factor receptor (EGFR) exon 20 insertion mutations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Atezolizumab *(TECENTRIQ®)* TAG recommendation: Mar 2020

for use in: with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer (terminated appraisal) as per NICE TA618 - Jan 2020 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2020.

Specific points: March 2020 - NICE is unable to make a recommendation about the use in the NHS of atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer because Roche did not provide an evidence submission. The TAG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by Governing Body for Norfolk and Waveney CCG

Avapritinib *()* TAG recommendation: Oct 2021

for use in: unresectable or metastatic gastrointestinal stromal tumours as per TA730 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment. NICE is unable to make a recommendation about the use in the NHS of avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours. This is because Blueprint Medicines has confirmed that it does not intend to make a submission for the appraisal and will not be launching the technology in the UK

Bevacizumab *(Avastin®)* TAG recommendation: Sep 2009

for use in: First-line treatment of advanced and/or metastatic renal cell carcinoma - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2009.

Specific points: Refn: NICE Technology Appraisal Guidance 178

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Clinical indication not on the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Bevacizumab *(Avastin®)* TAG recommendation: Jul 2008

for use in: Treatment of non-small-cell lung cancer - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2008.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No.148 June 2008 - terminated appraisal.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Clinical indication not on the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Bevacizumab *(Avastin®)* TAG recommendation: Sep 2012

for use in: First-line treatment of metastatic breast cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2012.

Specific points: September 2012: The TAG noted NICE TA Guidance 263 (August 2012 http://guidance.nice.org.uk/TA263) - which states that: Bevacizumab, in combination with capecitabine, is not recommended within its marketing authorisation for the first-line treatment of metastatic breast cancer, that is, when treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate, or when taxanes or anthracyclines have been used as part of adjuvant treatment within the past 12 months.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Clinical indication not on the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Bevacizumab *(Avastin®)* TAG recommendation: Sep 2015

for use in: Treatment for relapsed, platinum resistant epithelial ovarian, fallopian tube or primary peritoneal cancer - as per NICE TA 353 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2015.

Specific points: September 2015: The TAG noted NICE TA 353 (August 2015) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.
NICE unable to make a recommendation about the use of bevacizumab for this indication because no evidence submission was received from Roche Products.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and the TAG's recommendation.

Bevacizumab *(Avastin®)* TAG recommendation: Mar 2019

for use in: (with carboplatin, gemcitabine and paclitaxel) for first recurrence of platinum-sensitive advanced ovarian cancer - as per NICE TA 560 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 560 (February 2019) which did not recommend use of this treatment.
The TAG recommended a traffic light classifcation of Double Red (Not recommended for routine use) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk &Waveney CCGs' D&TC noted the TAG recommendation.

Bevacizumab *(Avastin®)* TAG recommendation: May 2017

for use in: Epidermal growth factor receptor mutation-positive non-small-cell lung cancer - as per NICE TA 436 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 436 (March 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Bortezomib *(Velcade®)* TAG recommendation: Sep 2015

for use in: Treatment of refractory antibody mediated rejection post kidney transplant - as per NHS England policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted A07/P/c (A07X03) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Bortezomib *(Velcade®)* TAG recommendation: Sep 2017

for use in: Relapsed Multiple Myeloma - as per NHS England policy & NICE TA 453 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: November 2007: TAG acknowledged the NICE Technology Appraisal Guidance - Bortezomib monotherapy for relapsed multiple myeloma published following appeal. The manufacturer has committed to refund drug costs for non-responding patients.

Commissioning responsibility of NHS England SCG from April 2013.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

September 2017: The TAG acknowledged NICE TA 453 (July 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs; D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Bosutinib *(Bosulif®)* TAG recommendation: May 2019

for use in: Untreated chronic myeloid leukaemia in adults - as per NICE TA 576 (terminated appraisal) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2019.

Specific points: May 2019:
The TAG noted NICE TA 576 (April 2019) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE commissioning responsibility treatment.

Brentuximab vedotin *(Adcetris®)* TAG recommendation: Sep 2019

for use in: Untreated advanced Hodgkin lymphoma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA594 – August 2019 and recommended a traffic light classification of Double Red (Not recommended for use/Not commissioned) for this NHS England commissioning responsibility treatment.

Cabazitaxel *(Jevtana®)* TAG recommendation: Jul 2012

for use in: Hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen - as per NICE TA 255 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2012.

Specific points: NICE TA 255 states that:
1.1 Cabazitaxel in combination with prednisone or prednisolone is not recommended for the treatment of hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.
1.2 People currently receiving cabazitaxel in combination with prednisone or prednisolone for the treatment of hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group confirmed that this treatment is not commissioned.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Clinical indication not on the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Cabozantinib *(Cometriq®)* TAG recommendation: May 2018

for use in: For treating medullary thyroid cancer - as per NICE TA 516 (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 516 (March 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendation

Capmatinib *()* TAG recommendation: Jun 2023

for use in: advanced non-small-cell lung cancer with MET exon 14 skipping TA884 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Carfilzomib *(n/a)* TAG recommendation: Dec 2022

for use in: with daratumumab and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) TA841 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Cemiplimab *(Libtayo ®)* TAG recommendation: Jan 2023

for use in: untreated PD-L1-positive advanced or metastatic non-small-cell lung cancer (terminated appraisal) TA848 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care
NICE is unable to make a recommendation on cemiplimab (Libtayo) for untreated PD-L1-positive advanced or metastatic non-small-cell lung cancer in adults. This is because Sanofi did not provide an evidence submission. We will review this decision if the company decides to make a submission.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Cemiplimab *((Libtayo®))* TAG recommendation: Jul 2023

for use in: recurrent or metastatic cervical cancer (terminated appraisal) TA901 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Ciltacabtagene autoleucel *()* TAG recommendation: Jun 2023

for use in: relapsed or refractory multiple myeloma TA889 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Cobimetinib ▼ (in combination with vemurafenib) *(Cotellic® ▼)* TAG recommendation: Nov 2016

for use in: Unresectable or metastatic BRAF V600 mutation-positive melanoma - as per NICE TA 414 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 414 (October 2016) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Dabrafenib *(Tafinlar®)* TAG recommendation: Mar 2019

for use in: (with trametinib (Mekinist®)) for treating advanced metstatic BRAF V600E mutation-positive non-small-cell lung cancer - as per NICE TA 564 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 564 (February 2019) - terminated appraisal. NICE was unable to make a recommendation about the use of this treatment in the NHS because no evidence submission was received from Novartis; NICE will review this decision if the company decides to make a submission.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Daratumumab *()* TAG recommendation: Mar 2022

for use in: with bortezomib, melphalan and prednisone for untreated multiple myeloma as per TA771 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2022.

Specific points: No prescribing in primary or secondary care. Not commissioned

Daratumumab (with lenalidomide and dexamethasone) *()* TAG recommendation: Jul 2020

for use in: untreated multiple myeloma as per TA634 (June 2020 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Daratumumab ▼ *(Darzalex® ▼)* TAG recommendation: Sep 2017

for use in: (with lenalidomide and dexamethasone) for relapsed or refractory multiple myeloma - as per NICE TA 454 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 454 (July 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Daratumumab with pomalidomide and dexamethasone *()* TAG recommendation: Oct 2021

for use in: relapsed or refractory multiple myeloma as per TA726 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment. NICE is unable to make a recommendation about the use in the NHS of daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma. This is because Janssen has confirmed that it does not intend to make an evidence submission for the appraisal. Janssen considers that the technology is unlikely to be a cost-effective use of NHS resources.

Dasatinib *()* TAG recommendation: Aug 2021

for use in: Philadelphia-chromosome-positive acute lymphoblastic leukaemia as per TA714 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2021.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Durvalumab *()* TAG recommendation: Dec 2020

for use in: in combination for untreated extensive-stage small-cell lung cancer as per TA662 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). Supported by D+TC and ratified by CCG Governing Body

Duvelisib *()* TAG recommendation: Aug 2021

for use in: relapsed follicular lymphoma after 2 or more systemic therapies as per TA717 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2021.

Duvelisib *(N/A)* TAG recommendation: Aug 2022

for use in: relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments (terminated appraisal) as per TA811 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

NICE is unable to make a recommendation about the use in the NHS of duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments. Secura Bio has confirmed that it is withdrawing the evidence submission for the appraisal because the technology will not be launched in the UK for treating this indication

Elotuzumab ▼ *(Empliciti® ▼)* TAG recommendation: May 2017

for use in: Multiple myeloma - as per NICE TA 434 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 434 (March 2017) (Terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Enfortumab vedotin *(N/A)* TAG recommendation: Jul 2022

for use in: previously treated locally advanced or metastatic urothelial cancer (terminated appraisal) as per TA797 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2022.

Specific points: NICE is unable to make a recommendation about the use in the NHS of enfortumab vedotin for treating locally advanced or metastatic urothelial cancer after platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. This is because Astellas did not provide an evidence submission. Astellas has confirmed that there is unlikely to be enough evidence that the technology is a costeffective use of NHS resources in this population.

Not commissioned. No NHS prescribing in primary or secondary care

Eribulin *(Halaven®)* TAG recommendation: May 2018

for use in: Locally advanced or metastatic breast cancer after 1 chemotherapy regimen - as per NICE TA 515 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 515 (March 2018), which recommends against use of this treatment, and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation

Erlotinib *(Tarceva®)* TAG recommendation: Jan 2016

for use in: Treating locally advanced or metastatic NSCLC that doesn't test positive for the EGFR TK mutation (as per NICE TA 374) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2015.

Specific points: January 2016:
The TAG noted NICE TA 374 which stated that erlotinib is not recommended for treating locally advanced or metastatic NSCLC that doesn't test positive for the EGFR TK mutation.

January 2016:
The N&W D&TCG noted the TAG's recommendation regarding this SCG-commissioning responsibility treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Erlotinib *(Tarceva®)* TAG recommendation: Jul 2011

for use in: Monotherapy for maintenance treatment of non-small-cell lung cancer - as per NICE TA 227 and NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2011.

Specific points: NICE Technology Appraisal Guidance 227 (June 2011) states that:
Erlotinib monotherapy is not recommended for maintenance treatment in people with locally advanced or metastatic non-small-cell lung cancer who have stable disease after platinum-based first-line chemotherapy.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Not included in the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Erlotinib *(Tarceva®)* TAG recommendation: Jul 2012

for use in: First-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer - as per NICE TA 258 and NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2012.

Specific points: NICE TA 258 states that:
1.1 Erlotinib is recommended as an option for the first-line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if:
* they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and
* the manufacturer provides erlotinib at the discounted price agreed under the patient access scheme (as revised in 2012).

2.1 Erlotinib (Tarceva, Roche Products) is an active inhibitor of the epidermal growth factor receptor tyrosine kinase (EGFR-TK). It blocks the signal pathways involved in cell proliferation and slows the growth and spread of the tumour. It has a UK marketing authorisation 'for the first-line treatment of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) with EGFR activating mutations'.

January 2013: Commissioned by NHS Norfolk & Waveney in line with Cancer Network regimens. Non-tariff treatment. Provided under Patient Access Scheme.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Not included in the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Everolimus *(Certican®)* TAG recommendation: Sep 2015

for use in: Treatment for preventing organ rejection in liver transplantation - as per NICE TA 348 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2015.

Specific points: September 2015: The TAG noted NICE TA 348 (July 2015) (review of NICE TA 85) which does not recommend the treatment for preventing organ rejection in patients having a liver transplant. The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment. Specialist centres only - as per NHSE IFR approval.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted the TAG's recommendation regarding this treatment.

Everolimus *(Votubia®)* TAG recommendation: May 2018

for use in: Renal angiomyolipoma associated with tubular sclerosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - NHS England policy B14X09L

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=

Everolimus *(Votubia®)* TAG recommendation: May 2018

for use in: Subependymal giant cell astrocytoma (SEGA) associated with tubular sclerosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Everolimus *(Certican®)* TAG recommendation: Nov 2017

for use in: Initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE TAs 481 & 482 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TAs 481 and 482 (Oct 17) which state that everolimus is not recommended by NICE as an initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant.

The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for these indications.

Ganetespib *()* TAG recommendation: May 2018

for use in: Cancer (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Gefitinib *(Iressa®)* TAG recommendation: Jan 2016

for use in: Treating NSCLC that has progressed after chemotherapy (as per NICE TA 374) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2015.

Specific points: January 2016:
The TAG noted NICE TA 374 which stated that gefitinib is not recommended for treating NSCLC that has progressed after chemotherapy.

January 2016:
The N&W D&TCG noted the TAG's recommendation regarding this NHS England SCG-commissioning responsibility treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Ibrutinib *(Imbruvica®)* TAG recommendation: Jul 2022

for use in: Waldenstrom's macroglobulinaemia as per TA795 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2022.

Specific points: Ibrutinib is not recommended, within its marketing authorisation, for treating Waldenstrom's macroglobulinaemia in adults who have had at least 1 previous therapy.

Ibrutinib (with obinutuzumab) *()* TAG recommendation: Jun 2021

for use in: untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (TA702 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of ibrutinib with obinutuzumab for untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma. This is because Janssen has confirmed that it does not intend to make an evidence submission for the appraisal

Ibrutinib (with rituximab) *()* TAG recommendation: Jun 2021

for use in: untreated chronic lymphocytic leukaemia (TA703 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of ibrutinib with rituximab for untreated chronic lymphocytic leukaemia. This is because Janssen has confirmed that it does not intend to make an evidence submission for the appraisal.

Ibrutinib ▼ *(Imbruvica® ▼)* TAG recommendation: Sep 2017

for use in: Untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation - as per NICE TA 452 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 452 (July 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Ibrutinib ▼ (with bendamustine and rituximab) *(Imbruvica® ▼)* TAG recommendation: May 2017

for use in: Relapsed or refractory chronic lymphocytic leukaemia after systemic therapy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 437 (March 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ibrutinib with rituximab *(Imbruvica®)* TAG recommendation: Jan 2020

for use in: Waldenstrom's macroglobulinaemia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2019.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Double Red (Not recommended for routine use/Not commissioned) for this NHS England commissioning responsibility treatment was afforded.

Idelalisib *(Zydelig®)* TAG recommendation: Nov 2019

for use in: Refractory follicular lymphoma that has not responded to 2 prior lines of treatment in adults (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA604 - October 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Idelalisib ▼ *(Zydelig® ▼)* TAG recommendation: Sep 2017

for use in: Chronic lymphocytic leukaemia (with ofatumumab (Arzerra®)) - as per NICE TA 469 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 469 (August 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Idelalisib ▼ *(Zydelig® ▼)* TAG recommendation: Jan 2015

for use in: Treatment of follicular lymphoma that is refractory to two prior treatments (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2014.

Specific points: January 2015: The TAG noted NICE TA 328 (terminated appraisal) and recommended a classification of Double Red (Not recommended for routine use) for this SCG commissioning responsibility treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

Imatinib mesylate (high dose) ▼ *(Glivec® ▼)* TAG recommendation: Jan 2017

for use in: Imatinib-resistant or intolerant chronic myeloid leukaemia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2016.

Specific points: January 2017: The TAG acknowledged NICE TA 425 (December 2016) and recommended a traffic light classification of Double Red (Not recommended for routine use) for use of high-dose imatininb, an SCG commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Imatinib mesylate ▼(high dose) *(Glivec® ▼)* TAG recommendation: Jan 2017

for use in: Imatinib-resistant Chronic Myeloid Leukaemia (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2016.

Specific points: NICE TA 241 states that high-dose imatinib is not recommended for treatment of chronic myeloid leukaemia which is resistant to standard doses of imatinib.
http://guidance.nice.org.uk/TA241

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Indication not included in the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2017:
NICE TA 425 (December 2016) replaces TA 241 (January 2012), and partially updates NICE TA 70 (last update January 2016) on imatinib for chronic myeloid leukaemia.

The TAG acknowledged NICE TA 425 (December 2016) for dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia. Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:
* they cannot have imatinib, or their disease is imatinib-resistant
* High-dose imatinib (i.e. 600mg in the chronic phase or 800mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant
and recommended traffic light classifications of:
Red (Hospital/Specialist only) for recommended uses of dasatinib and nilotinib
and
Double Red (Not recommended for routine use) for use of high-dose imatininb

for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Isatuximab with carfilzomib and dexamethasone *()* TAG recommendation: Oct 2021

for use in: relapsed or refractory multiple myeloma as per TA727 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment. NICE is unable to make a recommendation about the use in the NHS of isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma. This is because Sanofi has confirmed that it does not intend to make an evidence submission for the appraisal. Sanofi considers that the technology is unlikely to be a cost-effective use of NHS resources

Ixazomib *(Ninlaro®)* TAG recommendation: May 2018

for use in: Amyloidosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Lapatinib *(Tyverb®)* TAG recommendation: Jul 2012

for use in: 1st-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2012.

Specific points: NICE TA 257 states that:
1.1 Lapatinib in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses human epidermal growth factor receptor 2 (HER2).
1.2 Trastuzumab in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses HER2.
1.3 Postmenopausal women currently receiving lapatinib or trastuzumab in combination with an aromatase inhibitor that is not recommended according to 1.1 or 1.2 should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2012: Not commissioned by the Norfolk & Waveney Drugs & Therapeutics Commissioning Group.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Nintedanib *(Vargatef®)* TAG recommendation: May 2018

for use in: Ovarian cancer (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Nivolumab *(Opdivo®)* TAG recommendation: Sep 2018

for use in: Locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy - as per NICE TA 530 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2018.

Specific points: September 2018: The TAG noted NICE TA 530 (July 2018) which recommended against use of nivolumab for treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy. The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation

Nivolumab with ipilimumab *(Opdivo® with Yervoy®)* TAG recommendation: Oct 2021

for use in: and chemo for untreated metastatic non-small-cell lung cancer as per TA724 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment. Not recommended by NICE

Olaparib *(Lynparza)* TAG recommendation: Jan 2022

for use in: maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer after platinum-based chemotherapy as per TA750 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of olaparib for maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer in adults after platinum-based chemotherapy. This is because AstraZeneca has confirmed that it does not intend to make a submission for the appraisal. AstraZeneca considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources for this population.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Olaparib *()* TAG recommendation: Mar 2022

for use in: BRCA mutation-positive HER2-negative metastatic breast cancer after chemo as per TA762 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2022.

Specific points: No prescribing in primary or secondary care. Terminated appraisal

Paclitaxel *(Taxol®)* TAG recommendation: Mar 2009

for use in: Lymph node positive breast cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2009.

Specific points: March 2009: The TAG acknowledged NICE Clinical Guideline 80 - Early and locally advanced breast cancer (Feb 2009), which states that paclitaxel should not be offered as part of adjuvant chemotherapy regimen for lymph node positive breast cancer.

November 2013: Commissioning responsibility of NHS England SCG from April 2013. Clinical indication not listed in the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Paclitaxel *(Abraxane®)* TAG recommendation: Nov 2015

for use in: For untreated non-small-cell lung cancer (as albumin-bound nanoparticles with carboplatin) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2015.

Specific points: November 2015: The TAG noted NICE TA 362 (October 2015) (terminated appraisal) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Panitumumab *(Vectibix®)* TAG recommendation: Mar 2012

for use in: Treatment of metastatic colorectal cancer after first-line chemotherapy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2012.

Specific points: NICE TA 242 states that panitumumab monotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.
People currently receiving panitumumab monotherapy for the treatment of metastatic colorectal cancer that has progressed after first-line chemotherapy should have the option to continue treatment until they and their clinician consider it appropriate to stop.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.
Not commissioned for third-line monotherapy of patients with metastatic rectal adenocarcinoma.

Pegylated liposomal irinotecan *(Onivyde®)* TAG recommendation: May 2017

for use in: For treating metastatic adenocarcinoma of the pancreas in adults whose disease has progressed after gemcitabine-based therapy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2017.

Specific points: May 2017:
The TAG acknowledged NICE TA 440 (April 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

May 2017:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group noted the TAG's recommendation.

Pralsetinib *(Gavreto®)* TAG recommendation: Sep 2022

for use in: RET fusion-positive advanced non-small-cell lung cancer as per TA812 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Protein Kinase Inhibitors *(Various)* TAG recommendation: May 2018

for use in: Endocrinology non-malignant conditions (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Regorafenib *(Stivarga®)* TAG recommendation: May 2018

for use in: Previously treated advanced hepatocellular carcinoma - as per NICE TA 514 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 514 (March 2018) which recommends against use of this treatment, and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation

Regorafenib ▼ *(Stivarga® ▼)* TAG recommendation: May 2015

for use in: Metastatic colorectal cancer after treatment for metastatic disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2015.

Specific points: May 2015: The TAG acknowledged NICE TA 334 (February 2015) and recommended a classification of Double Red (Not recommended for routine use) for the SCG-commissioned treatment described within it.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Ripretinib *(Qinlock®)* TAG recommendation: Jun 2023

for use in: advanced gastrointestinal stromal tumour after 3 or more treatments TA881 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Ruxolitinib *(Jakavi®)* TAG recommendation: Nov 2015

for use in: Polycythaemia vera (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2015.

Specific points: November 2015: The TAG noted NICE TA 356 (September 2015) (terminated appraisal) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' noted the TAG recommendation.

Ruxolitinib *(n/a)* TAG recommendation: Dec 2022

for use in: treating chronic graft versus host disease refractory to corticosteroids (terminated appraisal) TA840 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Ruxolitinib *(n/a)* TAG recommendation: Dec 2022

for use in: acute graft versus host disease refractory to corticosteroids (terminated appraisal) TA839 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Selinexor *()* TAG recommendation: Jun 2021

for use in: with low-dose dexamethasone for treating refractory multiple myeloma (TA700 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of selinexor with low-dose dexamethasone for treating refractory multiple myeloma. This is because Karyopharm Therapeutics has confirmed that it does not intend to make an evidence submission for the
appraisal and will not be launching the technology in the UK

Sunitinib *(Sutent®)* TAG recommendation: Sep 2009

for use in: Second-line treatment of advanced and/or metastatic renal cell carcinoma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2009.

Specific points: Refn: Although previously recommended by NICE for first-line treatment of advanced and/or metastatic treatment of renal cell carcinoma, NICE Technology appraisal guidance 178 (August 2009) does not recommend second-line use for this indication.

April 2013: NHS England SCG took over commissioning responsibility.
Commissioned for treatment of pancreatic neuroendocrine carcinomas.

Tafasitamab *(Minjuvi®)* TAG recommendation: Jun 2023

for use in: relapsed or refractory diffuse large B-cell lymphoma TA883 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Teclistamab *(Tecvayli®)* TAG recommendation: Mar 2023

for use in: relapsed or refractory multiple myeloma after 3 or more therapies (terminated appraisal) TA869 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care
NICE is unable to make a recommendation about the use in the NHS of teclistamab for treating relapsed or refractory multiple myeloma in adults after 3 or more therapies. This is because Janssen has confirmed that it does not intend to make an evidence submission for the appraisal. Janssen considers that there is unlikely to be enough evidence that the technology is a cost-effective use of NHS resources for this population.

Temsirolimus *(Torisel®)* TAG recommendation: Nov 2010

for use in: Treatment of relapsed or refractory mantle cell lymphoma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2010.

Specific points: The TAG noted that NICE has terminated technology appraisal 207 on use of temsirolimus for mantle cell lymphoma and therefore recommended a Double Red classification.

April 2013: NHS England SCG took over commissioning responsibility.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Topotecan *(Hycamtin®)* TAG recommendation: May 2016

for use in: Treatment of advanced recurrent ovarian cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2016.

Specific points: May 2016: The TAG noted NICE TA 389 (April 2016) review of TA91 & TA 222 (ID468) Topotecan (Hycamtin®), pegylated liposomal doxorubicin hydrochloride (Caelyx®), paclitaxel, trabectedin (Yondelis®) and gemcitabine for advanced recurrent ovarian cancer:
* Paclitaxel in combination with platinum or as monotherapy is recommended as an option.
* Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended as an option.
* PLDH in combination with platinum is recommended as an option.
The following are not recommended for treating the first recurrence of platinum sensitive ovarian cancer:
* gemcitabine in combination with carboplatin
* trabectedin in combination with PLDH
* topotecan
The appraisal committee was unable to recommend use of these technologies to treat platinum sensitive ovarian cancer beyond the first recurrence.
*Topotecan is not recommended for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

The TAG recommended a classification of Red (Hospital/Specialist only) for the treatments recommended by NICEand Double Red (Not recommended for routine use/Not commissioned) for those treatments not recommended by NICE.
It was noted that these are SCG-commissioning responsibility treatments.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Trabectedin *(Yondelis®)* TAG recommendation: May 2016

for use in: (In combination with pegylated liposomal doxorubicin HCl) for relapsed ovarian cancer (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2016.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 222 which does not recommend use of trabectedin for this indication.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

November 2013: Not listed in NHSE SCG Cancer Drug Fund website.

May 2016: The TAG noted NICE TA 389 (April 2016) review of TA91 & TA 222 (ID468) Topotecan (Hycamtin®), pegylated liposomal doxorubicin hydrochloride (Caelyx®), paclitaxel, trabectedin (Yondelis®) and gemcitabine for advanced recurrent ovarian cancer:
* Paclitaxel in combination with platinum or as monotherapy is recommended as an option.
* Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended as an option.
* PLDH in combination with platinum is recommended as an option.
The following are not recommended for treating the first recurrence of platinum sensitive ovarian cancer:
* gemcitabine in combination with carboplatin
* trabectedin in combination with PLDH
* topotecan
The appraisal committee was unable to recommend use of these technologies to treat platinum sensitive ovarian cancer beyond the first recurrence.
*Topotecan is not recommended for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

The TAG recommended a classification of Red (Hospital/Specialist only) for the treatments recommended by NICEand Double Red (Not recommended for routine use/Not commissioned) for those treatments not recommended by NICE.
It was noted that these are SCG-commissioning responsibility treatments.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Trametinib *(Mekinist®)* TAG recommendation: Mar 2019

for use in: (with dabrafenib (Tafinlar®)) for treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer - as per NICE TA 564 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 564 (February 2019) - terminated appraisal. NICE was unable to make a recommendation about the use of this treatment in the NHS because no evidence submission was received from Novartis; NICE will review this decision if the company decides to make a submission.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Trastuzumab *(Herceptin®)* TAG recommendation: Jul 2012

for use in: In combination with an aromatase inhibitor, 1st-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2012.

Specific points: NICE TA 257 states that:
1.1 Lapatinib in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses human epidermal growth factor receptor 2 (HER2).
1.2 Trastuzumab in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses HER2.
1.3 Postmenopausal women currently receiving lapatinib or trastuzumab in combination with an aromatase inhibitor that is not recommended according to 1.1 or 1.2 should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2012: Not commissioned by the Norfolk & Waveney Drugs & Therapeutics Commissioning Group.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.1.5 - Protein Kinase Inhibitors

Trastuzumab deruxtecan *(Enhertu®)* TAG recommendation: Jun 2023

for use in: HER2-positive unresectable or metastatic gastric or gastro-oesophageal junction cancer after anti-HER2 treatment TA879 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Vandetanib *(Caprelsa®)* TAG recommendation: Jan 2019

for use in: For treating aggressive and symptomatic medullary thyroid cancer in adults with unresectable, locally advanced or metastatic disease - as per NICE TA 550 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2018.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per CDF policy - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

January 2019: The TAG noted NICE TA 550 (December 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHS England commissioning responsibility treatment

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Vismodegib ▼ *(Erivedge® ▼)* TAG recommendation: Jan 2018

for use in: Basal cell carcinoma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 489 (Nov 17) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.
January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

8.2.2 - Corticosteroids for inflammatory bowel disease

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.2 - Corticosteroids for inflammatory bowel disease

Budesonide orodispersible tablet *(Jorveza®))* TAG recommendation: Jul 2021

for use in: Eosinophilic oesophagitis in adults - maintenance treatment (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2021.

Specific points: Business case required to consider treatment for maintenance of remission. Until then, this is not commissioned. No NHS prescribing in primary or secondary care

Mycophenolate sodium *(Ceptava®, Myfortic®)* TAG recommendation: Nov 2017

for use in: Initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE TAs 481 & 482 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 481 (Oct 17) and NICE TA 482 (October 2017) which state that Rabbit anti-human thymocyte immunoglobulin, prolonged-release tacrolimus, mycophenolate sodium, sirolimus, everolimus and belatacept are not recommended by NICE as initial treatments to prevent organ rejection in adults, children and young people having a kidney transplant.
The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for these treatments for these indications.

Noted by the D&TCG.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.2 - Corticosteroids for inflammatory bowel disease

Sirolimus *(Rapamune®)* TAG recommendation: Nov 2017

for use in: Initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE TAs 481 & 482 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 481 (Oct 17) and re-affirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement) for sirolimus which is a SCG-commissioning responsibility treatments, the costs of which are currently being recouped by the CCGs from NHS England to cover any prescribing by GPs. The use of the current shared care agreement to be extended until the end of March 2018.

NICE TAs 481 and 482 also state that sirolimus is not recommended as an initial treatment to prevent organ rejection in adults, children and young people having a kidney transplant.
The TAG therefore also recommended a traffic light classification of Double Red (Not recommended for routine use) for these indications.

Noted by the D&TCG.

Tacrolimus (oral) - prolonged release *(Advagraf®, Envarsus®)* TAG recommendation: Nov 2017

for use in: Initial treatments to prevent organ rejection in adults, children and young people having a kidney transplant - as per NICE Tas 481 and 482 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TAs 481 and 482 (Oct 17) which state that Rabbit anti-human thymocyte immunoglobulin, prolonged-release tacrolimus, mycophenolate sodium, sirolimus, everolimus and belatacept are not recommended by NICE as initial treatments to prevent organ rejection in adults, children and young people having a kidney transplant.
The TAG therefore recommended a traffic light classification of Double Red (Not recommended for routine use) for these treatments for thess indications.

Noted by the D&TCG.

8.2.3 - Other immunomodulating drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.3 - Other immunomodulating drugs

Blinatumomab *(x)* TAG recommendation: May 2021

for use in: previously treated Philadelphia-chromosome-positive acute lymphoblastic leukaemia as per TA686 (terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2021.

Specific points: Terminated appraisal - Double Red (Not recommended for routine use / Not commissioned)

Gevokizumab *()* TAG recommendation: May 2018

for use in: Uveitis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nivolumab *(N/A)* TAG recommendation: May 2022

for use in: with cabozantinib for untreated advanced renal cell carcinoma (terminated appraisal) as per TA785 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2022.

Specific points: May 2022 - NICE is unable to make a recommendation about the use in the NHS of nivolumab with cabozantinib for untreated advanced or metastatic renal cell carcinoma. This is because Bristol Myers Squibb withdrew the evidence submission. We will review this decision if the company decides to make a submission - BLACK - Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.3 - Other immunomodulating drugs

Ocrelizumab ▼ *(Ocrevus® ▼)* TAG recommendation: May 2018

for use in: Multiple sclerosis in adults - as per NHS England policy (under review post NICE 533) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ofatumumab *(Arzerra®)* TAG recommendation: Sep 2017

for use in: Chronic lymphocytic leukaemia (with chemotherapy) - as per NICE TA 470 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 470 (August 2017) (terminated appraisal) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2018

for use in: Connective tissue disease - interstitial lung disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.3 - Other immunomodulating drugs

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2018

for use in: Nephritis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2018

for use in: Chronic inflammatory demyelinating polyneuropathy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2018

for use in: Primary Sjogren's syndrome (PSS) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

8.2.4 - Other immunomodulating drugs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Axicabtagene ciloleucel *((Yescarta®))* TAG recommendation: Jul 2023

for use in: relapsed or refractory follicular lymphoma TA894 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondniary care. Not recommended by NICE

Canakinumab *(Ilaris®)* TAG recommendation: May 2013

for use in: Treatment of gouty arthritis attacks and reducing the frequency of subsequent attacks - as per NICE TA 281 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2013.

Specific points: NICE TA 281 (April 2013) (terminated appraisal)
No evidence submission received from the manufacturer.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) decision - Not commissioned

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Canakinumab *(Ilaris®)* TAG recommendation: Jan 2014

for use in: Treatment of systemic juvenile idiopathic arthritis - - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: NICE TA 302 (Nov 2013) (terminated appraisal due to no evidence submitted)
in the treatment of systemic juvenile idiopathic arthritis.
N&W CCGs-D&TCG noted the TAG recommendation. SCG-commissioning responsibility.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Daclizumab *(Zinbryta®)* TAG recommendation: May 2018

for use in: Relapsing-remitting multiple sclerosis in adults - as per NICE TA 441 Specialist centre only - currently suspended (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 441 (April 2017) for treating multiple sclerosis in adults, only if:
* the person has active relapsing-remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing-remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and
* alemtuzumab is contraindicated or otherwise unsuitable
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
N.B. serum transaminase levels should be monitored monthly during treatment and up to 4 months after the last dose of Zinbryta®.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

May 2018:
The The NHS Norfolk & Waveney CCGs' D&TC noted the MHRA's report that use of Daclizumab (Zinbryta▼) has been suspended.
NHSE commissioning responsibility and currently classified as Red (Hospital only).
The D&TC agreed that it was appropriate to revise the classification to Double Red (Not recommended for routine use) until further information is available.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Interferon alfa *(Roferon-A®, Viraferon®)* TAG recommendation: May 1999

for use in: Adjunct to surgery in malignant melanoma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

September 2015: The TAG noted NG 14 (July 2015) - Assessment and management of melanoma in children, young people and adults which includes recommendations on:
* Assessing and staging melanoma
* Treating stages 0-II melanoma
* Treating stage III melanoma
* Treating stage IV melanoma
* Follow up after treatment
* Managing suboptimal vitamin D levels

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Interferon beta 1b (Betaferon®) *(Betaferon®)* TAG recommendation: Jul 2018

for use in: Multiple sclerosis - as per NICE TA 527 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2018.

Specific points: March 2002:
Funded by a DoH risk sharing scheme

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NICE TA32 (January 2002) and NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

July 2018:
The TAG acknowledged NICE TA 527: Beta interferons (Avonex®, Betaferon®, Extavia®, Rebif®) and glatiramer acetate (Copaxone®) for treating multiple sclerosis, which stated:
1.1 Interferon beta 1a is recommended as an option for multiple sclerosis only if:
* the person has relapsing-remitting multiple sclerosis and
* the companies provide it according to commercial arrangements.
1.2 Interferon beta 1b (Extavia) is recommended as an option for treating multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or
* the person has secondary progressive multiple sclerosis with continuing relapses and
* the company provides it according to the commercial arrangement.
1.3 Glatiramer acetate is recommended as an option for multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and
* the company provides it according to the commercial arrangement.
1.4 Interferon beta 1b (Betaferon) is not recommended as an option for treating multiple sclerosis.

Lenalidomide *(Revlimid®)* TAG recommendation: Nov 2019

for use in: With bortezomib and dexamethasone for untreated multiple myeloma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA603 - September 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for use/Not commissioned) for this NHS England commissioning responsibility treatment.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Lenalidomide *()* TAG recommendation: Apr 2022

for use in: relapsed or refractory mantle cell lymphoma as per TA774 (terminated) (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2022.

Specific points: Not commissioned. NICE is unable to make a recommendation about the use in the NHS of lenalidomide for treating relapsed or refractory mantle cell lymphoma. This is because Celgene has confirmed that it does not intend to make an evidence submission for the appraisal

Mosunetuzumab *(Lunsumio®)* TAG recommendation: Jul 2023

for use in: relapsed or refractory follicular lymphoma TA892 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care. Not recommended by NICE

Ozanimod *()* TAG recommendation: May 2018

for use in: Relapsing-remitting multiple sclerosis (RRMS) (x).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ozanimod *(Zeposia®)* TAG recommendation: Jul 2021

for use in: relapsing–remitting multiple sclerosis as per TA706 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2021.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Pomalidomide *(Imnovid®)* TAG recommendation: Nov 2019

for use in: With bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2019.

Specific points: December 2019: The NHS Norfolk & Waveeney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA602 - September 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for use/Not commissioned) for this NHS England commissioning responsibility treatment.

Pomalidomide ▼ *(Imnovid ▼)* TAG recommendation: May 2018

for use in: Myelofibrosis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ropeginterferon alfa 2b *()* TAG recommendation: May 2018

for use in: Hepatitis C (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.2.4 - Other immunomodulating drugs

Tisagenlecleucel *(n/a)* TAG recommendation: Dec 2022

for use in: follicular lymphoma after 2 or more therapies (terminated appraisal) TA824 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

8.3.4 - Hormone antagonists

Abiraterone *(Zytiga®)* TAG recommendation: Aug 2021

for use in: newly diagnosed high-risk hormone-sensitive metastatic prostate cancer as per TA721 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2021.

Specific points: NHS England commissioned treatment. Not commissioned. No NHS prescribing in primary or secondary care. NICE not recommended

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.3.4 - Hormone antagonists

Fulvestrant *(Faslodex®)* TAG recommendation: Mar 2018

for use in: Treatment of locally advanced or metastatic breast cancer - as per NICE TA 239 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2018.

Specific points: NICE TA Guidance 239 (December 2011 http://guidance.nice.org.uk/TA239) states that The guidance states that: Fulvestrant is not recommended, within its licensed indication, as an alternative to aromatase inhibitors for the treatment of oestrogen-receptor-positive, locally advanced or metastatic breast cancer in postmenopausal women whose cancer has relapsed on or after adjuvant anti-oestrogen therapy, or who have disease progression on anti-oestrogen therapy.
Post-menopausal women currently receiving fulvestrant for this indication should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

Not commissioned by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (January 2012).

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

March 2018: The TAG acknowledged NICE TA 503 (January 2018) for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer in postmenopausal women and recommended a traffic light classification of Double Red (Not recommended for routine use) for this NHSE (SCG)-commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

8.3.4.2 - Prostate cancer and gonadorelin analogues

Relugolix–estradiol–norethisterone acetate *(Ryeqo®)* TAG recommendation: Nov 2022

for use in: moderate to severe symptoms of uterine fibroids as per TA832 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: October 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

8.3.4.3 - Somatostatin analogue

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

8.3.4.3 - Somatostatin analogue

Fibroblast growth factor 1 (FGF1) gene therapy *()* TAG recommendation: May 2018

for use in: All indications (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pasireotide *(Signifor®)* TAG recommendation: May 2018

for use in: Acromegaly (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Not routinely commissioned. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.1 - Anaemias and some other blood disorders

Mitapivat *(Pyrukynd®)* TAG recommendation: Mar 2023

for use in: pyruvate kinase deficiency (terminated appraisal) TA867 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2023.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care
NICE is unable to make a recommendation about the use in the NHS of mitapivat for treating pyruvate kinase deficiency in adults. Agios has confirmed that it does not intend to make an evidence submission for the appraisal. This is because the technology will not be launched in the UK at this time for treating this indication.

9.1.1.1 - Iron decficiency anaemia

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.1.1 - Iron decficiency anaemia

Ferric maltol (Feraccru®) *(Feraccru®)* TAG recommendation: Nov 2018

for use in: Treatment of iron-deficiency anaemia in adults (see separate Red entry regarding use in IBD) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG noted that Feraccru® capsules containing 231.5mg ferric maltol (equivalent to 30mg ferrous iron), which are licensed to treat iron deficiency anaemia in inflammatory bowel disease (IBD) are currently used in-Trust at the NNUH but requests have also been made to GPs.
28 days' supply (56) costs £47.60 compared with ferrous fumarate or sulphate preparations costing £1 to £3.
Recommended by the Prescribing Reference Group to be added to the Norfolk & Waveney DROP List.
The TAG also recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of Feraccru® is submitted.

July 2017: Noted and supported by the D&TCG - Not commissioned

September 2017:
The TAG considered an NNUH application for use in iron deficiency anaemia (mild-moderate) in adult patients with inflammatory bowel disease that are intolerant or have failed 1st line oral iron agents.
The TAG was advised that where other iron preparations are not effective / not tolerated, the next treatment option is IV iron infusion. Feraccru® is significantly more expensive than standard oral iron preparations but is cheaper and less invasive than administering IV iron.
The TAG was concerned about the low quality of supporting evidence provided with this application (2 placebo-controlled RCTs), and also noted that the SMC had published their decision not to commission use of this treatment.
The TAG therefore agreed that a revised recommendation regarding this item is deferred until more evidence to support such use is provided particularly regarding the effectiveness and tolerability of Feraccru® compared to other iron salts

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG.

November 2017:
The TAG considered further information provided by the NNUH which aimed to clarify that ferric maltol is the next proposed treatment option in patients with clinically inactive disease after use of oral ferrous salt products have failed, either due to intolerance or inadequate response. The TAG agreed that use of ferric maltol was clinically acceptable, based on the available evidence, providing that all cost-effective oral ferrous salt products (i.e. sulphate, fumarate and gluconate) are tried before ferric maltol is used. The TAG also advised that if the local costs of running an IV iron service (which had been set up in primary care to treat patients found to be anaemic pre-operatively in order to ensure their fitness for surgery in a timely fashion) were greater than using ferric maltol in this specific patient group, then such use was reasonable.
The TAG agreed to recommend a revised traffic light classification from Double Red (Not recommended for routine use) to Red (Hospital / Specialist use only) until the treatment pathway is finalised via the D&TCG.

November 2017:
The D&TCG considered the additional information provided by the NNUH, and the TAG's revised recommendation. The D&TCG felt that it was unclear whether the patients who are currently taking ferric maltol had tried all other ferrous salt alternatives, which are considerably cheaper than the proposed treatment, before being moved to Feraccru®. There were also outstanding questions regarding the status of the IV iron

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.1.1 - Iron decficiency anaemia

service currently provided in primary care. The D&TCG therefore felt that the case for using ferric maltol (Feraccru®) was not sufficiently proven to be able to justify introducing a new product to the local health economy which costs more than standard oral care and which may not necessarily reduce the costs of delivering IV iron in the future. Whilst the D&TCG appreciated the NNUH's intentions in proposing use of Feraccru®, the committee was not convinced that adding Feraccru® to local treatment pathway would save enough to justify its additional costs. The D&TCG therefore decided to maintain the current commissioned position of Double Red (Not recommended for routine use / Not commissioned).

November 2018: The PRG recommendation that the TAG considers reviewing and updating the Double Red (Not recommended for routine use) classification to this treatment in line with its revised licensed indication for treatment of anaemia of any cause was supported by the TAG.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and D&TC recommendation.

March 2019: The TAG considered the NNUH's revised application, which proposed restricted use of this oral chelated iron product in a small number of patients with inflammatory bowel disease with iron deficiency anaemia who cannot tolerate standard oral iron salts and who then require IV iron infusions (~30 patients). Patients often require 2 day case appointments to complete the required IV treatment.
The TAG agreed to support the revised application and recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation) for a 12 week course only in patients with IBD who had been unable to tolerate 2 other oral iron preparations.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC supported the revised application for use in principle.
However due to concerns that use of Ferric maltol (Feraccru®) would become widespread in primary care as a general treatment for iron deficiency anaemia, the D&TC recommended a revised classification of Red (Hospital/Specialist use only), where the specialist provides the complete treatment course.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

9.1.2 - Drugs used in megalobalstic anaemias

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.2 - Drugs used in megalobalstic anaemias

Folic acid *(Generics are available)* TAG recommendation: Jul 2017

for use in: Secondary prevention of MI / reduce cardiovsacular risk post MI - as per NICE CG 172 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2013.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 172 - Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease which states:
1.2.4 Advise people not to take supplements containing beta-carotene. Do not recommend antioxidant supplements (vitamin E and/or C) or folic acid to reduce
cardiovascular risk. [2007]

Folic Acid *(Generics are available)* TAG recommendation: Jul 2017

for use in: For preventing hypertensive disorders during pregnancy - as per NICE CG 107 - Do Not Do (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2010.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 107 - Hypertension in pregnancy which states:

1.1.4.1 Do not recommend folic acid solely with the aim of preventing hypertensive disorders during pregnancy.

9.1.3 - Iron chelators

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.3 - Iron chelators

Deferasirox *(Exjade®)* TAG recommendation: May 2017

for use in: For blood transfusion related iron overload in patients with myelodysplastic syndrome (MDS) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2017:
The PAC has identified that use of iron chelators in MDS is CCG-commissioning responsibility and recommends against routine commissioning for this indication.

The TAG agreed to support the PAC's recommendations and recommended a traffic light classification of Double Red (Not recommended for routine use) for use of the iron chelators for blood transfusion-related iron overload in patients with myelodysplastic syndrome.

May 2017:
The D&TCG noted and supported the TAG's recommendations to adopt PAC guidance, and decided that use of iron chelators Deferasirox, Deferiprone, and Desferrioxamine for blood transfusion-related iron overload in patients with myelodysplastic syndrome (MDS) is Double Red (Not recommended for routine use) / Not commissioned

Deferiprone *(Ferriprox®)* TAG recommendation: May 2017

for use in: For blood transfusion related iron overload in patients with myelodysplastic syndrome (MDS) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2017:
The PAC has identified that use of iron chelators in MDS is CCG-commissioning responsibility and recommends against routine commissioning for this indication.

The TAG agreed to support the PAC's recommendations and recommended a traffic light classification of Double Red (Not recommended for routine use) for use of the iron chelators for blood transfusion-related iron overload in patients with myelodysplastic syndrome.

May 2017:
The D&TCG noted and supported the TAG's recommendations to adopt PAC guidance, and decided that use of iron chelators Deferasirox, Deferiprone, and Desferrioxamine for blood transfusion-related iron overload in patients with myelodysplastic syndrome (MDS) is Double Red (Not recommended for routine use) / Not commissioned

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.3 - Iron chelators

Desferrioxamine *(Desferal®)* TAG recommendation: May 2017

for use in: For blood transfusion related iron overload in patients with myelodysplastic syndrome (MDS) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2017:
The PAC has identified that use of iron chelators in MDS is CCG-commissioning responsibility and recommends against routine commissioning for this indication.

The TAG agreed to support the PAC's recommendations and recommended a traffic light classification of Double Red (Not recommended for routine use) for use of the iron chelators for blood transfusion-related iron overload in patients with myelodysplastic syndrome.

May 2017:
The D&TCG noted and supported the TAG's recommendations to adopt PAC guidance, and decided that use of iron chelators Deferasirox, Deferiprone, and Desferrioxamine for blood transfusion-related iron overload in patients with myelodysplastic syndrome (MDS) is Double Red (Not recommended for routine use) / Not commissioned

Dexrazoxane (Cardioxane®) *(Cardioxane®)* TAG recommendation: May 2018

for use in: Anthracycline cardiotoxicity (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.3 - Iron chelators

Eculizumab *(Soliris®)* TAG recommendation: Sep 2015

for use in: Treatment of refractory antibody mediated rejection post kidney transplant - as per NHS England policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted A07/P/b (A07X02) (July 2015) (NHS England Commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Eculizumab *()* TAG recommendation: Oct 2020

for use in: for treating relapsing neuromyelitis optica as per TA647 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This was supported by D+TC

Eculizumab *()* TAG recommendation: Jul 2020

for use in: Refractory myasthenia gravis as per TA636 (June 2020 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.3 - Iron chelators

Erythropoietin / Epoetin *(Eprex®, NeoRecormon® and others)* TAG recommendation: Apr 2005

for use in: Anaemia in renal failure pre-dialysis. (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2015.

Specific points: April 2005:
Use in pre-dialysis patients is not commissioned in Norfolk & Waveney.

May 2011: The TAG noted NICE Clinical Guideline 114 (February 2011) - Anaemia management in people with chronic kidney disease (www.nice.org.uk/CG114)
The advice in the NICE clinical guideline covers:
Detecting and diagnosing anaemia of chronic kidney disease managing anaemia of chronic kidney disease, and other health problems or treatments that may affect it.
It does not specifically look at anaemia in people with chronic kidney disease, where the anaemia may be caused by other problems.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

July 2015: The TAG and the D&TCG noted and acknowledged (NICE) NG 8 (June 2015) - Anaemia management in people with chronic kidney disease.

Hydroxycarbamide (hydroxyurea) as Siklos® ▼ *(Siklos® (not funded by NHS Norfolk))* TAG recommendation: Sep 2011

for use in: Sickle-cell disease (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG noted the EoE SCG Commissioning Policy v.1 (November 2009) - Hydroxycarbamide (hydroxyurea) in Sickle Cell Disease and acknowledged the document as a reference upholding the PCTs' decision not to fund Siklos®.
The TAG recommended a Double Red (Not recommended for routine use) classification for Siklos® and a Red (Hospital Only) classification for generic hydroxycarbamide for use in sickle cell disease.

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided to maintain the previous decision to fund only GENERIC hydroxycarbamide for use in sickle cell disease.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.3 - Iron chelators

Luspatercept *(n/a)* TAG recommendation: Dec 2022

for use in: anaemia caused by beta-thalassaemia (terminated appraisal) TA843 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Luspatercept *(n/a)* TAG recommendation: Dec 2022

for use in: anaemia caused by myelodysplastic syndromes (terminated appraisal) TA844 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

9.1.4 - Drugs used in platelet

Avatrombopag *(Doptelet®)* TAG recommendation: Jan 2023

for use in: primary chronic immune thrombocytopenia TA853 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: December 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.1.4 - Drugs used in platelet

Eltrombopag *(Revolade®)* TAG recommendation: Mar 2015

for use in: Thrombocytopenia which affects the initiation or maintenance of optimal interferon therapy in adults with chronic Hepatitis C (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2015: The TAG noted the PAC guidance document which stated that applications for funding should be made on an individual patient basis via locally agreed Prior Approval processes. The TAG therefore recommended a classification of Double Red (Not recommended for routine use) for this treatment pending the submission of a business case.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the PAC's guidance statement and the TAG's recommendation.

Eltrombopag *(Revolade®)* TAG recommendation: Mar 2016

for use in: Severe aplastic anaemia refractory to immunosuppressive therapy - as per NICE TA 382 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG noted NICE TA 382 (January 2016) and recommended a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) for this CCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation

9.2.1.1 - Nutrition and Blood

Sodium zirconium cyclosilicate *(Lokelma®)* TAG recommendation: Jan 2020

for use in: Hyperkalaemia in adults - continued use (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2019.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. The Trust formulary application for QEH was noted and a traffic light classification of Double Red (Not for routine use/Not commissioned) was afforded for continued use.

9.2.1.3 - Oral bicarbonate

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.2.1.3 - Oral bicarbonate

Potassium bicarbonate SR plus citrate *(N/A)* TAG recommendation: Dec 2022

for use in: distal renal tubular acidosis (terminated appraisal) TA838 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

9.4.1 - Foods for special diets

Sapropterin (Tetrahydrobiopterin (BH4, THB)) *(Kuvan®)* TAG recommendation: Sep 2015

for use in: Treatment of children with phenylketonuria (PKU) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted E06/P/a (E06X01) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

9.5.1.2 - Hypercalcaemia & hypercalciuria

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.5.1.2 - Hypercalcaemia & hypercalciuria

Cinacalcet *(Mimpara®)* TAG recommendation: Jan 2006

for use in: Secondary hyperparathyroidism & parathyroid cancer - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2007.

Specific points: In January 2007 the following guidance was issued by NICE, which did not recommend routine use but did specify criteria for limited use of cinacalcet, as follows -
NICE Guidance (TAG 117): Cinacalcet in secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy: Cinacalcet is not recommended for the routine treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.
Cinacalcet is recommended for the treatment of refractory secondary hyperparathyroidism in patients with end-stage renal disease (including those with calciphylaxis) only in those:
who have 'very uncontrolled' plasma levels of intact parathyroid hormone (defined as greater than 85 pmol/litre [800 pg/ml]) that are refractory to standard therapy, and a normal or high adjusted serum calcium level, and
in whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits.

The TAG therefore agreed to maintain the Double Red classification for routine use in secondary hyperparathyroidism and parathyroid cancer but agreed to support a Red (Hospital use only) classification for patients meeting the criteria specified by NICE - see separate entry.

April 2013: Commissioning responsibility for this treatment transferred to NHS England SCG.

October: NHS England issued the iterim
A03/S/a 2013/14 NHS STANDARD CONTRACT FOR SPECIALISED ENDOCRINOLOGY SERVICES (ADULT)
- http://www.england.nhs.uk/wp-content/uploads/2013/06/a03-spec-endo-adult.pdf
which covers use of cinacalcet for hyperparathyroidism.

Velcalcetide (aka Etelcalcetide) *(Parsabiv®)* TAG recommendation: May 2018

for use in: Secondary hyperparathyroidism in patients with chronic kidney disease on haemodialysis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.5.2.2 - Phosphate-binding agents

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.5.2.2 - Phosphate-binding agents

Patiromer *(VELTASSA®))* TAG recommendation: Mar 2020

for use in: hyperkalaemia as per TA623 - Feb 2020 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2020.

Specific points: March 2020 - The TAG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) pending provision of a business case. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by Governing Body for Norfolk and Waveney CCG

9.6 - Vitamins

Biotin (vitamin H) *(Qizenday®, Cerenday®, MD1003)* TAG recommendation: May 2018

for use in: Multiple sclerosis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility - not routinely commissioned. Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.6.2 - Vitamin B group

Nicotinamide *()* TAG recommendation: Mar 2020

for use in: Various indications (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG noted and supported the PRG recommendation of a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) due to the high cost of this medication. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCGs

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.6.2 - Vitamin B group

Riboflavin *()* TAG recommendation: Mar 2020

for use in: Various indications (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG noted and supported the PRG recommendation of a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) due to the high cost of this medication. Patients should be advised to purchase if needed. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Riboflavin (vitamin B2) *()* TAG recommendation: Nov 2015

for use in: Migraine prophylaxis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Limuted evidence support use for this indication. If provided on FP10 is an expensive "special". Can be purchased at a reasonable price OTC.

9.6.4 - Vitamin D

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.6.4 - Vitamin D

Calcium and Ergocalciferol combi tablets *(Generic tablets)* TAG recommendation: Nov 2015

for use in: Prevention of osteoporosis-related fractures and falls - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Rationale for inclusion on the DROP List / Double Red classification:
Prescrptions written as "calcium and ergocalciferol" or "calcium and vitamin D" without a strength wil be dispensed as the generic tablet which contains inadequate amounts of calcium and ergocalciferol to prevent osteoporosis-related fractures and falls.

CKS for "Managing osteoporotic risk factors
How should I manage risk factors for osteoporosis? " states:
* Assess for vitamin D deficiency and inadequate calcium intake.
People are at risk of vitamin D deficiency if they are aged over 65 years or are not exposed to much sunlight (because they are confined indoors for long periods or because they wear clothes that cover the whole body).
A calcium intake of at least 1000 mg/day is recommended for people at increased risk of a fragility fracture.
* Correct vitamin D deficiency and ensure an adequate calcium intake.
For elderly people who are housebound or living in a nursing home, prescribe 20 micrograms (800 units) of vitamin D combined with at least 1 g of calcium daily.
For people over 65 years of age and people of any age not exposed to much sun, who have an adequate dietary calcium intake of more than 1000 mg/day, prescribe 10 micrograms (400 units) of vitamin D without a full replacement dose of calcium.
* There are no plain UK licensed vitamin D tablets available for treating simple deficiency; however, there are multivitamin preparations that contain the recommended dose of vitamin D. Choices include Abidec® multivitamins (ergocalciferol 10 micrograms per 0.6mL), calcium and ergocalciferol tablets (calcium 97 mg, ergocalciferol 10 micrograms), and Dalivit® drops (ergocalciferol 10 micrograms per 0.6mL).
* Multivitamin tablets containing 10 micrograms of vitamin D are also available to buy from pharmacies and health food stores.
For people who have a dietary calcium intake of less than 1000 mg/day, prescribe 10 micrograms (400 units) of vitamin D with at least 1000 mg of calcium daily, available as Calcichew D3® chewable tablets (calcium 500 mg, colecalciferol 5 micrograms).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.6.4 - Vitamin D

Colecalciferol (Vitamin D) *(Various)* TAG recommendation: Jul 2017

for use in: To increase adherence to statin treatment - as per NICE CG 181 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2014.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 181 - Cardiovascular disease: risk assessment and reduction, including lipid modification which states:

1.3.44 Do not offer coenzyme Q10 or vitamin D to increase adherence to statin treatment

9.6.5 - Vitamin (tocopherols)

Vitamin E *(Various)* TAG recommendation: Sep 2017

for use in: NICE Do Not Do - Pharmacological neuroprotective therapy in Parkinson's disease - as per NG 71 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017:
The TAG acknowledged NICE NG 71 - Parkinson's disease in adults which recommended against use of vitamin E as pharmacological neuroprotective therapy in Parkinson's disease.

9.8.1 - Drugs used in metabolic disorders

Chenodeoxycholic acid *(Chenodeoxycholic acid sigma-tau)* TAG recommendation: May 2018

for use in: Cerebrotendinous xanthomatosis (CTX) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Not routinely commissioned.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

9.8.1 - Drugs used in metabolic disorders

Chenodeoxycholic acid *(Chenodeoxycholic acid sigma-tau)* TAG recommendation: May 2018

for use in: Primary biliary cirrhosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Not routinely commissioned.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Cholic acid *(Orphacol®, Kolbam®)* TAG recommendation: May 2018

for use in: Inborn errors in primary bile acid synthesis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Not routinely commissioned.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Glycerol phenylbutyrate *(Ravicti® 1.1 g/ml oral liquid)* TAG recommendation: May 2018

for use in: Urea cycle disorders (specialist use only) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

10.1 - Drugs used in rheumatic diseases and gout

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1 - Drugs used in rheumatic diseases and gout

Hyaluronate *(Hyalgan®)* TAG recommendation: Apr 2000

for use in: Intra-articular injection in osteoarthritis (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not strictly a licensed drug. Uncertainty over long-term value and effectiveness.

Hylan G-F 20 *(Synvisc®)* TAG recommendation: Apr 2000

for use in: Intra-articular injection in osteoarthritis (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Not strictly a licensed drug. Noted to be in use in Norfolk trusts, but as the NHS is funding research into its effectiveness at preventing the need for joint replacements, TAG felt unable to make a positive recommendation for its use.

10.1.1 - Non-steroidal anti-inflammatory drugs

Dexibuprofen *(Seractil®)* TAG recommendation: Jul 2018

for use in: Analgesia / musculoskeletal pain (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2018: The TAG agreed to support the PRG's recommendation of applying a Double Red (Not recommended for routine use) classification to this treatment due to a lack of evidence of additional benefit over standard care with ibuprofen to justify its additional cost.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.1 - Non-steroidal anti-inflammatory drugs

Ketoprofen/omeprazole *(Axorid®)* TAG recommendation: Nov 2015

for use in: Patients requiring ketoprofen for OA, RA and ankylosing spondylitis who are at risk of NSAID-associated DU or GU (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Combination product - prescribe equivalent components separately if required.

10.1.3 - Drugs that suppress the rheumatic disease process

Abatacept *(Orencia®)* TAG recommendation: May 2019

for use in: Psoriatic arthritis after DMARDs as per NICE TA 568 terminated appraisal (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: March 2019.

Specific points: May 2019: The TAG acknowledged NICE TA 568 (March 2019) which stated that NICE is unable to make a recommendation about the use in the NHS of this treatment in adults because no evidence submission was received from Bristol-Myers Squibb. NICE will review this decision if the company decides to make a submission.
The TAG confirmed a traffic light classification of Double Red (Not recommended for routine use)

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendation.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Abatacept *(various, plus biosimilars)* TAG recommendation: Jul 2021

for use in: moderate rheumatoid arthritis after conventional DMARDs have failed as per TA715 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2021.

Specific points: The most likely cost-effectiveness estimates for abatacept are higher than what NICE normally considers cost effective

Pathway currently under review

Not commissioned. No NHS prescribing in primary or secondary care. Not considered a cost-effective option by NICE

Adalimumab *(Humira®)* TAG recommendation: Sep 2015

for use in: Anti-TNF Alpha treatment option for paediatric patients with severe refractory uveitis (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D12/P/b (D12X02) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Sep 2015

for use in: Anti-TNF treatment option for adult patients with severe refractory uveitis - as per NHS England policy and NICE TA 460 (Not a licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D12/P/a (D12X01) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

September 2017: The TAG acknowledged NICE TA 460 (Adalimumab and dexamethasone intravitreal implant for treating non-infectious uveitis in the posterior segment of the eye in adults) and noted the difference in responsible commissioner for adalimumab (SCG-commissioning responsibility) and dexamethasone intravitreal implant (CCG-commissioning responsibility) for treating non-infectious uveitis in the posterior segment of the eye in adults and acknowledged that local use would be determined by designation of a specialist centre status in any of the local provider trusts.
The TAG acknowledged NICE TA 460 (July 2017) and recommended traffic light classifications of Double Red (Not recommended for routine use) for these SCG-commissioning responsibility and CCG-commissioning responsibility treatments pending the submission and approval of a business application for their use.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Anakinra *(Kineret®)* TAG recommendation: Nov 2002

for use in: Rheumatoid arthritis - as per NICE CG79 - Do Not Do (A licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2009.

Specific points: In November 2003 NICE recommended that, on the balance of its clinical benefits and cost effectiveness, anakinra is not recommended for the treatment of rheumatoid arthritis, except in the context of controlled, long-term clinical study.

In February 2009, NICE issued Clinical Guideline No.79 Rheumatoid Arthritis - management in adults.
The guideline states that anakinra is not recommended for treating RA, except in a controlled, long-term study.

April 2013: NHS England SCG took over commissioning responsibility for use in paediatric conditions.

Anifrolumab *(N/A)* TAG recommendation: Jul 2022

for use in: active autoantibody-positive systemic lupus erythematosus (terminated appraisal) as per TA793 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Apremilast *(Otezla® ▼)* TAG recommendation: May 2018

for use in: Paediatric indications - NHSE policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Ad per IFR approval only - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Belimumab *(N/A)* TAG recommendation: Aug 2022

for use in: lupus nephritis (terminated appraisal) as per TA806 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2022.

Specific points: Not commissioned. No NHS prescribing in primary or secondary care

NICE is unable to make a recommendation about the use in the NHS of belimumab for treating lupus nephritis. This is because GlaxoSmithKline has confirmed that it does not intend to provide an evidence submission

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Nov 2004

for use in: Behcet's Disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: Due to the current lack of supporting evidence it was agreed that use of the anti-TNF drugs infliximab and etanercept for treatment of patients with Behcet's disease is not recommended for routine use (Double Red).

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Filgotinib *()* TAG recommendation: May 2018

for use in: Paediatric indications (where adult TA available) - specialist centres only (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Forigerimod acetate *(Lupuzor®)* TAG recommendation: May 2018

for use in: Systemic lupus erythematosus (SLE) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Golimumab *(Simponi®)* TAG recommendation: Jul 2017

for use in: For induction of remission, with or without steroids, in patients with Crohn's disease colitis with moderate-severe disease as a third-line anti-TNF after failure of or adverse reaction to two previous agents (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2017: The TAG considered the NNUH's application is for the use of Golimumab as a third line anti-TNF agent in patients where neither adalimumab nor infliximab can be used either due to the presence of anti-drug antibodies (ADA) or adverse drug reactions (ADR).

The TAG supported the NNUH's application and proposed pathway (with amendments regarding the order of use of ustekinumab and vedolizumab as per NICE guidance), and recommended a traffic light classification of Red (Hospital/Specialist only).

July 2017: The D&TCG noted the TAG's recommendation and decided to classify this treatment as Double Red (Not recommended for routine use) in the interim, until the treatment pathway has been clarified and resubmitted.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Jul 2011

for use in: Treatment of methotrexate-naïve rheumatoid arthritis - as per NICE TA 224 (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 224 - terminated appraisal - http://guidance.nice.org.uk/TA224

"NICE is unable to recommend the use in the NHS of golimumab for the treatment of methotrexate-naive rheumatoid arthritis because no evidence submission was received from the manufacturer or sponsor of the technology."

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Mar 2018

for use in: Severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs - as per NICE TA 497 (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 497 (January 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment, pending submission of an application for its use and agreement on its place in the treatment pathway.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

Hydroxychloroquine 300mg preparations *(various)* TAG recommendation: Jul 2021

for use in: Treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: 300mg preparations not commissioned. No NHS prescribing in primary or secondary care. Costs significantly more than the 200mg preparation

Infliximab *(Various)* TAG recommendation: May 2018

for use in: Connective tissue disease - interstitial lung disease (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab *(Cost effective biosimilars available)* TAG recommendation: Sep 2015

for use in: Anti-TNF treatment option for adult patients with severe refractory uveitis - as per NHSE policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D12/P/a (D12X01) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Renal indications (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Hidradenitis Suppurativa (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(Remicade®, Inflectra® ▼, Remsima® ▼)* TAG recommendation: Sep 2015

for use in: Anti-TNF Alpha treatment option for paediatric patients with severe refractory uveitis - NHSE policy (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D12/P/b (D12X02) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Sarcoidosis (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab (Remicade®) *(Remicade®)* TAG recommendation: Jan 2016

for use in: Anti-TNF Alpha treatment option for paediatric patients with severe refractory uveitis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2016:
The TAG noted NHS England Clinical Commissioning Policy: - Reference: NHS England D12/P/b (Nov 2015) which stated that Infliximab (Remicade®) as an Anti-TNF Alpha treatment option for Paediatric Patients with Severe Refractory Uveitis is not routinely funded by NHS England.

Secukinumab *(Cosentyx®)* TAG recommendation: May 2018

for use in: Paediatric indications (where adult TA available) (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Sirukumab *(Plivensia®)* TAG recommendation: May 2018

for use in: Paediatric indications (where adult TA available) - as per NHSE policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.3 - Drugs that suppress the rheumatic disease process

Tocilizumab IV *(RoActemra® for infusion)* TAG recommendation: May 2018

for use in: Treatment of giant cell arteritis - as per NHS England Policy 16019/P (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: April 2018.

Specific points: March 2018: Not commissioned by NHS England as per NHS England Policy 16019/P

May 2018: The TAG acknowledged NICE TA 518 (April 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendation

NB not yet confirmed as commissioned by NHS Emgland therefore record held as Double Red in the interim.

Trientene dihydrochloride *(Metalite® (Japanese import))* TAG recommendation: May 2018

for use in: Wilson's Disease (where penicillamine not tolerated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

10.1.4 - Gout and cytotoxic-induced hyperuricaemia

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.4 - Gout and cytotoxic-induced hyperuricaemia

Pegloticase *(Krystexxa®)* TAG recommendation: Jul 2013

for use in: Severe debilitating chronic tophaceous gout (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2013.

Specific points: Pegloticase is a polyethylene glycol conjugate of a recombinant enzyme uricase, also known as urate oxidase. It catalyses the oxidation of uric acid to allantoin, which is water soluble and can be excreted in urine, resulting in lowered serum uric acid levels. It is administered by intravenous infusion

NICE TA 291 (June 2013) states that pegloticase is not recommended within its marketing authorisation, that is, for treating severe debilitating chronic tophaceous gout in adults who may also have erosive joint involvement and in whom xanthine oxidase inhibitors at the maximum medically appropriate dose have failed to normalise serum uric acid, or for whom these medicines are contraindicated.

Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) decision: SCG-commissioning responsibility. NICE guidance noted. Not commissioned in NHS England.

10.1.5 - Other drugs used for rheumatic diseases

Chondroitin *(Various)* TAG recommendation: Jul 2017

for use in: Osteoarthritis - as per NICE CG 177 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2014.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 177 - Osteoarthritis: care and management which states:

1.4.5 Do not offer glucosamine or chondroitin products for the management of osteoarthritis. [2014]

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.1.5 - Other drugs used for rheumatic diseases

Glucosamine *(Various)* TAG recommendation: Jul 2017

for use in: Osteoarthritis - as per NICE CG 177 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2014.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 177 - Osteoarthritis: care and management which states:

1.4.5 Do not offer glucosamine or chondroitin products for the management of osteoarthritis. [2014]

Glucosamine, Glucosamine & Chondroitin *(Alateris and various)* TAG recommendation: Jul 2010

for use in: Osteoarthritis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: GPs are advised to stop prescribing on the basis of the NICE CG for osteoarthritis in adults states that these products are not recommended. BNF 59 March 2010 states that glucosamine is not recommended due to the mechanism of action not being understood and there being limited evidence showing effectiveness. Available to purchase without prescription at a 10th of the cost to the NHS.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

10.2 - Not listed

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.2 - Not listed

Diaminopyridine (-3,4) (amifampridine base) *(Generic)* TAG recommendation: Sep 2011

for use in: Treatment of myasthenias - as per NHS England policy (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility.
Commissioning policy states that amifampridine phosphate (Firdapse) is not routinely commissioned - http://www.england.nhs.uk/wp-content/uploads/2013/10/d04-ps-a.pdf
Individual Funding Request approval required.

10.2.1 - Drugs that enhance neuromuscular transmission

Amifampridine (phosphate) ▼ *(Firdapse® ▼)* TAG recommendation: Sep 2011

for use in: Treatment of myasthenias - Lambert-Eaton syndrome - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility - policy states that amifampridine phosphate (Firdapse) is not routinely commissioned - http://www.england.nhs.uk/wp-content/uploads/2013/10/d04-ps-a.pdf
Individual Funding Request approval required.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.2.1 - Drugs that enhance neuromuscular transmission

Fampridine *(Fampyra®)* TAG recommendation: Jul 2012

for use in: Improvement of walking in adults with Multiple Sclerosis with walking disability (EDSS 4-7) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: The TAG agreed that the evidence in support of the effectiveness of the treatment is not substantial, the potential costs are likely to be significant and to be greater than the NICE threshold for cost per QALY, and there were sufficient concerns regarding potential adverse effects associated with the treatment.

Prescriber's Rating: 7. "Not acceptable - product without evident benefit over others but with potential or real disadvantages"

19th July 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided not to commission use of fampridine.

17th January 2013: the D&TCG confirmed that despite the price of fampridine had reduced, it was still not commissioned in view of previous concerns regarding poor effectiveness and adverse effects.

April 2013: NHS England SCG took over commissioning responsibility. NHSCB/D04/PS/c states that Fampridine is not routinely funded for Improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 4-7) - http://www.england.nhs.uk/wp-content/uploads/2013/10/d04-ps-c.pdf

January 2015: The TAG noted and supported NICE CG 186 regarding the following drug treatment recommendations under Section 1.5 - MS symptom management and rehabilitation:
For spasticity:
First- line: Use baclofen or gabapentin. If not tolerated consider switching to the other drug. Consider combining baclofen and gabapentin if individual drugs do not provide adequate relief, or side effects from individual drugs prevent the dose being increased.
Second-line: Consider tizanidine or dantrolene.
Third-line: Consider benzodiazepines; be aware of their potential benefit in treating nocturnal spasms. DO NOT offer Sativex® for spasticity in MS.
For oscillopsia:
First-line: Gabapentin.
Second-line: Consider memantine. Refer for specialist advice if there is no improvement after treatment with gabapentin and memantine, or side effects prevent continued use.
Lack of mobility in MS:
DO NOT use fampridine as it is not cost-effective. Fatigue in MS:
Offer amantadine. DO NOT use vitamin B12 injections for fatigue.
Relapse and exacerbation: Offer oral methylprednisolone 0.5 g daily for 5 days. Do not use lower doses, nor provide a rescue course to treat next relapse.
The TAG noted that the full NICE Clinical Guideline 186 also states that "modafanil should not be used to treat fatigue in MS."
Other treatments:
Consider amitriptyline to treat emotional lability.
DO NOT offer vitamin D solely for MS.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.2.1 - Drugs that enhance neuromuscular transmission

DO NOT offer omega-3 or -6 fatty acids.
Although the TAG decided not to assign new “traffic light” recommendations to any of the above-listed treatments, it was agreed that previous Double Red (Not recommended for routine use) recommendations for Sativex® for spasticity and for fampridine for reduced mobility were in line with NICE CG 186 and should be maintained.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations regarding NICE CG 186 with particular reference to the treatments which are not recommended which will be drawn to the attention of local prescribers.

NICE NG220 - June 2022 - Do not offer fampridine to treat mobility problems in people with MS. Fampridine is a clinically effective treatment for some people, but it is not cost effective at the current list price. [2022]. This recommendation does not apply to people who have already started treatment with fampridine in the NHS, who should be able to continue treatment until they and their NHS clinician think it appropriate to stop.

10.2.2 - Skeletal muscle relaxants

Cannabis (all forms, including nabilone) *(excludes Sativex® spray)* TAG recommendation: May 2018

for use in: All indications - as per local policy (July 2011) (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is of uncertain commissioning responsibility and is not supported for use by local CCGs.

Revisited by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

November 2018: The TAG and the D&TC acknowledged the Department of Health & Social Care / NHSE: Guidance for clinicians -Gateway Publications clearance: 08539, which announced plans to reschedule certain cannabis-based products for medicinal use , which will come into force on 1st November 2018. Themian points are:
* Under the proposed new regime, all cannabis-based products for medicinal use (except Sativex®) would be unlicensed medicines.
* Due to the limited evidence base and unlicensed status, the DoH has restricted the decision to prescribe cannabis-based products for medicinal use to only clinicians listed on the General medical Council’s Specialist Register (GMCSR).
* Prescribing must be on a "named patient" basis. Rigorous and auditable safeguards re prescribing to be followed, with existing protocols on CDs
* Cannabis-based products for medicinal use only to be prescribed for indications where there is clear published evidence of benefit or UK Guidelines, and in patients where there is a clinical need which cannot be met by a licensed medicine, and where established treatment options have been exhausted.
* Specialist doctors on the GMCSR should only prescribe within their own area of practice and training (e.g. physicians for adults should not prescribe for children) and the decision to prescribe should be agreed by the multidisciplinary team.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.2.2 - Skeletal muscle relaxants

Cannabis-based medicinal preparations - unlicenced *(excludes Sativex® spray - see separate entry)* TAG recommendation: Jul 2020

for use in: All indications as per PAC guidance statement Jan 2020 (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2020 - The PAC guidance was acknowledged by the TAG. The TAG agreed to extend the Double Red (Not recommended for routine use / Not commissioned) classification for unlicenced cannabis-based medicinal preparations to all indications. This recommendation was supported by the D+TC

Sept 2022 - application accepted for sativex spray for adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy (see separate entry)

Pridinol *(Myopridin)* TAG recommendation: Jul 2021

for use in: central and peripheral muscle spasms, lumbar pain, torticollis and general muscle pain in adults (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: No NHS prescribing in primary or secondary care. To be reviewed again if / when evidence becomes available

10.3.1 - Enzymes

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.3.1 - Enzymes

Collagenase Clostridium Histolyticum *(Xiapex®)* TAG recommendation: Jan 2020

for use in: Peyronie's Disease (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2018: The TAG considered the NNUH's application for use in a small number of patients and agreed to support use in line with the application and proposed treatment pathway, with a recommended traffic light classification of Red (Hospital use only).

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the recommended traffic light classification of Red (Specialist only), in line with the NNUH's application for this treatment option which is outside of the NICE work plan.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. It was noted that due to the discontinuation of the product in the UK this was now likely to be a non cost-effective use of NHS resources. A traffic light classification of Double Red (Not for routine use/Not commissioned) was afforded.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.3.1 - Enzymes

Collagenase clostridium histolyticum *(Xiapex®)* TAG recommendation: Jan 2020

for use in: Dupuytren's contracture with a palpable cord in adults - as per NICE TA 459 (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 459 (July 2017) which recommends that people who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, are encouraged to participate in the study.
For people not taking part in the ongoing clinical trial, CCH is recommended as an option only if all of thecriteria specified in the NICE TA guidance apply.

The TAG acknowledged NICE TA 459 and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

November 2018: The TAG considered the NNUH's application for use post NICE TA 459 and agreed to support use in line with the application and proposed treatment pathway only, with a recommended traffic light classification of Red (Hospital use only).

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation. The treatment would be monitored as a High Cost Drug and would be provided via Outpatients.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and D&TC recommendation.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. It was noted that due to the discontinuation of the product in the UK this was now likely to be a non cost-effective use of NHS resources. A traffic light classification of Double Red (Not for routine use/Not commissioned) was afforded.

Sebelipase alfa *(Kanuma®)* TAG recommendation: May 2018

for use in: Lysosomal acid lipase deficiency (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

10.3.2 - Rubefacients -

Rubefacients *(Various -)* TAG recommendation: Jul 2017

for use in: Osteoarthritis - as per NICE CG 59 - Do Not Do (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2008.

Specific points: July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 59 - Osteoarthritis which states:

1.4.2.3 Rubefacients are not recommended for the treatment of osteoarthritis

11.4.1 - Corticosteroids

Dexamethasone intravitreal implant *(Ozurdex®)* TAG recommendation: Oct 2022

for use in: diabetic macular oedema as per TA824 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Fluocinolone acetonide intravitreal implant *(Iluvien®)* TAG recommendation: Jan 2020

for use in: Chronic diabetic macular oedema insufficiently responsive to available therapies in an eye with a natural lens (phakic eye) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: November 2019.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020 and afforded a traffic light classification of Double Red (Not recommended for routine use/Not commissioned).

11.8.2 - Ocular diagnostic and peri-operative preparations

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

11.8.2 - Ocular diagnostic and peri-operative preparations

Bevacizumab *(Avastin®)* TAG recommendation: Jan 2011

for use in: Early (pre-NICE criteria) treatment of wet AMD and related conditions (Not a licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: January 2011: A commissioning proposal from NHS Great Yarmouth & Waveney and the JPUH was not supported by the TAG due to the lack evidence to support use in early wet AMD and related conditions and the lack outcome and safety data.
Noted by NHS Norfolk Drug & Therapeutics Commissioning Group on 21st January 2011.

Brolucizumab *(Beovu®)* TAG recommendation: Sep 2022

for use in: diabetic macular oedema as per TA820 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Pegaptanib sodium *(Macugen®)* TAG recommendation: Sep 2008

for use in: Neovascular (wet) age-related macular degeneration (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: August 2008.

Specific points: NICE Technology Appraisal Guidance No. 155 August 2008 states that pegaptanib is not recommended for the treatment of wet age-realted macular degeneration.

Ranibizumab *(Lucentis)* TAG recommendation: Jul 2020

for use in: treating diabetic retinopathy as per TA637 (June 2020 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC

12.1.1 - Ear, nose and oropharynx

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

12.1.1 - Ear, nose and oropharynx

Phenazone 40mg and lidocaine hydrochloride 10mg *(Otigo)* TAG recommendation: May 2022

for use in: otitis media (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: No NHS prescribing in primary or secondary care. Evidence is poor. Application required

12.1.3 - Removal of ear wax

Ear wax softening products *(Various)* TAG recommendation: Sep 2017

for use in: Softening of excessive ear wax to aid removal - selfcare & purchasing encouraged (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of ear wax softening medical devices - simple remedies such as olive oil, almond oil and sodium bicarbonate; proprietary products containing ingredients such as docusate sodium and urea-hydrogen peroxide, and agreed that self-care should be encouraged and also used by patients prior to mechanical removal of ear wax.
Not recommended for prescribing on the NHS.

September 2017:
The N&W D&TCG noted and supported the PRG and the TAG's recommendations - Not commissioned.

12.2.1 - Drugs used in nasal allergy

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

12.2.1 - Drugs used in nasal allergy

Dymista (fluticasone propionate /azelastine HCl) *(Dymista® metered dose nasal spray)* TAG recommendation: Nov 2015

for use in: Moderate to severe seasonal and perennial rhinitis, if monotherapy with antihistamine or corticosteroid is inadequate - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

This is a premium price combination product with no evidence of any benefit over established products.

12.2.3 - Topical decolonisation of MRSA carriers

Prontoderm bacterial decolonisation foam/nasal gel *(Prontoderm® foam and Prontoderm® nasal gel)* TAG recommendation: Sep 2017

for use in: Topical decolonisation of MRSA carriers (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Prontoderm® foam and Prontoderm® nasal gel which stated:
Not recommended for routine use; current randomised controlled trial evidence is limited and suggests that a single Prontoderm® decolonisation course is not effective in eradicating methicillin-resistant staphylococcus aureus (MRSA) carriage.
Selection and prescribing of products for bacterial decolonisation should be in accordance with local guidelines.

The PRG and the TAG agreed with the PAC's recommendation and recommended a classification of Double Red (Not recommended for routine use).

September 2017:
The N&W D&TCG notd and supported the TAG's recommendation - not commissioned.

12.3.4 - Mouthwashes, gargles, and dentifrices

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

12.3.4 - Mouthwashes, gargles, and dentifrices

Chlorhexidine Mouthwash *(Various)* TAG recommendation: Jul 2017

for use in: prophylaxis against
infective endocarditis to people at risk of infective endocarditis undergoing

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2016.

Specific points: September 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations including NICE CG 64 - Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures which states:

1.1.4 Chlorhexidine mouthwash should not be offered as prophylaxis against
infective endocarditis to people at risk of infective endocarditis undergoing
dental procedures. [2015]

13.4 - Topical Corticosteroids

Betamethasone plasters *(BETESIL®)* TAG recommendation: Apr 2020

for use in: Treatment of inflammatory skin disorders that do not respond to less potent corticosteroids (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: April 2020 - The PRG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). They are not prescribed locally and so use is no longer supported

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

13.5.1 - Preparations for eczema

Crisaborole *()* TAG recommendation: Jun 2021

for use in: mild to moderate atopic dermatitis in people 2 years and older (TA701 - terminated appraisal) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2021.

Specific points: NICE is unable to make a recommendation about the use in the NHS of crisaborole for treating mild to moderate atopic dermatitis in people 2 years and older. This is because Pfizer withdrew its evidence submission.

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.5.3 - Drugs affecting the immune response

Abrocitinib *(Cibinqo®)* TAG recommendation: Aug 2022

for use in: moderate to severe atopic dermatitis as per TA814 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Deucravacitinib *(SOTYKTU®)* TAG recommendation: Jul 2023

for use in: moderate to severe plaque psoriasis TA907 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: June 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

Dupilumab *()* TAG recommendation: Oct 2020

for use in: treating chronic rhinosinusitis with nasal polyps as per TA648 (terminated) (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned. This was supported by the D+TC

Risankizumab *(Skyrizi®)* TAG recommendation: Jun 2023

for use in: previously treated moderately to severely active Crohn's disease TA888 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: May 2023.

Specific points: NWICB are committed to fund positive NICE TA treatments. Awaiting clarification of place in pathway and commissioning arrangements. Further guidance will be issued when available. For all other treatments, formulary application and discussion will be required

13.6 - Acne and Rosacea

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.6 - Acne and Rosacea

Nicotinamide *()* TAG recommendation: Mar 2020

for use in: Mild to moderate acne (Various indications).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG noted and supported the PRG recommendation of a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) due to the high cost of this medication. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCGs

13.6.2 - Oral antibacterials for acne

Minocycline *(Acnamino®, Minocin®, Sebomin®)* TAG recommendation: Nov 2015

for use in: Acne vulgaris (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: January 2015.

Specific points: November 2015:
Minocycline is no longer recommended for use due to reported safety issues and its high costs not being justifiable since it is no more effective or better tolerated than other tetracyclines.

Other once daily options are available.
See local Antibiotics Formulary via Knowledge Anglia - http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formularies.htm

As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Safety issues:
Minocycline has been associated with the following patterns of serious reactions (Cochrane review, CD002086, 2012):

* early-onset dose-related toxicity reactions resulting in single organ dysfunction (including potentially fatal liver failure)
* autoimmune disorders (such as systemic lupus erythematosus-like syndrome, which has a strong relationship with duration of exposure, and autoimmune hepatitis)
* hypersensitivity reactions (including eosinophilia, pneumonitis and nephritis).

In addition, minocycline can cause slate-grey hyperpigmentation of the skin, which may be irreversible (Drug and Therapeutics Bulletin, 2006).

13.6.3 - Topical preparations for rosacea

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.6.3 - Topical preparations for rosacea

Brimonidine tartrate gel *(Mirvaso®)* TAG recommendation: Mar 2015

for use in: Treatment of facial erythema (rosacea) (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2015: The TAG noted that the PAC Guidance Statement and also noted that it did not explain why the committee considered brimonidine gel to be a cosmetic product when there are other cosmetic treatments that appear in the Drug Tariff which are low priority, but can be prescribed. TAG members felt that the robustness of the PAC statement should perhaps be challenged.

However since local clinicians have noted the PAC recommendation without further comment to date, the TAG recommended a classification of Double Red (Not recommended for routine use) pending the submission of a business case, should any interest arise in using the treatment.

March 2015: The Norfolk & Waveney CCGs' D&TCG was advised of information received from the PAC which clarified the rationale behind the Guidance Statement as follows:
"The PAC concluded that the available evidence did not indicate that Brimonidine gel for facial erythema would constitute a cost-effective treatment, and therefore recommended that it should not be routinely commissioned. It was also agreed that this decision is in line with the current local position on laser treatment for facial erythema, which is considered to be a cosmetic treatment and therefore a low priority for funding."

The D&TCG noted the above clarification and supported the PAC's recommendation not to commission use of Brimonidine tartrate gel (Mirvaso®) for treatment of facial erythema due to it not being a cost-effective treatment option.

The D&TCG therefore also supported the TAG's recommendation of Double Red (Not recommended for routine use).

13.8.1 - Sunscreen preparations

Dundee sunscreen *()* TAG recommendation: Nov 2022

for use in: photosensitivity disorders where the patient is sensitive to visible light, most commonly solar urticaria and porphyrias, particularly erythropoietic protoporphyria (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.8.1 - Sunscreen preparations

Ingenol mebutate topical gel *(Picato®)* TAG recommendation: Jan 2020

for use in: Non-hypertrophic actinic keratosis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG noted and supported (subject to agreed amendments) a pharmacological treatment pathway for actinic keratosis which specified the place of ingenol mebutate gel as being suitable for GPs to prescribe following specialist recommendation.

January 2017: The published version of the treatment pathway was noted and supported by the TAG and the Norfolk & Waveney CCGs' D&TCG.

Available via: http://nww.knowledgeanglia.nhs.uk/tag/actinic_keratosis_pathway.pdf

January 2020 - Traffic light classification amended to Double Red following MHRA Class 2 recall - concerns around possible risk of skin malignancy

Tirbanibulin *(Klisyri®)* TAG recommendation: May 2022

for use in: actinic keratoses (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2022 - Black - Not commissioned. No NHS prescribing in primary or secondary care. Pathway required

13.10.2 - Antifungal preparations

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.10.2 - Antifungal preparations

Amorolfine *(Loceryl and other equivalent preparations)* TAG recommendation: Nov 2015

for use in: Fungal nail infections - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Systemic treatments are more effective, if antifungal treatment is indicated. Nail lacquers are expensive. Available OTC for mild cases and treatment of a maximum of two nails.

Nail lacquer- Amorolfine & Ticonazole *(Loceryl® & Trosyl®)* TAG recommendation: Nov 2015

for use in: Fungal nail infections (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TC these treatments are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Tioconazole *(Trosyl nail solution)* TAG recommendation: Nov 2015

for use in: Fungal nail infections (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Systemic treatments are more effective, if antifungal treatment is indicated. Nail lacquers are expensive. Available OTC for mild cases and treatment of a maximum of two nails.

13.10.4 - Parasiticidal preparations

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

13.10.4 - Parasiticidal preparations

Head lice devices and products - including combs *(Various)* TAG recommendation: Nov 2015

for use in: Head lice (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Wet combing method recommended.
Includes all lotions, sprays, foams, combs.
Available to purchase from pharmacies.

September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Head lice devices and products - not recommended. Current Double Red classification maintained.

September 2017:
Noted and supported by the N&W D&TCG.

13.13 - Topical circulatory preparations

Heparinoid 0.3% Cream / Gel *(Hirudoid® Cream / Gel)* TAG recommendation: Nov 2015

for use in: Improving circulation in bruising, superficial thrombophlebitis, chilblains, varicose veins (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Of limited clinical value and effectiveness. Not recommended for NHS provision.

14.4 - Vaccines and antisera

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

14.4 - Vaccines and antisera

HIV vaccine *(HIV vaccine)* TAG recommendation: May 2018

for use in: HIV infection prophylaxis (x).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Influenza vaccination *(Various)* TAG recommendation: Nov 2003

for use in: Vaccination of non-target patients on the NHS (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2003.

Specific points: Following non-target patients requesting flu vaccination on the NHS from GPs, the TAG agreed that if vaccination is not medically necessary nor recommended by NHS policy, it should not be provided.
Patients can approach another GP, with whom they are not registered, to request private provision.

Influenza vaccine - intradermal *(Intanza®)* TAG recommendation: Jul 2010

for use in: Influenza vaccination (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: GP practices are advised to refrain from ordering Intanza® due to there being no evidence that this product delivers more positive outcomes and due to the significant increased cost over standard vaccines.

15.2 - Local anaesthesia

Double Red - 'Not recommended for routine use / Not commissioned'

These drugs have not been recommended for routine use at present.

The recommendation is specific to the indication.

The grounds for these decisions are typically a combination of one or more of:
- Effectiveness is uncertain or not proven: negative results, mixed results, controversy over results, not compared against current practice, atypical setting when used in a trial, small numbers in a trial, trial design is weak or otherwise flawed, short term follow-up for long term treatment, other aspects indicating insufficient evidence of effectiveness.
- Evidence not sufficiently robust to allow recommendation for use in routine practice.
- Better alternative.
- A small or uncertain treatment effect with large cost implications - poor cost-effectiveness.
- Taking into account advice from TAG and other sources, funding decisions by PCG/Ts and the Health Authority have, on grounds of priority, favoured other drugs or service developments.

These are general policy decisions, and it may not be appropriate to apply them in every individual case. All health service staff should be prepared to consider whether an individual has grounds for being treated as an "exceptional case" - for example, an exceptional ability to benefit.

These recommendations will be reviewed when there is sufficient evidence to consider a change of policy or guidance is received from NICE.

15.2 - Local anaesthesia

Lidocaine / Prilocaine Spray *(Fortacin®)* TAG recommendation: Jul 2019

for use in: Primary premature ejaculation in adult men (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: July 2019: The TAG noted the PRG recommendation and recommended a traffic light classification of Double Red (Not recommended for routine use/not commissioned)

July 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Agalsidase alfa and beta *(Replagal® (alpha) / Fabrazyme® (beta))* TAG recommendation: May 2018

for use in: Fabry disease (α-galactosidase A deficiency) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Highly specialised criteria.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Albutrenpenonacog alfa *(Idelvion)* TAG recommendation: May 2018

for use in: Haemophilia B - as per NHS England policy SSC1652 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Refn: SSC1652. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Alglucosidase alfa *(Myozyme®)* TAG recommendation: May 2018

for use in: Pompe disease (a lysosomal storage disorder caused by deficiency of acid alpha-glucosidase) - as per NHS England (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.
Specialist centre use only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Antihaemophilic Factor *((von Willebrand Factor Complex))* TAG recommendation: May 2018

for use in: As per BCSH Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Antithrombin III *()* TAG recommendation: May 2018

for use in: As per BCSH Guidelines (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BCSH guidelines apply.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Antithymocyte immunoglobulin *(Thymoglobuline®)* TAG recommendation: May 2018

for use in: Aplastic anaemia, organ transplant - as per BCSH guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BCSH Guidelines - Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Apraclonidine eye drops *(Iopidine®)* TAG recommendation: Jan 2020

for use in: Short-term adjunctive therapy of chronic glaucoma in patients on maximally tolerated medical therapy who require additional intraocular pressure (IOP) reduction to delay laser treatment or glaucoma surgery. (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020 of a traffic light classification of Red (Hospital/Specialist only).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Asfotase alfa ▼ *(Strensiq® ▼)* TAG recommendation: Sep 2017

for use in: Paediatric-onset hypophosphatasia (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE Highly Specialised Technology Guidance HST 6 (August 2017) for treating paediatric-onset hypophosphatasia only:
* for people who meet the criteria for treatment within the managed access arrangement (see section 4.18), and
* for the duration of this arrangement and in line with the other conditions it specifies
and recommended a traffic light classification of Red (Specialist Centre only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ataluren ▼ *(Translarna® ▼)* TAG recommendation: Nov 2016

for use in: Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene in people aged ≥5 years who can walk - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2016.

Specific points: September 2015:
The TAG noted E09/P/a (E09X01) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

Not routinely commissioned pending a final decision from NICE.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

November 2016:
The TAG noted NICE Highly Specialised Technologies Guidance - HST3 (July16) recommended by NICE for treatment of, only when the company provides ataluren with the discount agreed in the patient access scheme.
The conditions under which ataluren is made available are set out in the managed access agreement between the company and NHS England, including those in sections 5.12-5.15 and 5.23 of the guidance.
And recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' noted the TAG recommendation.

Atidarsagene autotemcel *(Libmeldy)* TAG recommendation: Mar 2023

for use in: metachromatic leukodystrophy HST18 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Autologous chondrocyte implantation *(x)* TAG recommendation: Nov 2017

for use in: For treating symptomatic articular cartilage defects of the knee (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 477 (Oct 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
Providers are NHS tertiary referral centres.
Recommended as an option by NICE.

Noted by the D&TCG

Autologous chondrocyte implantation *(Spherox®)* TAG recommendation: May 2018

for use in: For treating symptomatic articular cartilage defects of the knee - as per NICE TA 508 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 508 (March 2018) (Autologous chondrocyte implantation using chondrosphere) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Axicabtagene ciloleucel *(Yescarta®)* TAG recommendation: Mar 2019

for use in: Relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma in adults after 2 or more systemic therapies - as per NICE TA 559 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE TA 559 (January 2019) which recommended use as an option, for use within the Cancer Drugs Fund, only if the conditions in the managed access agreement are followed.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Beractant *(Survanta®)*

for use in: Respiratory distress syndrome neonates (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Trust guidelines for use.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Betaine *(Cystadane® oral powder (orphan drug))*

for use in: Homocystinuria (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Service Specification - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Botulinum neurotoxin type A *(Xeomin®)* TAG recommendation: Nov 2019

for use in: Chronic sialorrhoea (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA605 - October 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this CCG commissioning responsibility treatment.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020 to accept the business case presented. The traffic light classification of Red (Hospital/Specialist only) to remain.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Burosumab *(Crysvita®)* TAG recommendation: Nov 2018

for use in: X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children aged 1 year and over, and in young people with growing bones - as per NICE HST 8 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2018.

Specific points: November 2018: The TAG noted NICE HST 8 (Oct 18) and recommended a classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Corneal epithelial cells (human) with stem cells *(Holoclar)* TAG recommendation: Sep 2017

for use in: (Holoclar for) Limbal stem cell deficiency after eye burns - as per NICE TA 467 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 467 (August 2017) Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Defibrotide *(Defitelio®)* TAG recommendation: Jul 2015

for use in: Treatment of hepatic veno-occlusive disease in adults and children undergoing haematopoietic stem cell transplant - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2015: The TAG and the D&TCG noted NHS England Clinical Commissioning Policy B04/P/c (January 2015): Defibrotide (Defitelio®) for severe veno-occlusive disease (VOD) of the liver / sinusoidal obstruction syndrome following stem cell transplant

NHS England SCG-commissioning responsibility

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Dibotermin alfa *(InductOs®)* TAG recommendation: May 2018

for use in: Complex spinal surgery - as per NHS England Policy 16063/P (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - BSR registry.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Dibotermin alfa (RH bone morphogenetic protein-2) *(InductOs 12)* TAG recommendation: Mar 2015

for use in: Acute tibial fractures with Grade IIIB fractures (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2015: The TAG noted the revised PAC Guidance Statement (Update January 2015) for Bone morphogenetic proteins - Dibotermin alfa, and considered the more restrictive recommendations.

Confirmation was received from the PAC regarding the changes to the guidance as follows:
"PAC Bone morphogenetic protein (BMP) recommendations were reviewed after the withdrawal of Osigraft, Eptotermin (rhBMP-7) from the market in August 2014. Osigraft was licensed for the treatment of non-union of tibia of at least 9 month duration and its use was included in the original PAC recommendations.
InductOs, Dibotermin (rhBMP-2), which is currently the only BMP on the UK market, is indicated for the treatment of acute tibia fractures in adults only, (and for spinal surgery which is not covered by the PAC guidance document).
The revised PAC guidance statement therefore only covers the use of dibotermin for the treatment of acute tibia fractures."

March 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the clarification from PAC and agreed to support the revised guidance statement as a revised commissioning position.

The previous TAG recommendation of Red (Hospital use only) for use of dibotermin alfa but only for acute tibial fractures with Grade IIIB fractures was maintained.

May 2015: The TAG had requested clarification on why the new PAC guidance is restricted to fewer clinical indications than the previous policy.
PAC response: “The revised policy reflects the licensed indication of InductOs (dibotermin alfa) for treatment of acute tibia fractures in adults. (The guidance does not cover use in spinal surgery)”.
The PAC’s response was noted by the TAG.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG’s recommendation.
Only commissioned for licensed indication as per the PAC’s Guidance Statement.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Dupilumab ▼ *(Dupixent® ▼)* TAG recommendation: Nov 2018

for use in: For adults with severe atopic dermatitis who have failed to respond, or who are intolerant of or ineligible for all approved therapies - as per NICE TA 534 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2017:
The TAG noted the NHS England Early Access to Medicines Scheme (EAMS) decision regarding dupilumab and agreed to recommend support for the PAC's proposed position statement regarding this treatment as follows:
"CCGs will not automatically continue to fund treatment for patients initiated under the EAMS scheme upon the product becoming licensed unless a positive NICE TA is in place. It is the responsibility of initiating Trusts to ensure funding is available for the continuation of treatment once a product licence is granted until a positive NICE TA is published"

The TAG also recommended an interim traffic light classification of Double Red (Not recommended for routine use) until a local business application for its use is supported following a positive NICE TA related to this treatment.

May 2017:
The D&TCG noted and supported the TAG's recommendations and decided that Dupilumab for adults with severe atopic dermatitis who have failed to respond, or who are intolerant of or ineligible for all approved therapies is Double Red (Not recommended for routine use) / Not commissioned until a local business application for its use is supported following a positive NICE TA related to this treatment.

July 2018:
The TAG acknowledged NICE Final Appraisal Determination (FAD) which recommended use of dupilumab for treating moderate to severe atopic dermatitis after topical treatments in combination with topical corticosteroids, for treating moderate to severe atopic dermatitis in adults only if:
* the disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated
* the company provides dupilumab according to the commercial arrangement
* Stop dupilumab at 16 weeks if the atopic dermatitis has not responded adequately. An adequate response is:
  * at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started and
  * at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started.

The final TA was due to be published on 1st August 2018. Since dupilumab has already been in use via the NHS EAMS (Early Access to Medicines Scheme), there is an expectation that the TA should be implemented within 30 days of its publication. The TAG was advised that a local Trust business case would be expected at Sept 2018 TAG, which would be a few days after the 30 day deadline set for commissioning this treatment (assuming that the NICE TA remains positive and is published to time as planned).

July 2018: The NHS Norfolk & Waveney CCGs' D&TC confirmed that the interim position for this treatment is Double Red (Not recommended for routine use) / Not commissioned pending the submission of a business application from local provider Trusts and agreement on its place in the treatment pathway for atopic dermatitis.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

September 2018: The TAG noted NICE TA 534 (August 2018) and recommended a traffic light classification of Red (Specialist only) for this CCG-commissioning responsibility treatment, as per the application submitted concurrently by the NNUH. The TAG recommended that the Eczema Area and Severity Index (EASI) score should be used for the starting criteria and that treatment could be commenced at EASI ≥16. The TAG noted that the East of England Priorities Advisory Committee (PAC) is currently liaising with dermatology specialists and NICE regarding implementation of NICE TA 534 and also the criteria for initiating and reviewing treatment with dupilumab.

September 2018: The D&TC noted information provided from the PAC around entry and continuation criteria for use of dupilumab and agreed

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

that a considered approach in line with other EoE CCGs, using measurable and consistent assessment tools, was appropriate.
The D&TC therefore decided to wait on the PAC's decisions and to maintain a Not (yet) commissioned position in the interim.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

November 2018: The TAG recommended that the Eczema Area and Severity Index (EASI) score should be used for the starting criteria and that treatment could be commenced at EASI ≥16.
The TAG otherwise supported the NNUH business case and recommended a traffic light classification of Red (Hospital / Specialist use only).

November 2018: The NHS Norfolk & Waveney CCGs' D&TC recommended to the JSCC that dupilumab should be commissioned for use by the NNUH in line with NICE guidance and as per the criteria agreed by the East of England Priorities Advisory Committee (PAC), with applications for use to be managed via BlueTeq. Review after 6 months to check that use is in line with the NNUH's business application.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and the D&TC recommendations.

Efraloctocog alfa *()* TAG recommendation: May 2018

for use in: Haemophilia A - as per NHS England policy SSC1652 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eftrenonacog alfa *()* TAG recommendation: May 2018

for use in: Haemophilia B - as per NHS England SSC1652 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As ;per SSC1652 - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Eliglustat ▼ *(Cerdelga® ▼)* TAG recommendation: Jul 2017

for use in: Treatment of Type 1 Gaucher disease (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE FAD (June/July 2017) and recommended a traffic light classification of Red (Specialist Centre only) for this SCG-commissioning responsibility treatment.

NICE also published Highly specialised technologies guidance [HST5] on 28 June 2017

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Etelcalcetide ▼ *(Parsabiv® ▼)* TAG recommendation: Jul 2017

for use in: Secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis - as per NICE TA 448 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 448 (June 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

FreeStyle Libre BGS device (sensors are "Green") *(FreeStyle Libre)* TAG recommendation: Apr 2019

for use in: Blood Glucose Monitoring in diabetes - as per NHSE criteria March 2019 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2016: The TAG and the N&W D&TCG noted and supported Prescribing Reference Group's Devices Advisory Group (DAG) recommendation that due to there being no therapeutic added value in this costly device, its use is classified as Double Red (Not recommended for routine use /Not commissioned).

May 2017: The TAG noted the draft PAC recommendations and reaffirmed its previous recommended traffic light classification of Double Red (Not recommended for routine use) (May 2016).

May 2017: The NHS Norfolk & Waveney's D&TCG noted and supported the TAG's recommendation to support the PAC's recommendations and reaffirmed that use of the Freestyle Libre® Glucose Recording System is Double Red (Not recommended for routine use) / Not commissioned.

November 2017:
The TAG acknowledged the final published version of the EoE PAC's interim recommendations regarding the FreeStyle Libre® Glucose Monitoring System which state:
1. The routine use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not recommended.
2. FreeStyle Libre® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by NICE, is not recommended for routine funding in primary care.
3. This recommendation will be reviewed in the light of new evidence to support the cost effective use of FreeStyle Libre®.

The TAG also acknowledged the Regional Medicines Optimisation Committees (RMOC) (North) Position Statement on FreeStyle Libre, which recommended use under specified criteria.
The TAG considered that the evidence resources used as reference for these recommendations were not as broad or robust as the detailed evidence review undertaken by the EoE PAC. The TAG therefore felt that the RMOC recommendations were not based on any further evidence that would persuade the TAG to change its previous view.

The TAG therefore recommended that the local position for use of FreeStyle Libre should remain in line with the interim EoE PAC recommendations as listed above until further agreement on its use is reached.

Noted and supported by the D&TCG.

May 2018:
The TAG considered recommendations from the East of England Priorities Adviosry Committee (PAC) regarding criteria for use of flash glucose monitoring systems (FGS) in adults and children and young people with Tye 1 diabetes mellitus.

The TAG broadly supported the PAC's guidance and recommended them for consideration by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee (DTC).

May 2018:
The DTC The D&TC acknowledged that the numbers of patients estimated by the specialist clinicians under each agreed criteria for use are small.
The D&TC debated the classification for prescribing responsibility of the sensors - Specialist (Red - possible Homecare provision) as recommended by the PAC, versus GP (Green - specialist recommendation) as recommended by the TAG. The D&TC was uncertain regarding the hospital / specialist's ability to prescribe on-going supplies and any related activity costs to the CCGs, and agreed to investigate further to ensure that the most cost-effective process was recommended.

Red - 'Hospital / Specialist only'

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- Enzymes

The issue would be queried with specialist contacts at the PAC and also raised at the next (May 2018) NIDDM and NCH&C D&T meeting and returned to the June 2018 D&TC meeting to ensure that an informed recommendation is made to the JSCC.

June 2018: The June 2018 DTC meeting was cancelled. The item to be discussed further as a matter arising at the July 2018 DTC meeting before referral to the Norfolk and Waveney CCGs' JSCC.

November 2018: The TAG acknowledged the East of England Priority Advisory Committee (PAC)'s published commissioning recommmendations regarding use of FGS in adults, and in children and young adulst aged 4 to 18 years of age, on which previous TAG recommendations were based (May 2018).
The TAG was advised that finance leads at the CCGs' Joint Commissioning and Contracting Executive (JCCE) committee had not supported the prospective costs of using the FGS product, Freestyle Libre, for use within the current financial year. This recommendation would be taken forward to the JSCC for a decision and final sign off.

November 2018: The Norfolk and Waveney CCGs' D&TC recommended that if the CCGs decide not to fund use within this financial year then this decision should be communicated to local stakeholders.
The D&TC also acknowledged NHS England's communication regarding a commitment to make Flash Glucose Monitoring more widely available to people with type 1 diabetes from April 1st 2019.

April 2019: The Norfolk and Waveney CCGs' JSCC commissioned use of Freestyle Libre as follows:

Flash Glucose Sensors (FGS) FreeStyle Libre will only be funded in line with NHSE criteria (March 2019) for patients with type 1 diabetes only, using the following process agreed by the Norfolk and Waveney CCGs:

* Specialist only initiation at the next routine appointment
* Practices should NOT refer specifically for FGS initiation
* The specialist will assess against NHSE criteria and will send the practice a copy of the Patient Contract and FGS Initiation letter giving authority to prescribe
* The specialist will provide the Scanning Device and ONE sensor (14 days)

Practices will be asked to prescribe:
* FreeStyle Libre Sensor x 2 (1 month's supply)
* Maximum Issues: 6 (SIX)
* Do NOT prescribe more than 13 sensors in 6 months

Template should be non- repeatable (untick this option)

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Fumaric acid ester *(Fumaderm (unlicensed product))* TAG recommendation: Jul 2006

for use in: Severe psoriasis - specialist use only (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: Not licensed in the UK. Agreed for use by dermatologists at the NNUH.
4th line option in severe psoriasis, after trying ciclosporin but before use of etanercept.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Givosiran *(Givlaari)* TAG recommendation: Mar 2023

for use in: Hepatic porphyria HST16 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Glucarpidase *(Voraxase)* TAG recommendation: Mar 2015

for use in: Urgent treatment of methotrexate-induced renal dysfunction in patients receiving high-dose MTX chemotherapy - as per NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2015: The TAG noted and acknowledged NHS England SSC 1571 (February 2015): Clinical Commissioning Policy regarding glucarpidase (a licensed treatment in the US by the FDA) for the urgent treatment of methotrexate-induced renal dysfunction in patients receiving high-dose methotrexate chemotherapy.

NHS England SCG-commissioning responsibility.

March 2015: NHSE SSC 1571 noted by the Norfolk and Waveney CCGs' Drugs & Therapeuitcs Commissiong Group.

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The advice is specific to the indication.

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- Enzymes

Haem Arginate *(Normosang®)* TAG recommendation: May 2018

for use in: Hepatic porphyria (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Idursulfase *(Elaprase®)* TAG recommendation: May 2018

for use in: Mucopolysaccharidosis - highly specialised criteria (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per NHS England Service Specification

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Intrathecal drug delivery *(Procedure)* TAG recommendation: Sep 2015

for use in: Treatment of severe cancer pain (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted D08/P/b (D08X02) (July 2015) (NHS England policy) and recommended a classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment delivery option.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Jaw rehabilitation devices *(Therabite®)* TAG recommendation: Jan 2019

for use in: Following head and neck radiotherapy or head and neck surgery when recommended by an appropriate Secondary Care Specialist (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2019: The TAG considered the PRG's recommendation that these devices not be commissioned pending a formal application for their use, but agreed that in view of these devices already being used and issued by the hospital for a specific patient group, a more pragmatic recommendation is Red (Hospital use only).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Lanadelumab *(Takhzyro®)* TAG recommendation: Nov 2019

for use in: Prevention of recurrent attacks of hereditary angioedema (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA606 - October 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Laronidase *(Aldurazyme®)* TAG recommendation: May 2018

for use in: Treatment of non-neurological manifestations of mucopolysaccharidosis I - as per NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Service Specification - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Letermovir *(Prevymis®)* TAG recommendation: Sep 2019

for use in: Prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients of an allogeneic haematopoietic stem cell transplant (HSCT) - NHSE responsibility (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2019.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA591 - July 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Lutetium(177Lu) oxodotreotide *(Lutathera®)* TAG recommendation: Sep 2018

for use in: Unresectable or metastatic, progressive, well-differentiated (grade 1 or grade 2), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours in adults - as per NICE TA 539 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018: The TAG noted NICE TA 539 (August 2018) and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

The TAG also noted NICE NG 99 (July 2018) Management of brain tumours (primary) and brain metastases in adults

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Lymphoedema garments *(Various)* TAG recommendation: Sep 2017

for use in: Compression in management of lymphoedema assessed by the specialist service (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of lymphoedema garments.
Agreed for use by the specialist service only.
There is no identified funding to support prescribing by GPs.

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG.

Red - 'Hospital / Specialist only'

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Mexiletine (imported generic) unlicensed in the UK *(Unlicensed generic product in the UK)* TAG recommendation: May 2019

for use in: Ventricular tachycardia only (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2019: The TAG acknowledged the PRG's recommendation and after consideration of the wider issues agreed to apply the traffic light classifications of
Red (Hospital/Specialist use only) for ventricular tachycardia.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Mexiletine (Namuscla®) *(Namuscla® (licensed High Cost Drug))* TAG recommendation: May 2019

for use in: Treatment of myotonia in adults with non-dystrophic myotonic disorders (NDMD) - as per NHSE policy - specialist use only (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2019: The TAG acknowledged the PRG's recommendation and after consideration of the wider issues agreed to apply the traffic light classifications of
Red (Hospital/Specialist use only) for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders - as per NHSE commissioning policy.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGS' JSCC supported the TAG & D&TC recommendation.

Miglustat ▼ *(Zavesca® ▼)* TAG recommendation: May 2018

for use in: Mild to moderate type I Gaucher's disease for whom enzyme replacement therapy is unsuitable / Niemann-Pick (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Nitisinone *(Nitisinone Dipharma®, Orfadin®)* TAG recommendation: May 2018

for use in: Alkaptonuria (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nitisinone *(Nitisinone Dipharma®, Orfadin®)* TAG recommendation: May 2018

for use in: Hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nitric oxide *()* TAG recommendation: May 2018

for use in: Pulmonary Arterial Hypertension (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Trust Guidelines apply.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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Drugs for which the Trust is responsible for prescribing.

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Nonacog alpha *()* TAG recommendation: May 2018

for use in: Haemophilia - as per BCSH Guidelines (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nusinersen *(Spinraza®)* TAG recommendation: Sep 2019

for use in: (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA588 - July 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Onasemnogene abeparvovec *(Zolgensma)* TAG recommendation: Mar 2023

for use in: spinal muscular atrophy HST15 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Osimertinib ▼ *(Tagresso® ▼)* TAG recommendation: Nov 2016

for use in: Locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only after first-line treatment with an EGFR tyrosine kinase inhibitor (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2016.

Specific points: November 2016:
The TAG noted NICE TA 416 (October 2016) recommended by NICE as an option within the Cancer Drugs Fund and only if the conditions in the managed access agreement for osimertinib are followed, and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

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- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Panobinostat ▼ *(Farydak® ▼)* TAG recommendation: Mar 2016

for use in: Treatment of multiple myeloma (in combination with bortezomib and dexamethasone) after at least 2 previous treatments, including bortezomib and an immunomodulatory agent. (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG noted NICE TA 380 (January 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

Pegvisomant *(Somavert®)*

for use in: Acromegaly (where other treatments failed / not tolerated) - as per NHS England Policy 16050/P (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16050/P. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pentosan polysulfate sodium 100mg capsules *(Elmiron®)* TAG recommendation: Jan 2020

for use in: Bladder pain syndrome / Interstitial Cystitis characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2018: PRG recommendation that the TAG considers applying a Double Red (Not recommended for routine use) classification for this product as an interim measure, until a formal application for use is submitted via usual processes was supported by the TAG.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020 and afforded a traffic light classification of Red (Hospital/Specialist only).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Poractant alfa *(Curosurf®)* TAG recommendation: May 2018

for use in: Respiratory distress syndrome (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only - Trust Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Radium-223 dichloride ▼ *(Xofigo® ▼)* TAG recommendation: Nov 2016

for use in: Hormone-relapsed prostate cancer with bone metastases. (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: March 2016: The TAG noted NICE TA 376 (January 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

November 2016:
The TAG noted NICE TA 412 (September 2016) (updating and replacing NICE TA 376) recommended as an option by NICE only if the company provides radium 223 dichloride with the discount agreed in the patient access scheme, and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Reslizumab ▼ *(Cinqaero® ▼)* TAG recommendation: Nov 2017

for use in: Treatment of severe eosinophilic asthma inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids plus another drug - as per NICE TA 479 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 479 (Oct 17) which states:
Reslizumab is recommended for treating severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids plus another drug, only if:
* the blood eosinophil count has been recorded as 400 cells per microlitre or more
* the person has had 3 or more severe asthma exacerbations needing systemic corticosteroids in the past 12 months

The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Sarilumab ▼ *(Kevzara® ▼)* TAG recommendation: Mar 2018

for use in: Treatment of moderate to severe active rheumatoid arthritis in adults (with and without methotrexate) - as per NICE 485 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 485 (Nov 17) which recommends:
1.1 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if:
* disease is severe (a disease activity score [DAS28] of more than 5.1) and
* the company provides sarilumab with the discount agreed in the patient access scheme.
1.2 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if:
* disease is severe (a DAS28 of more than 5.1) and
* they cannot have rituximab and
* the company provides sarilumab with the discount agreed in the patient access scheme.
1.3 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if:
* disease is severe (a DAS28 of more than 5.1) and
* the company provides sarilumab with the discount agreed in the patient access scheme.
1.4 Sarilumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.
1.5 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.

Noted and supported by the D&TCG.

March 2018: Sarilumab is considered to be cost competitive as a third line option in line with tocilizumab and abatacept.
The TAG considered and agreed to support the QEH's application along with the proposed treatment pathway and recommended a revised classification of Red (Hospital use only).

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Selective internal radiation therapies *(QuiremSpheres®)* TAG recommendation: May 2021

for use in: hepatocellular carcinoma as per TA688 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: Red (Hospital / Specialist use only)

Selumetinib *(Koselugo)* TAG recommendation: Mar 2023

for use in: symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over HST20 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2022.

Talimogene laherparepvec ▼ *(Imlygic® ▼)* TAG recommendation: Nov 2016

for use in: Unresectable, regionally or distantly metastatic (Stage IIIB, IIIC or IVM1a) melanoma that has not spread to bone, brain, lung or other internal organs, only if treatment with systemically administered immunotherapies is not suitable (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 410 (September 2016) recommended by NICE, in adults, as an option only if the company provides talimogene laherparepvec with the discount agreed in the patient access scheme.and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Thrombin *(Various)* TAG recommendation: May 2018

for use in: Pseudoaneurysm - as per NICE IPG060 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2004.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NICE IPG060

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Tisagenlecleucel *(Kymriah®)* TAG recommendation: Jan 2019

for use in: Relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years - as per NICE TA 554 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 554 (December 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHS England-commissioning responsibility treatment

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Tisagenlecleucel *(Kymriah®)* TAG recommendation: May 2019

for use in: For treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies - as per NICE 567 (NHSE commissioning responsibility) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2019.

Specific points: May 2019:
The TAG noted NICE TA 567 (March 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

May 2019: The TAG's recommendation was noted by the D&TC.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

- Enzymes

Turoctocog alfa *(NovoEight®)* TAG recommendation: May 2018

for use in: Haemophilia A - as per BCSH Guidelines (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BCSH Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Unlicensed drugs *(Various)*

for use in: Various (Not a licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: This is general advice on unlicensed drugs. It is not intended to refer to licensed drugs which become unlicensed because of a special preparation, nor necessarily use of licensed drugs for unlicensed indications.

Vaginal dilators or trainers *(Femmax®, Ameille Care® and Ameille Comfort®)* TAG recommendation: Jan 2019

for use in: Following vaginal reconstruction surgery or following pelvic radiotherapy when recommended by an appropriate Secondary Care Specialist (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2019: The TAG considered the PRG's recommendation that these devices not be commissioned pending a formal application for their use, but agreed that in view of these devices already being used and issued by the hospital, a more pragmatic recommendation is Red (Hospital use only).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

1.4.2 - Antimotility drugs

Teduglutide *(Revestive®)* TAG recommendation: Aug 2022

for use in: short bowel syndrome as per TA804 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

1.5 - Drugs used in chronic bowel disorders

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5 - Drugs used in chronic bowel disorders

Infliximab (biosimilar) *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Jan 2009

for use in: Acute exacerbations of ulcerative colitis - as per the local treatment pathway (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2008.

Specific points: NICE Technology Appraisal Guidance no.163 - Infliximab for acute exacerbations of ulcerative colitis.
Infliximab is recommended as a possible treatment for people with acute, severely active ulcerative colitis only if:
* ciclosporin is considered inappropriate for them,
or
* they are taking part in a research study (clinical trial)

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

September 2017:
The N&W D&TCG considered and supported a proposed treatment pathway for use of biologics in the treatment of ulcerative colitis which placed infliximab for use in patients within unstable disease or where rapid control is required.

1.5.3 - Drugs affecting the immune response

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Adalimumab *(Humira®)* TAG recommendation: Jul 2010

for use in: Severe active Crohn's disease which has not responded to conventional therapy - as per NICE TA 187 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2010.

Specific points: July 2010: the TAG noted NICE TA 187 (May 2010) which provides revised guidance on use of infliximab and new guidance on the use of adalimumab as follows: Infliximab and adalimumab, within their licensed indications, are recommended as treatment options for adults with severe active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab or adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed to determine whether ongoing treatment is still clinically appropriate.
Treatment should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules. Full guidance is available via www.nice.org.uk/nicemedia/live/12985/48553/48553.doc

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in Crohn's disease.
The TAG agreed to support the pathway which recommended use of Adalimumab as the first line (biologic) choice for most patients with Crohn's Disease. The TAG noted that adalimumab will be available as a biosimilar in 2018 and the cost will reduce. In use since 2008, it has a well-established safety profile.

September 2017:
The N&W D&TCG noted and supported the traetment pathway for the use of biologics in Crohn's disease.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Adalimumab *(Humira®)* TAG recommendation: Mar 2015

for use in: Moderate to severe ulcerative colitis (primary) - as per NICE TA 329 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: March 2015:
The TAG acknowledged the NICE TA329 (which included a review of TA 262) and recommended a classification of Red (Hospital/Specialist use only) for the options of using infliximab, adalimumab or golimumab, after the failure of conventional therapy, pending the receipt of a business case.
The TAG noted that treatment of adults is CCG-commissioning responsibility.

The TAG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

March 2015: Regarding the CCG-commissioning responsibility of treatment of adults with moderately to severely active ulcerative colitis after the failure of conventional therapy with the options of using infliximab, adalimumab or golimumab, the NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation of Red (Hospital/Specialist use only) for the treatments described within NICE TA 329 (February 2015), pending the receipt of a business case.

The D&TCG also recommended that any business application submitted should include a clear treatment pathway clarifying proposed use of these treatments.

The D&TCG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

September 2017:
The N&W D&TCG considered and supported a proposed treatment pathway for use of biologics in the treatment of ulcerative colitis which placed adalimumab as the first line choice (biologic) for most patients with Ulcerative Colitis.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Golimumab *(Simponi®)* TAG recommendation: Mar 2015

for use in: 2nd line (Biologic) treatment option for moderately to severely active ulcerative colitis after the failure of conventional therapy - as per NICE TA 329 and the local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: March 2015: The TAG acknowledged the NICE TA329 and recommended a classification of Red (Hospital/Specialist use only) for the options of using infliximab, adalimumab or golimumab, after the failure of conventional therapy, pending the receipt of a business case. The TAG noted that treatment of adults is CCG-commissioning responsibility.

The TAG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

March 2015: Regarding the CCG-commissioning responsibility of treatment of adults with moderately to severely active ulcerative colitis after the failure of conventional therapy with the options of using infliximab, adalimumab or golimumab, the NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation of Red (Hospital/Specialist use only) for the treatments described within NICE TA 329 (February 2015), pending the receipt of a business case.
The D&TCG also recommended that any business application submitted should include a clear treatment pathway clarifying proposed use of these treatments.

The D&TCG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

September 2017:
The N&W D&TCG considered and supported a proposed treatment pathway for use of biologics in the treatment of ulcerative colitis which placed golimumab as a second line option where a SC injection is preferred and Adalimumab or Infliximab is not suitable.

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Moderately to severely active ulcerative colitis after the failure of conventional therapy - use in children, aligning with NICE TA 329 (NHSE responsibility) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Infliximab *(Various brands available)* TAG recommendation: May 0208

for use in: Crohn's disease - use in children, aligning with NICE TA 187 (NHSE responsibility) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Acute exacerbations of ulcerative colitis - use in children, aligning with NICE TA 163 (NHSE responsibility) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab (biosimilar) *(Cost -effective biosimilar to be used)* TAG recommendation: Sep 2017

for use in: Immunotherapy toxicity (causing colitis) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2017: The TAG considered an application for infliximab for immune-related colitis refractory to high doses of corticosteroids which is widely adopted in oncology treatment centres nationally for this indication. The aim is to limit exposure to very high steroid doses, and to avoid life-threatening toxicity.
In view of the limitations of using alternative treatment (high-dose steroids), the TAG agreed to support the application (on a majority basis only) as Red (Hospital/Specialist only), providing that such support would not be considered by the Trusts to set a precedent for future applications with similar paucity of supporting data.
The TAG also recommended a Prescriber's Rating of 4. Possibly helpful - the product has minimal additional value, and should not change prescribing habits except in rare circumstances.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG acknowledged that despite the limited evidence base, that this treatment was recognised as accepted practice within the specialism and would be used only after careful consideration by local specialists and following positive diagnosis of severe colitis.
The D&TCG therefore agreed to commission use of infliximab for immunotherapy toxicity (colitis) as Red (Hospital/Specialist only) on this basis

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Infliximab (biosimilar) *(As cost-effective biosimilar of choice)* TAG recommendation: Jul 2010

for use in: Crohn's disease which has not responded to conventional therapy - as per NICE TA 187 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2010.

Specific points: July 2010: the TAG noted NICE TA 187 (May 2010) which provides revised guidance on use of infliximab and new guidance on the use of adalimumab as follows: Infliximab and adalimumab, within their licensed indications, are recommended as treatment options for adults with severe active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab or adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed to determine whether ongoing treatment is still clinically appropriate.
Treatment should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules. Full guidance is available via www.nice.org.uk/nicemedia/live/12985/48553/48553.doc

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in Crohn's disease.
The TAG agreed to support the pathway which recommended use of Infliximab in unstable disease or where rapid control is required.

September 2017:
The N&W D&TCG noted and supported the traetment pathway for the use of biologics in Crohn's disease.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Infliximab (biosimilar) *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Mar 2015

for use in: Subacute manifestations of moderately to severely active ulcerative colitis - as per NICE TA 329 and the local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: The TAG acknowledged NICE Technology Appraisal Guidance No. 140 which does not recommend use of infliximab for subacute manifestations of moderately to severely active ulcerative colitis.

March 2015: The TAG acknowledged the NICE TA 329 (which included a review of NICE TA 140) and recommended a classification of Red (Hospital/Specialist use only) for the options of using infliximab, adalimumab or golimumab, after the failure of conventional therapy, pending the receipt of a business case.
The TAG noted that treatment of adults is CCG-commissioning responsibility.
The TAG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

March 2015: Regarding the CCG-commissioning responsibility of treatment of adults with moderately to severely active ulcerative colitis after the failure of conventional therapy with the options of using infliximab, adalimumab or golimumab, the NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation of Red (Hospital/Specialist use only) for the treatments described within NICE TA 329 (February 2015), pending the receipt of a business case.
The D&TCG also recommended that any business application submitted should include a clear treatment pathway clarifying proposed use of these treatments.
The D&TCG also noted that treatment of children and adolescents aged 6 to 17 years is SCG-commissioning responsibility.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

September 2017:
The N&W D&TCG considered and supported a proposed treatment pathway for use of biologics in the treatment of ulcerative colitis which placed infliximab for use in patients within unstable disease or where rapid control is required.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Vedolizumab *(Entyvio®)* TAG recommendation: May 2018

for use in: Paediatric indications (where an adult NICE TA is available - TAs 342 & 352)) - Specialist Centre only (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Vedolizumab ▼ *(Entyvio® ▼)* TAG recommendation: Sep 2017

for use in: 3rd line biologic treatment option for moderately to severely active Crohn's disease - as per NICE TA 352 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2015.

Specific points: September 2015: The TAG noted NICE TA 352 (August 2015) for the treatment of moderately to severely active Crohn's disease after prior therapy only if:
* a tumour necrosis factor-alpha inhibitor has failed (i.e. inadequate response or lost response to treatment)
* or cannot be tolerated, or is contraindicated
Recommended by NICE as an option for treatment under specified criteria and only if the company provides it with discount agreed under the PAS.
The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) pending the submission of a business case and treatment pathway.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation. The committee was also advised that the NNUH is developing an application for use of this treatment.

November 2015: The TAG supported the NNUH's application and recommended that Vedolizumab (Entyvio®) for treating moderately to severely active ulcerative colitis in adults and for treating moderately to severely active Crohn's disease after prior therapy is classified as Red (Hospital / Specialist use only).

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG requested that due to the cost of the treatment monitoring should take place via the NEL CSU Anglia PMMT service.
The D&TCG otherwise noted and supported the TAG's recommendation of Red (Hospital / Specialist use only).

September 2017: The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in Crohn's disease.
The TAG agreed to support the pathway which recommended use of vedolizumab as a third line option (or where patients have an absolute contraindication to the other three therapies) for treating moderately to severely active Crohn's disease in adults. Because of its higher cost, use of vedolizumab will require notification from the Trusts.
The TAG therefore affirmed the previously recommended traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment in line with NICE TA 352 (August 2015) and the local treatment pathway.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.
Use of ustekinumab as a second line option for treating moderately to severely active Crohn's disease in adults is commissioned as Red (Hospital/Specialist only) in line with NICE TA 456 (July 2017) and as specified in the local treatment pathway.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.5.3 - Drugs affecting the immune response

Vedolizumab ▼ *(Entyvio® ▼)* TAG recommendation: Nov 2015

for use in: 3rd line (biologic) treatment option for moderately to severely active ulcerative colitis in adults - as per NICE TA 342 and the local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: May 2015: The TAG noted the NICE FAD (March 2015) and agreed to recommend that a future classification for Vedolizumab (Entyvio®) for treating moderately to severely active ulcerative colitis in adults would be Red (Hospital use only) pending publication of the NICE TA guidance and the development of a treatment pathway.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and decided that the treatment is Not Commissioned - i.e. Double Red (Not recommended for routine use), pending publication of the related NICE Technology Appraisal Guidance.

July 2015: The TAG acknowledged NICE TA 342 (June 2015) and recommended a classification of Double Red (Not recommended for routine use/not commissioned) pending the submission of a treatment pathway for this condition.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

October 2015: Entry updated to "In progress - Not recommended for routine use until local commissononing arrangements are finalised"

November 2015: The TAG supported the NNUH's application and recommended that Vedolizumab (Entyvio®) for treating moderately to severely active ulcerative colitis in adults and for treating moderately to severely active Crohn's disease after prior therapy is classified as Red (Hospital / Specialist use only).

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG requested that due to the cost of the treatment monitoring should take place via the NEL CSU Anglia PMMT service.
The D&TCG otherwise noted and supported the TAG's recommendation of Red (Hospital / Specialist use only).

September 2017:
The N&W D&TCG considered and supported a proposed treatment pathway for use of biologics in the treatment of ulcerative colitis which placed vedolizumab as third line use or where patients have an absolute contraindication to anti TNF, since it is the most costly choice. Notification of Vedolizumab use is required via Bluteq.

1.9.1 - Drugs affecting biliary composition and flow

Odevixibat *(Bylvay)* TAG recommendation: Mar 2023

for use in: progressive familial intrahepatic cholestasis HST17 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

1.9.2 - Bile acid preparations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

1.9.2 - Bile acid preparations

Obeticholic acid ▼ *(Ocaliva® ▼)* TAG recommendation: May 2017

for use in: Primary biliary cholangitis - as per NICE TA 443 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 443 (April 2017) for treating primary biliary cholangitis
* in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or
* as monotherapy for people who cannot tolerate ursodeoxycholic acid
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
Clinicians to assess the response to obeticholic acid after 12 months. Only continue if there is evidence of clinical benefit.

2.3.2 - Ventricular arrhythmias

Mexiletine *(Namuscla®)* TAG recommendation: Jan 2022

for use in: myotonia in non-dystrophic myotonic disorders as per TA748 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Propafenone *(Arythmol)* TAG recommendation: Jun 2023

for use in: cardiovascular indications (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

2.5.1 - Vasodilator antihypertensive drugs

Ambrisentan *(Volibris®)* TAG recommendation: Nov 2011

for use in: Pulmonary Arterial Hypertension - specialist centre only (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.5.1 - Vasodilator antihypertensive drugs

Bosentan *(Tracleer®)* TAG recommendation: Sep 2015

for use in: Treatment of digital ulceration in systemic sclerosis - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted A13/P/b (A13X04) (July 2015) (NHS England document) and recommended a traffic light classification of Red (Specialist use only) for this NHSE-commissioning responsibility treatment.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

July 2018:
The TAG acknowledged a shared care protocol for bosentan for this indication for use in use in Cambridgeshire. Bosentan has significant monitoring requirements which would not be funded under the current local enhanced service guidelines. The TAG therefore agreed that the agreement should not be considered for adoption locally and that the current classification of Red (Hospital use only) for bosentan would be maintained.

July 2018:
Noted and supported by the D&TC.

Iloprost *(Ventavis®)* TAG recommendation: Sep 2011

for use in: Primary pulmonary arterial hypertension (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (July 2008) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.5.1 - Vasodilator antihypertensive drugs

Riociguat ▼ *(Adempas® ▼)* TAG recommendation: Sep 2015

for use in: Treatment chronic thromboembolic Pulmonary Hypertension in adults (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG acknowledged NHS England commissioning policy A11/P/c (A11X03) (July 2015) Targeted Therapies Treatment chronic thromboembolic Pulmonary Hypertension in Adults. This applies to people assessed as in WHO-FC III or IV, in one of the following clinical classifications: * Group 1 Pulmonary arterial hypertension (PAH)
* Group 1* Pulmonary veno-occlusive disease (PVOD) and/or pulmonary capillary haemangiomatosis (PCH)
* Group 4 Inoperable chronic thromboembolic pulmonary hypertension
* (CTEPH) [NB This includes patients with potentially operable disease who refuse surgery or who are waiting for acceptance for surgery].
The TAG recommended a traffic light classification of Red (Specialist use only) for these SCG-commissioning responsibility treatments.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Sildenafil *(Generic)* TAG recommendation: Sep 2016

for use in: Connective tissue diseases (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2016: The TAG agreed to recommend Red (Hospital / specialist use only) classifications for PDE5Is (such as sildenafil and tadalafil) for use in Raynaud's disease or connective tissue diseases in order to support GPs against prescribing these treatments in Primary Care for these specialist indications

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the TAG's recommendations and agreed that use of PDE5Is (such as sildenafil and tadalafil) for treatment of Raynaud's disease or connective tissue diseases is commissioned as Red (Hospital / specialist use only).

January 2017:
The TAG acknowledged the significantly lower costs to the NHS and the changes to the Drug Tariff status of generic sildenafil, that have occurred since the original recommendation.

The TAG agreed to support a shared care proposal submitted for secondary Raynaud's phenomenon with digital ulceration, subject to recommended amendments and recommended a revised classification of Amber (Option for GP prescribing under an approved shared care agreement).
Available via: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation to use the shared care agreement.

The shared care agreement does not cover use in connective tissue diseases - the TAG classification for this indication therefore remains as Red (Hopsital only).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.5.1 - Vasodilator antihypertensive drugs

Sildenafil (Revatio®) *(Revatio®)* TAG recommendation: Nov 2011

for use in: Pulmonary Arterial Hypertension (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.
These are:
Hammersmith Hospital, Royal Brompton Hospital and the
Royal Free Hospital in London.
Papworth Hospital near Cambridge.
Royal Hallamshire Hospital , Sheffield.
Great Ormond Street Hospital provides PAH services for children.

The TAG noted and acknowledged the SCG policy and recommended that the above-mentioned treatments for Pulmonary Arterial Hypertension (PAH) are classified as Red (Not for use in Primary Care / Specialised funding only).

On 17th November 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided it had no responsibility to fund the above-mentioned treatments for pulmonary arterial hypertension for use in Primary Care due to Specialised Commissioning arrangements already being in place.

April 2013:
NHS England SCG took over commissioning responsibility for this treatment.

Tadalafil (Adcirca) *(Adcirca®)* TAG recommendation: Sep 2016

for use in: Raynaud's disease or connective tissue diseases (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2016: The TAG agreed to recommend Red (Hospital / specialist use only) classifications for PDE5Is (such as sildenafil and tadalafil) for use in Raynaud's disease or connective tissue diseases in order to support GPs against prescribing these treatments in Primary Care for these specialist indications.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the TAG's recommendations and agreed that use of PDE5Is (such as sildenafil and tadalafil) for treatment of Raynaud's disease or connective tissue diseases is commissioned as Red (Hospital / specialist use only)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.5.1 - Vasodilator antihypertensive drugs

Tadalafil (Adcirca) *(Adcirca®)* TAG recommendation: Nov 2011

for use in: Pulmonary Arterial Hypertension (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

2.8.1 - Parenteral anticoagulants

Bivalirudin *(Angiox®)* TAG recommendation: Sep 2011

for use in: Treatment of ST-segment-elevation myocardial infarction - as per NICE TA 230 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2011.

Specific points: NICE TA 230 (http://guidance.nice.org.uk/TA230) states:
Bivalirudin in combination with aspirin and clopidogrel is recommended for the treatment of adults with ST-segment-elevation myocardial infarction undergoing primary percutaneous coronary intervention.

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and agreed to commission and fund bivalirudin for the treatment of ST-segment-elevation myocardial infarction as per NICE TA 230 (July 2011), for use in hospital only.

Epoprostenol *(Flolan®)* TAG recommendation: Sep 2011

for use in: Primary pulmonary hypertension - as per NHS England policy - specialist centres only (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (July 2008) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.1 - Parenteral anticoagulants

Fondaparinux sodium *(Arixtra®)* TAG recommendation: Mar 2011

for use in: Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in adults for whom urgent (< 120 mins) invasive management i.e. percutaneous coronary intervention (PCI) is not indicated - as per regional network policy (A

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2010.

Specific points: The Anglia Stroke & Heart Network-wide guidance on the use of anticoagulants in Unstable Angina and NSTEMI (February 2011) recommended a switch from Low Molecular Weight Heparin to fondaparinux, a synthetic inhibitor of factor Xa which offers once daily dosing, no requirement for weight adjustment, a better side-effect profile and cost savings. The ASH Network planned roll out of the switch to fondaparinux by 1 June 2011.

Heparin - Low Molecular Weight (LMWH) *(Various)* TAG recommendation: Mar 2011

for use in: Use in obstetrics for management of VTE in high risk patients (e.g. overweight, multiparous, or who smoke) and require LMWH post partum (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: (Dalteparin, Enoxaparin, Tinzaparin)

May 2011: NHS Norfolk reached agreement with the NNUH regarding provision of a 6-week treatment course for high risk patients post partum, and following major abdominal surgery .
The Acute Trusts are able to provide LMWH more cheaply than in Primary Care, therefore the 6-week treatment course should be supplied by the hospital, for which the PCT (now CCGs) will provide reimbursement.

Heparin - Low Molecular Weight (LMWH) *(Various)* TAG recommendation: Apr 2000

for use in: Unstable angina/coronary artery disease/NSTEMI (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: (Dalteparin, Enoxaparin, Tinzaparin)

2.8.2 - Oral anticoagulants

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.2 - Oral anticoagulants

Apixaban *(Eliquis®)* TAG recommendation: Jul 2015

for use in: Treatment of calf vein deep vein thrombosis (as per NICE TA 341) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed its commissioning position regarding use of apixaban specifically for this indication as part of implementation of NICE TA 341 (June 2015) as follows:

Treatment of calf vein deep vein thrombosis (the 6-week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care) - as per NICE TA 341 (June 2015), but commissioned only regarding DVT, not PE.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read: "Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Apixaban *(Eliquis®)* TAG recommendation: Mar 2012

for use in: Thromboprophylaxis post hip and knee surgery (as per NICE TA 245) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2012.

Specific points: NICE TA 245 states: Apixaban is recommended as an option for the prevention of venous thromboembolism in adults after elective hip or knee replacement surgery.
The TAG noted that Apixaban, as per NICE TA 245, is an "In-Tariff"treatment and is therefore the hospitals' responsibility to provide.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.2 - Oral anticoagulants

Dabigatran etexilate *(Pradaxa®)* TAG recommendation: Jan 2015

for use in: Treatment of calf vein deep vein thrombosis (as per NICE TA 327) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2014.

Specific points: January 2015: The TAG noted NICE TA 327 for the use of Dabigatran as an option for treating and for presenting recurrent deep vein thrombosis and pulmonary embolism in adults and recommended that debigatran is classified in line with previous recommendations only for rivaroxaban, as follows:

Red (Hospital/Specialist only) for:
Calf vein DVT - the 6 week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation pending any changes arising from wider discussions regarding commissioning of anticoagulants across a range of clinical indications (including use in pulmonary embolisim which has yet to be agreed upon).

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed its commissioning position regarding use of dabigatran specifically for this indication as part of implementation of NICE TA 327 (December 2014) as follows:

Treatment of calf vein deep vein thrombosis (the 6-week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care) – as per NICE TA 327 (December 2014), but commissioned only regarding DVT, not PE.

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Dabigatran etexilate *(Pradaxa®)* TAG recommendation: Nov 2008

for use in: Prevention of venous thromboembolism after hip or knee surgery in adults (as per NICE TA 157) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2008.

Specific points: November 2008: The TAG noted NICE TA 157 (September 2008). In-tariff treatment to be provide by the hospital.

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.2 - Oral anticoagulants

Edoxaban ▼ *(Lixiana® ▼)* TAG recommendation: Sep 2016

for use in: Treatment of calf vein deep vein thrombosis (as per NICE TA 354) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2015.

Specific points: April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed its commissioning position regarding use of edoxaban specifically for this indication as part of implementation of NICE TA 354 (August 2015) as follows:

Treatment of calf vein deep vein thrombosis (the 6-week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care) - as per NICE TA 354 (August 2015), but commissioned only regarding DVT, not PE

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Rivaroxaban *(Xarelto®)* TAG recommendation: May 2015

for use in: Prevention of adverse outcomes after acute management of acute coronary syndrome in people with elevated cardiac biomarkers (as per NICE TA 335) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2015.

Specific points: May 2015: The TAG acknowledged the NICE TA 335 (March 2015) and recommended a classification of Double Red (Not recommended for routine use) until a clear place for this NICE-recommended treatment can be determined in a local treatment pathway.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation and agreed not to commission until the treatment pathway is agreed.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed that use of rivaroxaban for this indication is commissioned as Red (Hospital only).

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.2 - Oral anticoagulants

Rivaroxaban ▼ *(Xarelto® ▼)* TAG recommendation: Nov 2012

for use in: Treatment of calf vein deep vein thrombosis (as per NICE TA 261) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2012.

Specific points: NICE Guidance July 2012 http://guidance.nice.org.uk/TA261 recommends rivaroxaban as an option for these indications.

September 2012:
The TAG considered an NNUH business case for first-line use of rivaroxaban over warfarin and were concerned that there is differing clinical opinion about rivaroxaban between the clinicians across local Acute Trusts. Although rivaroxaban is effective there is no evidence of benefit over warfarin in well-controlled patients. There is also a significant price to the local health economy.

D&TCG decisions October - November 2012:
Rivaroxaban is non-inferior to warfarin. Patients at risk of bleeding (e.g. Hx of GI bleed, SSRI use) are contraindicated.

The 6 week treatment course for Calf Vein DVT will be supplied by the hospital to avoid inappropriate continuation in Primary Care.

Other commissioned patient groups suitable for GP to prescribe continued treatment following specialist initiation (see separate "Green" recommendation):

* Proximal DVT associated with active cancer (total 6 months/ 26 wks treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed its commissioning position regarding use of rivaroxaban specifically for this indication as part of implementation of NICE TA 261 (July 2012) as follows:

Treatment of calf vein deep vein thrombosis (the 6-week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care) - as per NICE TA 261 (July 2012), but commissioned only regarding DVT, not PE.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read: "Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.8.2 - Oral anticoagulants

Rivaroxaban ▼ *(Xarelto® ▼)* TAG recommendation: May 2009

for use in: Prevention of venous thromboembolism in adults after total hip or total knee replacement (as per NICE TA 170) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2009.

Specific points: May 2009: the TAG noted NICE TA 170 (April 2009).
In-tariff treatment to be provided by the hospital.

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

2.8.3 - Anticoagulant reversal agents

Andexanet alfa *(Ondexxya®)* TAG recommendation: Apr 2022

for use in: reversing anticoagulation from apixaban or rivaroxaban as per TA697. Not for use with edioxaban patients (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2021.

Specific points: Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case.

April 2022 - formulary application accepted. Only for use for patients on apixaban or rivaroxaban. Not commissioned for edoxaban patients

2.9 - Antiplatelet drugs

Abciximab *(ReoPro®)*

for use in: Prevention of MI during PCTA - as per NICE TA 47 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2002.

Specific points: NICE: September 2002 TAG No.47 replaces guidance from September 2000 (No.12).
NICE has recommended that a GP IIb/IIIa inhibitor should be considered in the management of unstable angina or non-ST-segment-elevation MI.
A GP IIb/IIIa inhibitor is recommended for patients at high risk of myocardial infarction or death when percutaneous coronary intervention (PCI) is desirable but does not occur immediately; either eptifibatide or tirofiban is recommended in addition to other appropriate drug treatment.
A GP IIb/IIIa inhibitor is recommended as an adjunct to percutaneous coronary intervention:
* when early PCI is indicated but it is delayed;
* in patients with diabetes;
* if the procedure is complex.
NB only abciximab is licensed as an adjunct to PCI.
For patients undergoing acute or elective percutaneous coronary intervention (PCI), the intravenous use of GP IIb/IIIa inhibitors (consistent with current UK licensing) is recommended.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.9 - Antiplatelet drugs

Clopidogrel *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: Jul 2009

for use in: Prophylaxis pre-elective PCI (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2009: pre-PCI prophylaxis with clopidogrel should be provided by the hospital via pre-admission clinics. GPs should not be approached to prescribe treatment that is a part of the hospital procedure.

September 2009: The NNUH confirmed that clopidogrel pre-elective PCI would be provided via pre-admission clinics.

Eptifibatide *(Integrilin®)*

for use in: Prevention of MI in unstable angina - as per NICE TA 47 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2002.

Specific points: NICE TA 47 (last update March 2010): For high-risk patients with unstable angina or non-Q-wave myocardial infarction the intravenous use of the glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors (consistent with current UK licensing), in addition to aspirin and low (adjusted) dose unfractionated heparin, is recommended.

Tirofiban *(Aggrastat®)*

for use in: Prevention of MI in unstable angina (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2002.

Specific points: NICE September 2002 (Glycoprotein IIb/IIIa inhibitors for acute coronary syndromes No. 47):
Includes abciximab, eptifibatide, and tirofiban - these drugs should be considered in the management of unstable angina or non-ST-segment-elevation MI.
For patients at high risk of MI or death when early Percutaneous Coronary Intervention (PCI) is desirable but does not occur immediately; either eptifibatide or tirofiban is recommended in addition to other appropriate drug treatment.
A Glycoprotein IIb/IIIa Inhibitor is recommended as an adjunct to PCI:
* when early PCI is indicated but is delayed
* in patinets with diabetes
* if the procedure is complex
NB only abciximab is licensed as an adjunct to PCI.
unstable angina or non-Q-wave myocardial infarction the intravenous use of the glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors (consistent with current UK licensing), in addition to aspirin and low (adjusted) dose unfractionated heparin, is recommended.

2.10.2 - Fibrinolytic drugs

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.10.2 - Fibrinolytic drugs

Alteplase *(Actilyse®)* TAG recommendation: Nov 2012

for use in: Treatment of acute ischaemic stroke - as per NICE TA 264 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2012.

Specific points: NICE TAG 264 : (Sept 2012 http://guidance.nice.org.uk/TA264)
Alteplase is recommended within its marketing authorisation for treating acute ischaemic stroke in adults if:
- treatment is started as early as possible within 4.5 hours of onset of stroke symptoms, and
-intracranial haemorrhage has been excluded by appropriate imaging techniques.

2.11 - Antifibrinolytic drugs

Dried Prothrombin (complex) *()* TAG recommendation: May 2018

for use in: Licensed indications incl treatment and peri-operative prophylaxis of haemorrhage in patients with congenital deficiency of factors II, VII, IX, or X if purified specific coagulation factors not available (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Factor VIII and IX *(Various)* TAG recommendation: Mar 1998

for use in: Deficiency states (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: Recombinant Factor VIII is supported for use in new patients.

Fibrin sealants *(Fibrin sealants)* TAG recommendation: May 2018

for use in: Haemostatic / tissue glue (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.11 - Antifibrinolytic drugs

Fibrinogen, dried (Human) *()* TAG recommendation: May 2018

for use in: Treatment of haemorrhage in congenital hypofibrinogenaemia or afibrinogenaemia - as per BCSH guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Fostamatinib *(Tavlesse®)* TAG recommendation: Jan 2023

for use in: treating refractory chronic immune thrombocytopenia as per TA835 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Jan 2023 - application accepted and amended to red

Protein C concentrate *(Ceprotin®)* TAG recommendation: May 2018

for use in: Congenital protein C deficiency - as per B(C)SH Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per British Society of Haematology guidelines: https://b-s-h.org.uk/guidelines/guidelines-listing-plain-text/

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.11 - Antifibrinolytic drugs

Prothrombin Complex *(Beriplex®, Octaplex®)* TAG recommendation: May 2018

for use in: As per B(C)SH Guidelines (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BCSH Guidelines / CMU framework.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

2.12 - Lipid-regulating drugs

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.12 - Lipid-regulating drugs

Alirocumab ▼ *(Praluent® ▼)* TAG recommendation: May 2018

for use in: Treating primary hypercholesterolaemia and mixed dyslipidaemia - as per NICE TA 393 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2016.

Specific points: May 2016: The TAG noted the East of England Priorities Advisory Committee (PAC) Guidance Statement which does not support use of alirocumab or evolocumab ahead of a positive NICE TA. The TAG recommended a traffic light classification of Double Red (Not for routine use/Not commissioned) for these CCG-commissioning responsibility treatments pending the provision and assessment of outcome data or following a positive NICE TA.

The N&W D&TCG noted and supported the TAG's recommendation and agreed that use of either Alirocumab (Praluent®) or evolocumab (Repatha®) for primary hypercholesterolaemia and mixed dyslipidaemia is Not Commissioned ahead any positive NICE technology appraisal.

July 2016: The TAG noted NICE TA 393 (June 2016) which recommends use of alirocumab as follows:

For treating primary hypercholesterolaemia (primary) and mixed dyslipidaemia only if:
* LDL concentrations are persistently above the specified thresholds despite maximal tolerated lipid-lowering therapy.
* alirocumab is provided with the discount agreed under PAS.

The TAG recommended maintaining the current traffic light classification of Double Red (Not recommended for routine use/Not commissioned) pending the submission of a business case for this CCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs; D&TCG noted and supported the TAG recommendation. The treatment is not commissioned until a local business application is submitted and supported.

March 2017: The TAG noted the revised guidance from the East of England Priorities Advisory Committee (PAC) which outlines recommendations for use of PCSK9 Inhibitors alirocumab and evolocumab in line with NICE TA guidance 393 and 394.

The TAG also considered a local application proposing use of these agents which was recommended to be returned to the committee with additional information.

March 2017 - Noted by the N&W D&TCG.

Sepetmber 2017:
The TAG considered a revised application and supporting information; there are likely to be around 250 patients a year across the Norfolk & Waveney area costing £5k per head. Due to concerns regarding the threshold for use of the drugs, it was agreed that the treatment pathway was key to managing the number of patients being referred to a specialist service.
The TAG recommended that a meeting be arranged with specialists from local trusts to see if a cross-county pathway could be developed in order to achieve a compromise between the NICE TAs and affordability within the local health economy.

September 2017:
The TAG's recommendation was noted and supported by the N&W Drugs & Therapeutics Commissioning Group.

November 2017:
The TAG was advised that meetings were taking place between the CCGs and the Trusts' lipidology specialists during November 2017 to discuss a treatment pathway and likely numbers and costs of using PCSK-9 inhibitors. The TAG also recommended that the Trusts should work together on finalising a joint treatment pathway.

November 2017:
Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.12 - Lipid-regulating drugs

December 2017:
The D&TCG discussed and supported a business case and treatment pathway for use of alirocumab and for evolocumab subject to details on potential costs being clarified. The D&TCG also debated how costs might be contained if actual use exceeded the numbers estimated in the Trust's business application. The item was in progress and actions were being chased.

April 2018: A final business application and treatment pathway for use of the PCSK-9 inhibitors was considered and supported by the CCGs' Joint Strategic Commissioning Committee (JSCC) as Red (Hospital / Specialist use only).

May 2018: The TAG was advised of the JSCC's positive commissioning decision.

Colestilan *()* TAG recommendation: May 2018

for use in: Management of hyperphosphataemia in adults on renal dialysis (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Trust guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.12 - Lipid-regulating drugs

Evolocumab ▼ *(Repatha® ▼)* TAG recommendation: May 2018

for use in: For treating primary hypercholesterolaemia and mixed dyslipidaemia - as per NICE TA 394 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2016.

Specific points: May 2016: The TAG noted the East of England Priorities Advisory Committee (PAC) Guidance Statement which does not support use of evolocumab or alirocumab ahead of a positive NICE TA. The TAG recommended a traffic light classification of Double Red (Not for routine use/Not commissioned) for these CCG-commissioning responsibility treatments pending the provision and assessment of outcome data or following a positive NICE TA.

The N&W D&TCG noted and supported the TAG's recommendation and agreed that use of either Alirocumab (Praluent®) or evolocumab (Repatha®) for primary hypercholesterolaemia and mixed dyslipidaemia is Not Commissioned ahead any positive NICE technology appraisal.

July 2016: The TAG noted NICE TA 394 (June 2016) which recommends use of evolocumab as follows:
For treating primary hypercholesterolaemia (primary) and mixed dyslipidaemia only if:
* The dosage is 140 mg every 2 weeks.
* LDL concentrations are persistently above the specified thresholds despite maximal tolerated lipid-lowering therapy.
* evolocumab is provided with the discount agreed under PAS.

The TAG recommended maintaining the current traffic light classification of Double Red (Not recommended for routine use/Not commissioned) pending the submission of a business case for this CCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation. Evolocumab is not commissioned until a local business application is submitted and supported.

March 2017: The TAG noted the revised guidance from the East of England Priorities Advisory Committee (PAC) which outlines recommendations for use of PCSK9 Inhibitors alirocumab and evolocumab in line with NICE TA guidance 393 and 394.

The TAG also considered a local application proposing use of these agents which was recommended to be returned to the committee with additional information.

March 2017 - Noted by the N&W D&TCG.

Sepetmber 2017:
The TAG considered a revised application and supporting information; there are likely to be around 250 patients a year across the Norfolk & Waveney area costing £5k per head. Due to concerns regarding the threshold for use of the drugs, it was agreed that the treatment pathway was key to managing the number of patients being referred to a specialist service.
The TAG recommended that a meeting be arranged with specialists from local trusts to see if a cross-county pathway could be developed in order to achieve a compromise between the NICE TAs and affordability within the local health economy.

September 2017:
The TAG's recommendation was noted and supported by the N&W Drugs & Therapeutics Commissioning Group.

November 2017:
Costing information provided by the manufacturer of evolocumab (Amgen) had been passed to the CCGs, which indicates that actual costs of using the treatment would be much lower than previously thought.
The TAG was also advised that meetings were taking place between the CCGs and the Trusts' lipidology specialists during November 2017 to discuss a treatment pathway and likely numbers and costs of using PCSK-9 inhibitors. The TAG also recommended that the Trusts should work together on finalising a joint treatment pathway.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

2.12 - Lipid-regulating drugs

November 2017:
Noted by the D&TCG.

December 2017:
The D&TCG discussed and supported a business case and treatment pathway for use of alirocumab and for evolocumab subject to details on potential costs being clarified. The D&TCG also debated how costs might be contained if actual use exceeded the numbers estimated in the Trust's business application. The item was in progress and actions were being chased.

April 2018: A final business application and treatment pathway for use of the PCSK-9 inhibitors was considered and supported by the CCGs' Joint Strategic Commissioning Committee (JSCC) as Red (Hospital / Specialist use only).

May 2018: The TAG was advised of the JSCC's positive commissioning decision.

Metreleptin *((Myalepta®))* TAG recommendation: Mar 2023

for use in: Dyslipidaemia - Generalised lipodystrophy and partial lipodystrophy HST14 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Volanesorsen *(Waylivra)* TAG recommendation: Mar 2023

for use in: Familial chylomicronemia syndrome HST13 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2020.

3.4.2 - Allergen immunotherapy

Bee and wasp venom *(Pharmalgen®)* TAG recommendation: Mar 2012

for use in: Bee and wasp venom allergy - as per NICE TA 246 - specialist centre only (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2012.

Specific points: NICE TA 246 states that: Pharmalgen is recommended as an option for the treatment of IgE-mediated bee and wasp venom allergy in people who have had a severe systemic reaction to bee or wasp venom, or a moderate reaction and other risk factors or anxiety about future stings. Treatment with Pharmalgen should be started and monitored in a specialist centre experienced in venom immunotherapy.

Noted by the NHS N&W D&TCG on 15th March 2012. Commissioned for specialist centre use only.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.4.2 - Allergen immunotherapy

Benralizumab *(Fasenra®)* TAG recommendation: May 2019

for use in: Severe eosinophilic asthma (specialist use only) - as per NICE TA 565 (NHSE commissioning responsibility) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2019.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

May 2019:
The TAG noted NICE TA 565 (March 2019) which states that benralizumab is recommended as follows:
For treating severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids and long-acting beta-agonists, only if:
* the person has agreed to and followed the optimised standard treatment plan and
* the blood eosinophil count has been recorded as 300 cells per microlitre or more and the person has had 4 or more exacerbations needing systemic corticosteroids in the previous 12 months, or has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months (that is, the person is eligible for mepolizumab) or
* the blood eosinophil count has been recorded as 400 cells per microlitre or more with 3 or more exacerbations needing systemic corticosteroids in the past 12 months (that is, the person is eligible for reslizumab).
* the company provides it according to the commercial arrangement.

The TAG noted NICE TA 565 (March 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) f this NHSE-commissioning responsibility treatment.

May 2019: The TAG's recommendation was noted by the D&C

Mepolizumab *(Nucala®)* TAG recommendation: Mar 2021

for use in: severe eosinophilic asthma as per TA671 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.4.2 - Allergen immunotherapy

Mepolizumab ▼ *(Nucala® ▼)* TAG recommendation: Mar 2017

for use in: Severe refractory eosinophilic asthma in adults - as per NICE TA 431 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2017.

Specific points: March 2017: The TAG acknowledged NICE TA 431 (January 2017) For treating severe refractory eosinophilic asthma in adults whose:
* blood eosinophil count is 300 cells/microlitre or more in the previous 12 months and
* the person has agreed to and followed the optimised standard treatment plan and
 - has had 4 or more asthma exacerbations needing systemic corticosteroids in the previous 12 months or
 - has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Omalizumab *(Xolair®)* TAG recommendation: Jan 2017

for use in: For previously treated severe chronic spontaneous urticaria in adults and young people aged 12 years and over (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: May 2015: The TAG noted the NICE FAD (March 2015) and agreed to recommend that a future classification for Omalizumab (Xolair®) for previously treated severe chronic spontaneous urticaria in adults and young people aged 12 years and over would be Red (Hospital/Specialist use only).

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and decided that the treatment is Not Commissioned - i.e. Double Red (Not recommended for routine use), pending publication of the related NICE Technology Appraisal Guidance.

July 2015: The TAG noted the NICE TA 339 (June 2015) and recommended a classification of Red (Hospital only) for this SCG-commissioning responsibility treatment.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

January 2017: The TAG noted the application submitted by the local Acute Trust as a result of the treatment transferring from NHS England to CCG commissioning responsibility, and recommended a traffic light classification of Red (Hospital only) for this CCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and agreed to commission Omalizumab (Xolair®) for chronic spontaneous urticaria as per NICE TA 339 and the local business application.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.4.2 - Allergen immunotherapy

Omalizumab *(Xolair®)* TAG recommendation: Jul 2005

for use in: Severe persistent allergic asthma in patients aged 12 years and over (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: November 2007.

Specific points: NICE technology Appraisal 133: Omalizumab for severe persistent allergic asthma:
Omalizumab is recommended, within its licensed indication, as an option for the treatment of severe persistent allergic (IgE mediated) asthma as add-on therapy to optimised standard therapy, only in adults and adolescents (12 years and older) who have been identified as having severe unstable disease.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Omalizumab *(Xolair®)* TAG recommendation: May 2013

for use in: Treatment of severe persistent allergic asthma in children aged 6 to under 12 years (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2013.

Specific points: The TAG acknowledged the NICE TA 278 and recommended the re-classification to Red (Hospital only) for omalizumab (Xolair®) for treatment of severe persistent allergic asthma in children aged ≥ 6 years who have needed at least four treatment courses of corticosteroids in the previous year.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Palforzia *()* TAG recommendation: Mar 2023

for use in: peanut allergy in children and young people as per TA769 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: Formulary application and pathway required

March 2023 - Local policy has now been developed for use within clinics

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Tezepelumab *(Tezspire®)* TAG recommendation: Jun 2023

for use in: severe asthma TA880 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.4.2 - Allergen immunotherapy

Wasp / Bee venom extract (Pharmalgen®) *(Pharmalgen® Wasp / Bee venom extract)* TAG recommendation: May 2018

for use in: Wasp / Bee venom allergy - as per NICE TA 246 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2012.

Specific points: May 2018:
This treatment is CCG commissioning responsibility. Not for primary care prescribing - Hospital only prescribing (Red).

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

3.4.3 - Respiratory system - Angioedema

Berotralstat *(Orladeyo®)* TAG recommendation: Nov 2021

for use in: preventing recurrent attacks of hereditary angioedema as per TA738 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Conestat alfa *(Ruconest®)* TAG recommendation: May 2018

for use in: Hereditary angiodema - acute treatment only - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Icatibant *(Firazyr®)* TAG recommendation: May 2018

for use in: Hereditary angiodema - prophylactic treatment - as per NHSE policy (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per NHS England Policy 16045/P

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.4.3 - Respiratory system - Angioedema

Icatibant *(Firazyr®)* TAG recommendation: Jan 2013

for use in: Hereditary angioedema - acute treatment (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2012: The East of England Priorities Advisory Committee's (PAC) Policy Statement (September 2012) supported the use of Icatibant in symptomatic treatment of acute attacks of HAE in adults with C1-esterase-inhibitor deficiency. PAC decision has taken into account The Patient Access Scheme to improve cost effectiveness.

Commissioning responsibility transferred to National Commissioning Board (NCB) from April 2013. The NCB will provide icatibant via commissioned services.

Comissioned by NHSE as per Policy B09/P/b

3.7 - Mucolytics

Dornase alfa *(Pulmozyme®)* TAG recommendation: Mar 2015

for use in: Cystic fibrosis - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts 28 days.

NICE has not issued any guidance.

Specific points: NNUH shared care protocol available - redesigned version supported by the TAG in September 2004.

March 2008: A revised version was developed by the NNUH and approved by the TAG.

May 2008: The JPUH and the QEH agreed to adopt the shared care protcol.

September 2010: Version reviewed and approved by the TAG.

January 2013: Supported by the TAG for use until National Specialised Commissioning Group (NSCG) takes over commissioning responsibility with likely transfer to homecare providers during 2013. To be reviewed in 2014.

The Shared Care Protocol is available via the Knowledge Management website: http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

March 2014: Shared Care Agreement reviewed and use extended until March 2015. Supported by the TAG and D&TCG.

March 2015: The TAG was asked to review classification from Amber (Option for GP prescribing under an approved Shared Care Agreement) to Red since confirmation had been received that all local patients have been repatriated to specialist care under NHS England Specialised Commissioning arrangements. The shared care agreement could therefore be revoked.
The TAG confirmed that classification of Red (Hospital/Specialist only) should be recommended for Dornase Alfa in Cystic Fibrosis (CF).

March 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation to re-classify Dornase Alfa for use in patients with cystic fibrosis to Red (Hospital/Specialist only).

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.7 - Mucolytics

Ivacaftor ▼ *(Kalydeco® ▼)* TAG recommendation: Sep 2015

for use in: Cystic Fibrosis (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: NHS England Specialised Commissioning responsibility from April 2013: policy available via http://www.england.nhs.uk/wp-content/uploads/2013/09/a01-p-a.pdf

Ivacaftor is effective only in a small and identifiable proportion of the CF population that has a specific genetic mutation (patients age 6 years and older who have the G551D mutation in the CFTR gene)
It is the first treatment for CF that targets the underlying cause of the disease rather than treats its symptoms.

September 2015: The TAG acknowledged A01/P/c (July 2015) (NHS England will commission in accordance with specified criteria and only if the manufacturer provides it with the discount agreed- replaces A01/P/a (A01X01) and reaffirmed the previously recommended traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Mannitol (dry powder for inhalation) *(Bronchitol®)* TAG recommendation: Jan 2013

for use in: (Adjunctive) treatment of cystic fibrosis (CF) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2012.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.7 - Mucolytics

Sodium Chloride (Hypertonic 3-7%) for inhalation *(MucoClear®, Nebusal®)* TAG recommendation: May 2013

for use in: Clearance of mucosal secretions in Cystic Fibrosis and Bronchiectasis (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Commissioning responsibility now with NHS England Specialised Commissioning (SCG).
Part of the Cystic Fibrosis tariff and is one of a number of treatments which SCG has stated should be repatriated to Secondary care and in the future be provided via Homecare. In theory GPs should not be prescribing this treatment.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decision:
Red (Hospital/Specialist prescribing only) for all patients.

September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Inhalation solutions - hypertonic sodium chloride solutions for nebulisation which stated that use outside of hospital considered for those with cystic fibrosis (CF) or non-CF bronchiectasis, where recommended by a specialist. Initiation must take place in secondary care to ensure safety and suitability for the individual.

The TAG agreed to maintain the current Red (Specialist use only classification) for any new use of this treatment since May 2013.

September 2017:
Noted and supported by the N&W D&TCG.

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Tezacaftor, Ivacaftor and Elexacaftor *(Kaftrio®))* TAG recommendation: Mar 2022

for use in: treat eligible patients 6 years and over who have cystic fibrosis (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a traffic light classification of Red (Hospital/Specialist Only). This was supported by the D+TC

March 2022 - licence updated to include patients 6 years and over

3.11 - Collagen inhibitor

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

3.11 - Collagen inhibitor

Pirfenidone *(Esbriet®)* TAG recommendation: Mar 2018

for use in: Idiopathic Pulmonary Fibrosis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2018.

Specific points: Pirfenidone (Esbriet, InterMune) is an immunosuppressant that is thought to have anti-inflammatory and antifibrotic effects. Pirfenidone has a UK marketing authorisation for the treatment of mild-to-moderate idiopathic pulmonary fibrosis in adults. The recommended dosage of pirfenidone is 3×267 mg capsules 3 times a day (2403 mg/day).

NHS England SCG-commissioning responsibility from April 2013.

May 2013: NICE TA 282 (April 2013)
Recommended as an "option" under specific criteria and PAS.

The TAG noted NICE TA 282 Pirfenidone for idiopathic pulmonary fibrosis and recommended a re-classification of Red (Hospital Only).

July 2013: The TAG noted NICE CG 163 (June 2013) - Idiopathic pulmonary fibrosis
NHS England Specialised Commissioned.

Drugs which are NOT recommended for use for IPF by NICE are:
* ambrisent
* azathioprine
* bosentan
* co-trimoxazole
* mycophenolate mofetil
* prednisolone
* sildenafil
* warfarin

March 2018: The TAG acknowledged NICE TA 504 (February 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility
treatment.

March 2018: NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

4.1.1 - Hypnotics

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.1.1 - Hypnotics

Melatonin (immediate-release formulations) *(Various (Bio-Melatonin))* TAG recommendation: Sep 2003

for use in: Management of sleep disorders in children with ADHD and behavioural disorders (Not a licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2003: The TAG noted that melatonin is available on a named-patient basis only. Costs to primary care likely to be higher than when purchased by hospitals.

September 2008: The TAG agreed that the newly available melatonin prolonged-release product Circadin, licensed for treatment of primary insomnia adults aged 55 years and over, is not recommended for routine use for this indication.
The TAG also noted that MHRA restrictions on the import of unlicensed melatonin products do not apply to products which are manufactured to GMP standards in the UK.

March 2011: The TAG agreed to support a joint shared care proposal from the NWMHP and NCH&C for use of Circadin only in sleep disorders in children with behavioural disorders. Available via http://nww.knowledgeanglia.nhs.uk/tag/index.htm
Use of all- other unlicensed melatonin products remains with specialists.

September 2013: The TAG noted baseline audit results from NCH&C. Current version of shared care agreement agreed to be extended until March 2014 pending publication of audit results from local specialist services (NCH&C). Request form Trusts to add Bio-melatonin to the current Shared Care Agreement not supported in the interim.

N&W CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) supported the TAG recommendation. Bio-melatonin not to be prescribed in primary care at present - i.e. Red (Hospital/Specialist only). NSFT to be requested to undertake similar audit.

Melatonin Prolonged Release (Circadin) *(Circadin®)* TAG recommendation: Jan 2018

for use in: Monotherapy in short term management of primary insomnia characterised by poor quality of sleep in patients aged 55 years or over whilst at the Julian Hospital, Norwich (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts whilst in the Julian unit..

NICE has not issued any guidance.

Specific points: January 2018: The TAG noted and supported the NSFT's application for In-Trust use of Circadin within a specialist dementia unit where patients can experience disrupted sleep patterns and exhibit symptoms of agitation and "sundowning" syndrome due to their environment and clinical condition. Agreed for in-trust use only - not to be continued in primary care.

January 2018: The Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TCG's recommendation - commissioned as Red (Hospital / Specialist use only).

August 2020 - This returned to TAG following conflicting advice from NICE and the local Trusts. The TAG recommended that the existing recommendation of Red (Hospital / Specialist use only) for in-Trust use only should remain in place.
A statement will be sent to the Trusts to remind them not to request that this item be prescribed post-discharge.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.1.1 - Hypnotics

Sodium oxybate *(Xyrem®)* TAG recommendation: Jul 2020

for use in: Cataplexy associated with narcolepsy in adults aged ≥19 years (under specialist supervision) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2013: Discussions have taken place across the East of England region regarding the cost of sodium oxybate and the poor quality evidence base for its use.
An evidence review will be considered by the NHS East of England Priorities Advisory Committee (PAC) in June 2013.
The TAG agreed to reconsider this issue once guidance from the PAC becomes available.

N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Commissioning Decision:
No new patients in Norfolk and Waveney should be started on sodium oxybate until the PAC publishes its policy on treatment and the D&TCG reviews the current commissioning position.

July 2013: NHS East of England - Priorities Advisory Committee (PAC)
Draft recommendation:
Funding of sodium oxybate in the management of narcolepsy with cataplexy is low priority and will not be routinely funded. This statement will be reviewed in light of new evidence.

The D&TCG confirmed that the current TAG classification of Amber (option for Shared Care prescribing) should be revised to Double Red (Not recommended for routine use / Not commissioned).
i.e. no new patients or re-initiations of treatment should be taken on by GPs.
The current TAG Shared Care Prescribing document will be revised as a Prescribing Information resource for GPs with existing patients.

January 2014: NHS East of England-Priorities Advisory Committee (PAC) Final Policy Statement - June 2013 recommends that the treatment is a low priority and will not be routinely funded. The PAC policy statement was noted and the current classification remains.

May 2017: The TAG acknowledged the PAC's following recommendations following review of their previous guidance:
* Cost-effectiveness has NOT been demonstrated for the use of sodium oxybate for the management of narcolepsy with cataplexy in any patient group (children or adults).
* There has been no new evidence of efficacy since the previous PAC policy was written in 2013.
* The high cost of sodium oxybate and resulting Scottish Medicines Consortium (SMC) cost per QALY calculations remain unchanged and do not demonstrate cost effectiveness for use in adults.
The TAG noted the PAC's updated recommendations and reaffirmed its previous recommended traffic light classification of Double Red (Not recommended for routine use).
The TAG acknowledged that any younger patients started on treatment below the age of 19 years of age would have to be considered on an individual basis once they reach adulthood and funding responsibility transfers from NHSE SCG to CCGs.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations to adopt the PAC's recommendations and reaffirmed that Sodium oxybate (Xyrem®) for Management of narcolepsy with cataplexy in adults aged ≥19 years is Double Red (Not recommended for routine use) / Not commissioned.
The D&TCG also acknowledged that younger patients who had started sodium oxybate below 19 years of age would have to be considered on an individual basis once they reached adulthood if treatment was still required. The D&TCG considered that such patients should have undertaken a trial period without treatment (drug holiday), to ensure that it was still necessary, at a suitable opportunity leading up to their 19th birthday, and ahead of funding responsibility transferring from NHSE SCG to CCGs.
The D&TCG also requested ePACT data is monitored regularly to check for any unplanned additional use in primary care in Norfolk & Waveney.

The GP Prescribing Information for sodium oxybate (last agreed July 2013) was withdrawn from use.

July 2020 - PAC guidance pubished in March 2020. The TAG agreed that local policy should follow the PAC recommendations. Therefore,

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.1.1 - Hypnotics

traffic light classification for this indication will be amended to Red (Hospital / Specialist use only). This must only be prescribed by a Specialist Centre. Locally, this would be Papworth. This recommendation was supported by the D+TC

Sodium oxybate *(Xyrem®)* TAG recommendation: May 2017

for use in: Management of narcolepsy with cataplexy in children aged <19 years (specialist centre use only - commisioned by NHS England) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2017:
Historically, NHS England did not routinely fund for use in children (≤18 years old). However, in Dec16, it issued a positive policy for use in children from puberty until 19 years of age, where they have not responded to or cannot have current treatments.

The TAG acknowledged that any younger patients started on treatment below the age of 19 years of age would have to be considered on an individual basis once they reach adulthood and funding responsibility transfers from NHSE SCG to CCGs and such use is Double Red / Not commissioned for routine use by the CCGs.

May 2017:
The D&TCG also acknowledged that younger patients who had started sodium oxybate below 19 years of age would have to be considered on an individual basis once they reached adulthood if treatment was still required. The D&TCG considered that such patients should have undertaken a trial period without treatment (drug holiday), to ensure that it was still necessary, at a suitable opportunity leading up to their 19th birthday, and ahead of funding responsibility transferring from NHSE SCG to CCGs.
The D&TCG also requested ePACT data is monitored regularly to check for any unplanned additional use in primary care in Norfolk & Waveney.

4.2.1 - Antipsychotic drugs

Clozapine *(Clozaril®, Denzapine®, Zaponex®)* TAG recommendation: Jul 1998

for use in: Schizophrenia (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: March 2009.

Specific points: March 2009: NICE Clinical Guideline 82 - Schizophrenia

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.2.1 - Antipsychotic drugs

Risperidone *(Risperdal® (tablets))* TAG recommendation: May 2013

for use in: Unresponsive conduct disorder in ADHD (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts 6 weeks.

NICE issued Guidance in: March 2013.

Specific points: Used by specialists where there has been poor response to other therapy and where the ADHD includes conduct disorder (rare).

May 2013: The TAG noted NICE CG 158 (March 2013) - Antisocial behaviour and conduct disorder in children and young people: recognition, intervention and management which includes guidance on the use of risperidone for short-term management of severely aggressive behaviour in young people with a conduct disorder who have problems with explosive anger and severe emotional dysregulation and who have not responded to psychosocial interventions.

The TAG recommended Shared Care to support Primary Care prescribing where treatment is required beyond 6 weeks' use.
A shared care protocol will be agreed in the near future.

CCGs Commissioning Decision: The Drugs & Therapeutics Commissioning Group (D&TCG) commissioned risperidone as Red (Hospital / Specialist only) for the specified indication pending an approved Shared Care Agreement.

July 2018: Following the NSFT's request that the traffic light classification should be in line with other antipsychotic treatments (i.e. Green (GP prescribing following specialist initiation / recommendation)), a document detailing different treatments and indications for use of risperidone in children and young people to be produced for the TAG to consider.
CCG lead mental health commissioner to be contacted regarding who commissions the various services for children and adolescents.

November 2018:
Information on use of Risperidone within the NSFT CAMHS during 2017-18 in 7 individual cases with specialist neurodevelopmental disorder patient group (out of around 100 children and young people who have received medication overall).

The TAG noted the data and acknowledged the relatively infrequent use of risperidone for these patients. The TAG debated issues regarding ease of access to treatment by patients and their carers, the level of on-going monitoring recommended by NICE CG 158 where treatment is continued or where there are dosage changes, and whether GPs could provide that level of care. Practical issues regarding possible use of FP10HP forms were also discussed.
The specialist service to be asked to consider these issues and return the item to the TAG with more detailed proposals for further consideration.

January 2019:
No update on progress was available from the NSFT.
CCG members advised the TAG on the need to liaise with the local Children's commissioner regarding the treatment pathway and prescribing responsibility, and also with contract manager regarding the possibility of adding a clause to clarify interface prescribing issues.

March 2019:
The TAG noted that the issues of concern under this item would be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No change to the current traffic light classification were agreed.

4.2.2 - Antipsychotic depot injections

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.2.2 - Antipsychotic depot injections

Risperidone (Depot injection) ▼ *(Risperdal Consta® ▼)* TAG recommendation: Jan 2008

for use in: Schizophrenia and other psychoses in patients tolerant to risperidone by mouth. (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2002.

Specific points: January 2008: The TAG reviewed its previous decision and revised the Green classification back to "Red" since the majority of patients on Risperdal Consta are managed by the Norfolk & Waveney Mental Health Partnership NHS Trust due to issues regarding transfer from oral medication and also appropriate storage and preparation of the depot injection.
The TAG noted there is a small number of patients whose care is successfully managed in primary care and that this revised decision should not disrupt current arrangements for their care.

4.5 - Obesity

Liraglutide (marketed as Saxenda®)▼ *(Saxenda® ▼)* TAG recommendation: Apr 2022

for use in: Treatment of obesity as per TA664 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: September 2016: The TAG acknowledged the PAC Full Evidence Review (Oct-Dec15) Liraglutide (Saxenda®) for treatment of obesity and recommended a classification of Double Red (Not recommended for routine use) as an interim position pending the UK launch of this treatment.
The TAG also requested that the PAC be asked to consider the place of this treatment for patients on mental health treatments which have led to weight gain.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation and agreed that Naltrexone and Bupropion (Mysimba®) for treatment of obesity is Double Red (Not recommended for routine use) / Not commissioned as an interim position, pending the UK launch of this treatment and local applications proposing its use.

Jan 2021 - NICE published TA664. TAG acknowledged the guidance and maintained classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case. Supported by D+TC and ratified by CCG Governing Body

April 222 - CCG in process of commissioning specialist tier 3 weight management service. Liraglutide (saxenda®) will only be commissioned for use in this service

4.5.1 - Anti-obesity drugs acting on the GI tract

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.5.1 - Anti-obesity drugs acting on the GI tract

Orlistat *(Xenical®)* TAG recommendation: Jan 2015

for use in: Identification, assessment and management of overweight and obesity in children (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2014.

Specific points: January 2015: The TAG noted and supported NICE CG 189 regarding the following drug treatment recommendations under:
Section 1.8 Pharmacological interventions: outlines the place of orlistat in adults and young people. In children <12 years, drug treatment may be used only in exceptional circumstances if severe comorbidities are present. Prescribing should be started and monitored only in specialist paediatric settings. Drug treatment may be continued in primary care eg with a shared care protocol if local circumstances and/or licensing allow.
Section 1.9 Continued prescribing and withdrawal: Criteria and management strategies for use of orlistat in adults and children are outlined.
The TAG's previous recommendation of Double Green (suitable for GPs to initiate and prescribe) for olistat relates to use in adults only.
The TAG noted NICE CG 189 and recommended a classification of RED (Hospital/Specialist only) for the use of orlistat in children <12 years of age (to be reviewed should a local shared care agreement be agreed upon).

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

4.5.2 - Centrally acting appetite suppressants

Setmelanotide *(Imcivree)* TAG recommendation: Mar 2023

for use in: obesity caused by LEPR or POMC deficiency HST21 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

4.6 - Drugs used in nausea and vertigo

Aprepitant *(Emend®)* TAG recommendation: Jul 2012

for use in: Prevention of nausea and vomiting in patients on highly emetogenic chemotherapy - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2012:
Used by the NNUH for prevention of nausea and vomiting in patients receiving high-dose cisplatin chemotherapy and for refractory nausea & vomiting in patients on other highly emetogenic chemo, where a subcutaneous syringe driver is the only other option.

The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided to commission aprepitant (Emend®) as per an In-Tariff treatment - not funded for prescribing in Primary Care.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.6 - Drugs used in nausea and vertigo

Ondansetron + other 5HT3 antagonists *(Zofran®, various)* TAG recommendation: Mar 1998

for use in: Nausea & vomiting associated with chemotherapy and other hospital-led treatments (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 1998:
The hospital may prescribe treatment for up to 2 days after chemotherapy. After this time, ondansetron is no more effective than other anti-emetics. If nausea is a problem after this time, anti-emetics such as domperidone or metoclopramide should be used. There should be no need to renew prescriptions of ondansetron beyond that provided by the hospital.

November 2007: The TAG debated use of these anti-emetics for non-chemotherapy-induced nausea and vomiting, associated continued use beyond licensed period and subsequent transfer of prescribing to primary care.

The TAG noted examples of exceptional use terminal care situations e.g. end-stage renal failure and in patients suffering chronic pain and nausea secondary to use of opiates.
In general such off-label use will be the EXCEPTION RATHER THAN THE RULE and the need to continue use of ondansetron and related anti-emetics in primary care should be RARE.

November 2011: The TAG revisited this recommendation and agreed to maintain the current classification especially in view of the significant difference in cost of ondansetron between hospital and primary care.

September 2016: The TAG agreed to recommend that acute use of ondansetron (plain tablets only) for nausea and vomiting as a second line option in hyperemesis gravidarum be classified as Green (GP prescribing following consultant initiation / recommendation). The TAG also agreed to recommend that acute use of ondansetron (plain tablets only) for nausea and vomiting for drug-induced nausea and vomiting in palliative care be
classified as Green (GP prescribing following consultant initiation / recommendation)

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendations.

4.7.2 - Opioid analgesics

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.7.2 - Opioid analgesics

Fentanyl I-R sublingual tabs (Abstral®) *(Abstral®)* TAG recommendation: Dec 2021

for use in: 3rd line option for (Acute) breakthrough pain in cancer as part of an agreed pathway of care (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG agreed to recommend that Abstral® (sublingual tablets) is the immediate-release (I-R) fentanyl formulation of choice. Other immediate-release fentanyl preparations including buccal tablets, lozenges/lollipops, and intranasal spray, are not recommended for routine use (Double Red).
Sublingual fentanyl tablets are for use only in breakthrough pain in cancer as a third-line treatment option.
The maximum recommended number of daily doses must not be exceeded. Background analgesia must be adjusted if more than 4 episodes of breakthrough pain are experienced a day.
Use of Abstral® is recommended only under an approved shared care agreement with Palliative Care specialists i.e. Amber (option for shared care with a written agreement).
Abstral® is currently recommended as Red (Hospital Only) until a written shared care agreement is agreed by local Palliative Care consultants and approved by the TAG.
Prescriber's Rating of 4. Possibly helpful - the product has minimal additional value, and should not change prescribing habits except in rare circumstances.
Abstral® is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the CHM and MHRA Yellow Card scheme.

July 2012: The TAG noted NICE CG 140 Opioids in Palliative Care.

September 2016:
The TAG acknowledged NICE CG 140 (August 2016) - update includes recommendations on:
* communication
* starting strong opioids and titrating the dose
* first-line maintenance treatment
* first-line treatment using transdermal patches or subcutaneous delivery, if oral opioids are not suitable
* first-line treatment for breakthrough pain in patients who can take oral opioids
* managing constipation, nausea and drowsines

Dec 2021 - Regarding Abstral, TAG felt a shared care agreement was not
appropriate under these circumstances. Statement to be published on Netformulary. Under very rare/emergency circumstances (related to inability of consultant generated prescriptions being able to arrive with the patient in sufficient time to receive ongoing supplies) it is considered that a direct request from a
consultant to a GP to issue a very short-term limited emergency supply would be acceptable with no expectation of ongoing GP prescription responsibility

Methadone *(various)* TAG recommendation: Jun 2023

for use in: pain management in complex patients - refractory neuropathic pain, severe, iatrogenic opioid dependence patients, patients with chronic pain response to doses of strong opioid (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Please note: Patients who are currently receiving prescriptions for methadone in primary care and are STABLE should continue to do so. Do not re-refer to pain clinic. Contact the pain clinic only where further advice is required.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.7.4.2 - Antimigraine drugs

Botulinum Toxin Type A *(Botox®)* TAG recommendation: Jul 2012

for use in: Prophylaxis of headaches in adults with chronic migraine - as per locally agreed policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2012.

Specific points: September 2011: The TAG noted that the East of England Priorities Advisory Committee (PAC) has advised that use of botulinum toxin type A is not recommended for funding.

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the PAC's recommendation and decided NOT to commission or fund botulinum toxin type A for prophylaxis of migraine.

July 2012: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group decided that the treatment is not commissioned until treatment pathway and patient numbers and costs are clarified via Acute Trust business cases.

November 2012:
The TAG noted NICE CG 150 (September 2012 http://guidance.nice.org.uk/CG150) - Diagnosis and management of headaches in young people and adults
and agreed that a flowchart for the management of headaches would be useful. The TAG noted that a headache pathway was currently being developed by West Norfolk CCG.

January 2013:
A service specification for Botox for headaches is being considered by the West, Central and East commissioning groups to decide on the commissioned pathway to support implementation of NICE TA 260 (June 2012).

Eptinezumab *(VYEPTI®)* TAG recommendation: Jun 2023

for use in: preventing migraine TA871 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.7.4.2 - Antimigraine drugs

Fremanezumab *(Ajovy)* TAG recommendation: Mar 2022

for use in: Preventing migraine as per TA764 - Feb 2022 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case and pathway. This recommendation was supported by the D+TC

August 2020 - The TAG approved the business case and recommended a classification of Red (Hospital / Specialist use only). There was a request to consider development of a migraine pathway, key message document and guidance for primary care regarding treatment and referral. This was supported by the D+TC and ratified by the Norfolk and Waveney CCG Governing Body

Jan 2021 - The D+TC advised placing fremanezumab and galcanezumab temporarily above botox in treatment pathway for chronic migraine while covid risk is high. Patient to be assessed after 4 months. Ratified by Chair's Action on behalf of CCG Governing Body

TA631 replaced by TA764. Now covers both chronic and episodic migraine

Galcanezumab *(Emgality®)* TAG recommendation: Jan 2021

for use in: preventing migraine as per TA659 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case. Supported by D+TC and ratified by CCG Governing Body

Jan 2021 - Business case accepted and Red (Hospital / Specialist Only) classification awarded. The D+TC supported the TAG recommendation and advised placing fremanezumab and galcanezumab temporarily above botox in treatment pathway for chronic migraine while covid risk is high. Patient to be assessed after 4 months. Ratified by Chair's Action on behalf of CCG Governing Body

4.8.1 - Control of epilepsy

Cannabidiol *(Epidyolex®)* TAG recommendation: Jun 2023

for use in: seizures caused by tuberous sclerosis complex TA873 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.8.1 - Control of epilepsy

Cannabidiol with clobazam *(Epidyolex®)* TAG recommendation: Jan 2020

for use in: Seizures associated with Dravet syndrome (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Red (Hospital/Specialist only) was afforded for this NHS England commissioning responsibility treatment.

Cannabidiol with clobazam *(Epidyolex®)* TAG recommendation: Jan 2020

for use in: Seizures associated with Lennox–Gastaut syndrome (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: January 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Red (Hospital/Specialist only) was afforded for this NHS England commissioning responsibility treatment.

Fenfluramine *(Fintepla®)* TAG recommendation: Aug 2022

for use in: seizures associated with Dravet syndrome as per TA808 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

4.9.1 - Dopaminergic drugs used in parkinsonism

Apomorphine *(APO-go®)* TAG recommendation: Nov 2011

for use in: Patients with Parkinson's disease with disabling motor fluctuations (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts 3 months.

NICE has not issued any guidance.

Specific points: Presviously prescribed by GPs under a shared care agreement.

Prescribing responsibility returned to the hospital during 2011-12 and provided under homecare service.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.9.1 - Dopaminergic drugs used in parkinsonism

Co-careldopa intestinal gel *(Duodopa® ▼)* TAG recommendation: Sep 2015

for use in: Severe Parkinson's disease inadequately controlled by other preparations - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2006.

Specific points: September 2006:
After lengthy debate TAG members agreed that routine use could not be supported at present due to the lack of strong evidence for effectiveness and benefit.
TAG Decision: Double Red (Not Recommended for Routine Use) but with the exceptional route (criteria for which to be agreed) to be available, until better data and a more thorough evaluation of the drug are available.

September 2013: The TAG noted the draft Priorities Advisory Committee (PAC) policy statement that the commissioning of Duodopa in the management of advanced Parkinson's disease is not recommended. Deep Brain Stimulation (DBS) is not mentioned in the draft PAC statement but is in local and SCG commissioned treatment pathways by which IFRs have been approved and is the criteria which has helped identify exceptionality.

Draft PAC policy statement to be shared with local clinicians for comment and feedback to the PAC.

January 14: Final PAC policy statement September 2013 did not recommend the treatment. The TAG acknowledged the PAC statement and N&W CCGs-D&TCG noted that the treatment is not routinely commissioned in Norfolk & Waveney.

September 2015: The TAG noted D04/P/e (D04X07) (July 2015) (NHS England document) and recommended a revised traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.
The TAG also noted that LCIG is to be provided within designated specialist centres only. Patients to be assessed for eligibility by specialist multidisciplinary teams experienced in the management of advanced Parkinson's Disease which are based at or aligned to centres that provide all specialist treatments for advanced PD (including apomorphine and deep brain stimulation) and have access to clinicians experienced in placement and use of percutaneous endoscopic gastro (PEG) / jejunostomies (PEJ).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

4.9.3 - Drugs used in essential tremor, chorea, tics etc

Botulinum Toxin Type A *(Dysport®)* TAG recommendation: May 2009

for use in: Muscle spasticity in neuromuscular conditions - cerebral palsy - as per locally agreed policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG considered use of botulinum toxin type A for patients with cerebral palsy with muscle spasticity causing e.g. dynamic equinus (inability to achieve heel strike whilst walking).
Treatment would be provided during other visits to hospital for therapy.
The treatment is now commissioned and funded ex-tariff by NHS Norfolk.

September 2012: The TAG noted NICE CG 145 (July 2012 http://guidance.nice.org.uk/CG145) Spasticity in children and young people with non-progressive brain disorders which refers to use of this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.9.3 - Drugs used in essential tremor, chorea, tics etc

Botulinum Toxin Type A *(Botox®)* TAG recommendation: May 2009

for use in: Chronic anal fissure - as per locally agreed policy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Supported as a second-line treatment option after topical GTN, and before surgery.
The treatment is now commissioned and funded ex-tariff by NHS Norfolk.

Botulinum Toxin Type A *(Dysport®)* TAG recommendation: Nov 2011

for use in: Neurogenic and non neurogenic detrusor overactivity in paediatric patients who have not responded to antimuscarinic treatment - as per locally agreed policy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The NHS Norfolk and Waveney Drugs & Therapeutics Commissioning Group agreed to support the TAG's recommendation, providing it is limited to use by the NNUH only at this time in the absence of business applications from the other acute trusts. The committee agreed that an audit of total activity and drug costs should be carried out after 1 year's experience of the treatment and reported back to commissioners.

Botulinum Toxin Type A *(Botox®, Dysport®)* TAG recommendation: Mar 2011

for use in: Treatment of focal spasticity in Multiple Sclerosis or following stroke or brain injury - as per locally agreed policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG's recommendation was noted and approved by NHS Norfolk's D&TCG on 17th March 2011 subject to agreement on use of proforma to record use by specialists.

Botulinum Toxin Type A *(Botox®)* TAG recommendation: Nov 2011

for use in: Oesophageal spasm and nutcracker oesophagus - as per locally agreed policy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The NHS Norfolk and Waveney Drugs & Therapeutics Commissioning Group agreed to support the TAG's recommendation, which is limited to use by the NNUH only at this time in the absence of business applications from the other acute trusts.

The committee agreed that an audit of total activity and drug costs should be carried out after 1 year's experience of the treatment and reported back to commissioners.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.9.3 - Drugs used in essential tremor, chorea, tics etc

Botulinum Toxin Type A *(Botox® - 200 units injection)* TAG recommendation: Sep 2011

for use in: Treatment of achalasia and gastroparesis - as per locally agreed policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG agreed that botulinum toxin for use in achalasia and gastroparesis is a reasonable alternative to surgery but acknowledged that the evidence base is very limited but recommended Red (Hospital Only).

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided to commission and fund use of Botulinum Toxin A (Botox - 200 units injection) for treatment of achalasia and gastroparesis only if the providers agreed to use agreed local proformas to report on activity.

Botulinum Toxin Type A *(Botox®)* TAG recommendation: Sep 2009

for use in: Overactive bladder / detrusor overactivity - as per locally agreed policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2006.

Specific points: Recommended as a fourth line option after physical and psychological treatments, oral drugs, and intravesical oxybutynin.

The treatment is now commissioned and funded ex-tariff by NHS Norfolk.

See also NICE CG 40 Urinary incontinence Oct 2006.
September 2012: The TAG noted NICE CG 148 (August 2012 http://guidance.nice.org.uk/CG148) - Urinary incontinence in neurological disease.

Inotersen *(Tegsedi®)* TAG recommendation: Mar 2023

for use in: Amyloidosis HST9 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2019.

4.10 - Drugs used in substance dependence

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.10 - Drugs used in substance dependence

Naltrexone *(Nalorex® / Opizone®)* TAG recommendation: Jan 2008

for use in: Management of opioid dependence (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: January 2007.

Specific points: January 2011: regarding use in alcohol dependence, the TAG noted the following information:
Naltrexone, although not licensed for this indication in the UK, is used by specialists treating alcohol dependence because of its beneficial effects on the brain's reward system.
There is no current TAG recommendation on use of naltrexone for this indication therefore a business case and proposal for its use would be welcomed to support commissioning this treatment for use in Primary Care.

In the meantime, the TAG would support GPs who elect not to pick up prescribing until a local recommendation and commissioning decision is available.

May 2011: The TAG noted NICE Clinical Guideline 115 - Alcohol use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence.
This clinical guideline offers evidence-based advice on the diagnosis, assessment and management of harmful drinking and alcohol dependence in adults and in young people aged 10-17 years.

This is one of three pieces of NICE guidance addressing alcohol-related problems and should be read along with:
- Alcohol-use disorders: preventing the development of hazardous and harmful drinking. NICE public health guidance 24 (2010) - public health guidance on the price, advertising and availability of alcohol, how best to detect alcohol misuse in and outside primary care, and brief interventions to manage it in these settings.
- Alcohol-use disorders: diagnosis and clinical management of alcohol-related physical complications. NICE clinical guideline 100 (2010) - clinical guideline covering acute unplanned alcohol withdrawal including delirium tremens, alcohol-related liver damage, alcohol-related pancreatitis and management of Wernicke's encephalopathy.

4.10.1 - Drugs used in substance misuse

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.10.1 - Drugs used in substance misuse

Acamprosate *(Campral EC / generics are available)* TAG recommendation: May 2018

for use in: Maintenance of abstinence in alcohol-dependent patients (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: May 2018:
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

The TAG also noted that local alcohol misuse services are comissioned by Norfolk County Council, with service and prescribing provided by Change Grow Live (CGL)
Related treatments should therefore not be prescribed by the GPs.
The TAG recommended a classification of Red (Specialist only) to clarify this position.

May 2018: The D&TC noted and supported the TAG's recommendations and also confirmed that prescribing of treatments for alcohol misuse, including acamprosate and disulfiram (and also nalmefene) are the responsibility of the specialist since local alcohol misuse services are not commissioned from GPs practices - recommended to be classified as Red (Specialist only).

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations.

Disulfiram *(Generics are available)* TAG recommendation: May 2018

for use in: Maintenance of abstinence in alcohol-dependent patients (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: May 2018:
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

The TAG also noted that local alcohol misuse services are comissioned by Norfolk County Council, with service and prescribing provided by Change Grow Live (CGL)
Related treatments should therefore not be prescribed by the GPs.
The TAG recommended a classification of Red (Specialist only) to clarify this position.

May 2018: The D&TC noted and supported the TAG's recommendations and also confirmed that prescribing of treatments for alcohol misuse, including acamprosate and disulfiram (and also nalmefene) are the responsibility of the specialist since local alcohol misuse services are not commissioned from GPs practices - recommended to be classified as Red (Specialist only).

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.10.1 - Drugs used in substance misuse

Naltrexone *(Nalorex® / Opizone®)* TAG recommendation: Nov 2016

for use in: Alcohol misuse disorder - controlled drinking (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2011: The NWMHFT submitted an application for the use of naltrexone in alcohol misuse disorders. The aim of treatment is to reduce the desire for alcohol and the reward from it.

Two different aspects were considered; to maintain abstinence and to control drinking. NICE Clinical Guideline 115 (http://guidance.nice.org.uk/CG115) indicates that if a person carries on drinking naltrexone should be stopped, whereas the NWMHFT wish to use naltexone for people who can't stop drinking completely.

The TAG agreed that a future Shared Care Agreement should only cover use of naltrexone for abstinence and that patients who continue to drink should be managed by the consultant specialists.

The TAG did not approve use for controlled drinking in Primary Care but supported use of naltrexone to maintain abstinence from alcohol in principle.

The TAG recommended that in the interim no further requests for use of naltrexone should be made to Primary Care until clarification on its place in therapy has been agreed. i.e. Red (Hospital Only).

The NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group supported the TAG's interim recommendation on 17th November 2011.

March 2012:
The TAG considered a revised business case from the TADS which proposed use of naltrexone in maintaining abstinence from alcohol (as an alternative to acamprosate and disulfiram), and also for use as a short course for use in people to help them achieve abstinence - i.e. structured reduction in controlled drinking with the aim of achieving abstinence. The TAG noted that the latter proposed indication was a different patient group from that discussed previously and noted that the business case did not provide information to support both proposed indications for use.

The TAG agreed that due to the lack of evidence presented it was unable to support use of naltrexone for use in structured reduction of controlled drinking.

The TAG noted that the TADS application and shared care proposal stated that blood tests / LFTs should be carried out monthly whilst stating that NICE does not specifically recommend monitoring requirements for patients taking naltrexone in AUD. The TAG felt that if not required by NICE, GPs should not be asked to carry out these tests.

Although there was a wish amongst some TAG members to have separate business cases for each proposed indication, separate shared care proposals for each proposed indication, and independent evidence reviews for each indication, the TAG agreed that in the spirit of fairness and pragmatism, since the TAG's view on necessary information was evolving with each meeting, it would accept the case for use of naltrexone for abstinence in alcohol use disorder supported by NICE guidance, provided that the TADS covered monitoring requirements for the condition (LFTs etc).
The draft Shared Care Agreement would be amended to reflect the changes recommended by the TAG and taken through the Trust's own prescribing committee to ensure support if appropriate.

The TAG therefore recommended use of naltrexone in AUD is maintained as Red (Hospital /Specialist use only) until such time as final agreement could be reached on a shared care agreement to support GP prescribing for abstinence.

March 2012: Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

4.10.1 - Drugs used in substance misuse

November 2016:
The recommended changes to the Shared Care Prescribing Agreement for Naltrexone for Abstinence in Alcohol Use Disorder to be finalised and the revised version to be published on Knowledge Anglia.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the revised shared care agreement.

4.12 - miscellaneous

Patisiran *(Onpattro)* TAG recommendation: Mar 2023

for use in: hereditary transthyretin amyloidosis HST10 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

4.13 - Other Nervous System medicines

Cerliponase *((Brineura®))* TAG recommendation: Mar 2023

for use in: Neuronal Ceroid Lipofuscinosis, type 2 (CLN2) from birth, also known as tripeptidyl peptidase 1 (TPP1) deficiency HST12 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2019.

Vutrisiran *(Amvuttra®)* TAG recommendation: Mar 2023

for use in: hereditary transthyretin-related amyloidosis TA868 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

5.1 - Antibacterial drugs

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1 - Antibacterial drugs

Antibiotics - intravenous / inhalation *(Various)* TAG recommendation: Jul 2012

for use in: Cystic fibrosis (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: This includes the IV antibacterial drugs:
Amikacin, Azteronam, Ceftazidime, Cefotaxime, Cefoxitin, Ceftriaxone, Co-Amoxiclav, Colistin, Flucloxacillin, Gentamicin, Meropenem, Piperacillin, Tobramycin.

July 2012: The TAG noted a draft General policy on the treatment of adults and children with Cystic Fibrosis, from the Specialised Commissioning Group (SCG) / East of England Priorities Advisory Committee (PAC) which does not include management of bronchiectasis. National treatment centre is in Birmingham. Drug treatments not included in the contract but are provided in-tariff by local acute trusts.

April 2013: NHS England SCG took over commissioning responsibility for these treatments.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

5.1.2 - Cephalosporins, cephamycins, & other beta-lactams

Ceftriaxone *(Rocephin®)* TAG recommendation: Nov 2003

for use in: Cellulitis - as per local policy (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: Use is supported as part of a Shared Care Protocol developed by the Medical Assessment Unit at the NNUH.
Prescribing responsibility, provision of drug therapy and IV administration equipment, patient counselling regarding cannula care, training of community nursing staff, are carried out by the NNUH. (For further information contact Dr Rob Mallinson, Consultant in Emergency Medicine, or Julie Hart, Enhanced Practice Co-ordinator).

5.1.4 - Aminoglycosides

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.4 - Aminoglycosides

Gentamicin (nebulised) *()* TAG recommendation: May 2013

for use in: Ps. aeurginosa infection in non-Cystic Fibrosis bronchiectasis (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Given in-house at NNUH on a case by case basis as approved by microbiology. Request for patients who can tolerate it and for whom it is effective to have on-going treatment provided by Primary Care. Colistemethate is used first-line at the moment. Emerging evidence that gentamicin is more effective with potential for cost savings.
The TAG heard a report of an adverse event where a patient on gentamicin for this indication had suffered otoxicity with loss of hearing. Renal problems also reported with gentamicin.
The TAG agreed that if gentamicin were to be used within Primary care, appropriate guidance for GPs is required. The TAG could not support use of nebulised gentamicin in Primary Care for the time-being because of these issues.
Business application and shared care proposal covering both treatments to return to the TAG in July 2013.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decision:
Nebulised Colistimethate sodium, or nebulised gentamicin for Ps. Aeurginosa infection in non-CF bronchiectasis are commissioned as Red (Hospital /Specialist Only) until a Shared Care Agreement has otherwise been approved via the TAG.

July 2013: NNUH Shared Care Proposal for use of nebulised colistemethate sodium following business application (May 2013) -
Only issue is the provision of syringes in primary care. The document to be reworded to reflect the fact that syringes would be supplied by the Trusts.
Nebulised Colistimethate sodium for (non-CF) bronchiectasis was therefore recommended to be classified as Amber (Option for GP prescribing under an approved shared care agreement).

The D&TCG noted that it was likely that GPs had been prescribing for these patients as for patients with cystic fibrosis.
Costly treatment - use in Primary care will be monitored.

Confirmed as CCG-commissioning responsibility for this indication.
Commissioned as per TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.4 - Aminoglycosides

Tobramycin (nebulised) *(Tobi®, Bramitob®)* TAG recommendation: Mar 2015

for use in: Pseudomonas aeruginosa infection in patients with Cystic Fibrosis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts 28 days.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: March 2013: Shared care agreement reviewed to include Bramitob. Supported by the TAG and the D&TCG.

Use of shared care agreement to be continued during transition of CF services to the NHS England Specialised Commissioning Group (SCG) i.e. as Amber (option for GP prescribing under an approved shared care prescribing agreement) during 2013 as necessary.
Available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/tobramycin_nebuliser_sltn.pdf

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

March 2014: Shared Care Agreement reviewed and use extended until March 2015. Supported by the TAG and D&TCG.

March 2015: The TAG was asked to review classification from Amber (Option for GP prescribing under an approved Shared Care Agreement) to Red since confirmation had been received that all local patients have been repatriated. The shared care agreement could therefore be revoked.

The TAG confirmed that classification of Red (Hospital/Specialist only) should be recommended for Tobramycin Nebuliser Solution for chronic pulmonary infection in CF.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation to re-classify Tobramycin Nebuliser Solution for use in patients with cystic fibrosis to Red (Hospital/Specialist only).

November 2017:

Tobramycin Dry Powder Inhaler *(Tobi Podhaler®)* TAG recommendation: May 2013

for use in: Pseudomonas lung infection in Cystic Fibrosis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2013.

Specific points: May 2013: The TAG noted NICE TA 276 (March 2013) which confirmed the NICE FAD from January 2013. Colistimethate sodium and Tobramycin Dry Powders for Inhalation are the commissioning responsibility of Specialised Commissioning (NHS England) from April 2013 and are within the Cystic Fibrosis tariff.

Clarification regarding the repatriation of CF treatments to hospital specialists is being sought.

May 2013:
The N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG confirmed these treatments as Red (Hospital / Specialist only) in line with NICE TA 276 (March 2013)

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

5.1.7 - Polymyxin antibiotics

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.7 - Polymyxin antibiotics

Colistimethate sodium (nebulised) *(Colomycin®, Promixin®)* TAG recommendation: May 2013

for use in: Pseudomonas lung infection in Cystic Fibrosis (new patients from 1st April 2013) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2013.

Specific points: Colistimethate sodium and other treatments for CF are the commissioning responsibility of Specialised Commissioning (NHS England) from April 2013 and are within the Cystic Fibrosis tariff.

Clarification is being sought regarding the repatriation of CF treatments to hospital specialists in line with direction from the NHS England SCG.

Prescribing responsibility for new patients requiring this treatment (from April 1st 2013) should remain under specialist care.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Colistimethate sodium Dry Powder Inhaler *(Colobreathe® Dry Powder Inhaler)* TAG recommendation: May 2013

for use in: Pseudomonas lung infection in cystic fibrosis - as per NICE TA 276 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2013.

Specific points: Colistimethate sodium and Tobramycin Dry Powders for Inhalation are the commissioning responsibility of Specialised Commissioning (NHS England) from April 2013 and are within the Cystic Fibrosis tariff.

Clarification is being sought regarding the repatriation of CF treatments to hospital specialists in line with direction from the NHS England SCG.

Red (Hospital / Specialist only) in line with NICE TA 276 (March 2013)

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.7 - Polymyxin antibiotics

Linezolid *(Zyvox®)* TAG recommendation: Jul 2005

for use in: Pneumonia, complicated skin and soft tissue infections caused by G+ve bacteria (Not a licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: The CSM recommends FBC monitored weekly.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.7 - Polymyxin antibiotics

Rifaximin *(Targaxan®)* TAG recommendation: Jul 2012

for use in: Treatment and prophylaxis of secondary hepatic encephalopathy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2015.

Specific points: July 2012: NNUH application for use
Recommended for patients who are not drinking, are not on the liver transplant list, or for whom liver transplant is contraindicated, and who have received the maximum dose of lactulose and phosphate enemas to be suitable for therapy but without adequate response.
Rifamixin will be stopped in patients who have failed to respond after 7 to 10 days.

Prescriber's Rating: 3 "Offers an advantage The product has some value but does not fundamentally change present therapeutic practice"

The TAG recommended Rifaximin for this indication as Amber (option for shared care under an approved Shared Care Agreement (SCA)). Since the SCA has yet to be agreed the treatment will remain as Red (Hospital Only for this indication).

19th July 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided that the treatment is commissioned as per an In-Tariff treatment and recommended that provision should be via Homecare as appropriate.
TAG recommendation overturned to Red (Hospital Only) - Rifaximin is therefore not funded for prescribing in Primary Care for treatment and prophylaxis of secondary hepatic encephalopathy.

May 2015: The TAG acknowledged the NICE TA 337 (March 2015) - and recommended a classification of Red (Hospital Only) for Rifaximin (Targaxan®) for preventing episodes of overt hepatic encephalopathy in patients aged 18 years and older.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

January 2016:
The TAG considered a shared care proposal for use of rifaximin from the QEH and recommended some changes to the first draft.

March 2016:
The TAG acknowledged and supported the updated shared care proposal and the NNUH's revised business application and confirmed the previous clinical recommendation that use of rifaximin (Targaxan®) for reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age should be classified as Amber (Option for Shared Care Prescribing under an approved shared care agreement).

A holding traffic light recommendation of Red (Hospital/Specialist only) was recommended pending a final commissioning decision was reached.

March 2016:
The D&TCG decided not to change the current commissioning position for this treatment for the following reasons:
* The Trusts' business applications did not demonstrate clear cost savings for the local health economy.
* In view of the current financial position, local CCGs cannot currently justify additional costs in primary care where there is uncertainty regarding the cost benefit.
* The D&TCG did not feel that this group of patients would be disadvantaged by not approving GP-prescribing of rifaximin, since they already regularly attend hospital for specialist appointments as part of their care.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.7 - Polymyxin antibiotics

Rifaximin *(Xifaxanta/Targaxan)* TAG recommendation: Nov 2021

for use in: pouchitis in UC where previous treatment has failed (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: This classification only covers pouchitis in UC where treatment has failed. See additional entries for other indications

Teicoplanin *(Targocid®)* TAG recommendation: Mar 2002

for use in: Intravenous treatment at home (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: District nurses can administer if suitably trained.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

5.1.9 - Antituberculosis drugs

Bedaquiline ▼ *(Sirturo® ▼)* TAG recommendation: Sep 2015

for use in: Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted F04/P/a (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Patient selection: Bedaquiline (Sirturo®)
* Only for use as part of combination therapy (minimum four-drug treatment regimen), and
* For a maximum of 24 weeks (6 months) at a suggested dosing (400 mg daily for the first 2 weeks, then 200mg three times per week for 22 weeks); and
* Prescribed for treatment of adults (aged 18 to 65) with proven MDR- or XDR-TB and documented resistance to fluoroquinolones; and
* Provided as part of supervised treatment of adults

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

March 2016: The TAG noted NG 33 (January 2016) - Tuberculosis (SCG-commissioning responsibility)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.9 - Antituberculosis drugs

Delamanid *(Deltyba®)* TAG recommendation: Sep 2015

for use in: Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted F04/P/a (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Patient selection: Delamanid (Deltyba®)
* Only for use as part of a combination therapy (minimum four-drug treatment regimen) and
* For a maximum of 24 weeks (6 months) at 100 mg twice daily;
* Only for adults (aged 18 to 65) with proven MDR- or XDR-TB
* Provided as part of supervised treatment of adults

Bedaquiline and Delamanid must not be added alone to a failing regimen.

October 2015:
Noted by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

March 2016: The TAG noted NG 33 -Tuberculosis (January 2016) (SCG-commissioning responsibility).

5.1.12 - Quinolones

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.1.12 - Quinolones

Moxifloxacin *(Avelox®)* TAG recommendation: May 2013

for use in: Respiratory infection, including resistant TB (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: March 2011.

Specific points: Limited to Hospital Use only, under the advice of a consultant.

September 2010: The TAG agreed to support an application for use of moxifloxacin in resistant cases of tuberculosis as recommended by Consultant Microbiologists.

May 2011: The TAG Noted NICE Clinical Guideline 117 (March 2011) - Clinical diagnosis and management of tuberculosis, and measures for its prevention and control.
This updates and replaces NICE clinical guideline 33 (published March 2006). New recommendations on using interferon-gamma tests for the diagnosis of latent tuberculosis have been added.
The guideline offers evidence-based advice on the diagnosis and treatment of active and latent tuberculosis in adults and children, and on preventing the spread of tuberculosis, for example by offering tests to people at high risk, and by vaccination. The guideline does not explain tuberculosis or its treatments in detail.

May 2013: Patients presently receiving this treatment and who are exempt from prescription charges have the treatment provided via an FP10 in the community.
DoH regulations state that drug treatment of tuberculosis should be provided by specialist services in hospitals to monitor patient compliance with treatment.
Moxifloxacin is also associated with liver damage and is not generally suitable for GPs to prescribe.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decision -
Red (Hospital/Specialist prescribing only) for all patients.

CCGs will seek reimbursement for any Primary Care prescribing related to these patients.

March 2016: The TAG noted NG 33 -Tuberculosis (January 2016) (SCG-commissioning responsibility).

5.2 - Antifungal agents

Anidulafungin *(Ecalta®)* TAG recommendation: May 2018

for use in: Fungal infection - invasive candidiasis (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.2 - Antifungal agents

Isavuconazole *(Cresemba®)* TAG recommendation: May 2018

for use in: Systemic fungal infections (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Trust guidelines apply.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Voriconazole *(Vfend®)* TAG recommendation: Nov 2007

for use in: Systemic fungal infections (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: In view of the significant side-effects and monitoring requirements related to this drug, the TAG agreed that GPs should not be approached to prescribe voriconazole.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

5.2.1 - Triazole antifungals

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.2.1 - Triazole antifungals

Posaconazole *(Noxafil®)* TAG recommendation: Mar 2011

for use in: Systemic fungal infections - as per Trust Guidelines & NHSE policy (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: March 2011:
The Chronic pulmonary Aspergillosis Service was designated and nationally commissioned from April 2009. It is a single centre service provided at the University Hospital of South Manchester NHS Foundation Trust.
All anti-fungal therapies for the treatment of CPA are to be commissioned nationally.
There should be no local prescribing of anti-fungal therapies for the treatment of CPA.

Following a review of the evidence, in conjunction with the service provider, the following treatments are recommended:
* Short course IV amphotericin B for in-patient treatment to induce disease control in severely ill patients before transfer to oral itraconazole.
* Antifungal therapy limited to oral itraconazole (1st line) with oral voriconazole available only for those who are intolerant or resistant to itraconazole.
* Patients intolerant or resistant to voriconazole will receive either (i) supportive care or non-pharmaceutical intervention (subject to further presentation of evidence) or (ii) additional anti-fungal therapy offered only as part of a robust clinical trial commissioned and funded outside the NCG contract. Therefore, the use of posaconazole, long-term IV amphotericin B, IV micafungin or IV gamma interferon (the latter solely as a treatment for chronic pulmonary aspergillosis) should not be routinely commissioned because of the lack of evidence to support their use.
* Individual funding requests for patients considered to be exceptional to this policy will be submitted (subject to clarification of this process) and, where appropriate, funded by NCG.

November 2013: Policy adopted by the NHS England SCG - http://www.england.nhs.uk/wp-content/uploads/2013/06/a14-chron-pulm-asper-ad.pdf

May 2018:
May 2018:
This treatment is NHS England commissioning responsibility. Trust Guidelines & NHSE policy

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.2.4 - Echinocandin antifungals

Caspofungin *(Cancidas®)* TAG recommendation: Jul 2011

for use in: Systemic candidiasis - - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2011: The TAG agreed to support use of caspofungin as per the NNUH Trust's Guideline on Management of invasive candida infections / candidaemia.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

5.3 - Antiviral drugs

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3 - Antiviral drugs

Casirivimab and Imdevimab *(Ronapreve)* TAG recommendation: Oct 2021

for use in: •First monoclonal antibody treatment for COVID-19 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: NHS England commissioned treatment. Restriction - only for hospital patients who meet specific criteria - covid positive/seronegative.

HIV/AIDS treatments *(Various)* TAG recommendation: Jan 1997

for use in: HIV infection / post exposure prophylaxis (PEP) (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for these treatments.

March 2015: The TAG noted and acknowledged NHSE (Expert Advisory Group on AIDS) SSC 1458 (Nov 2014) which recommends a change to recommended antiretroviral regimen for post-exposure prophylaxis (PEP) for prevention of HIV.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted and acknowledged NHSE SSC 1458 (Nov 2014).

Molnupiravir *(Lagevrio®)* TAG recommendation: Dec 2021

for use in: Restricted for use in line with NHSE criteria for treatment of COVID-19 disease (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Nirmatrelvir and ritonavir *(Paxlovid)* TAG recommendation: Jan 2022

for use in: Treatment of covid-19 as per NHSE policy (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3 - Antiviral drugs

Palivizumab *(Synagis®)* TAG recommendation: Jul 2011

for use in: Prevention of Respiratory Syncytial Virus (RSV) in infants (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2011: The TAG noted that the recently updated section in Immunisations Against Infectious Disease ("The Green Book"), is now viewed as providing approved guidance in this condition.
Clinicians should refer to http://www.dh.gov.uk/en/Publichealth/Immunisation/Greenbook/index.htm

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Ribavirin *(Copegus®, Rebetol®)* TAG recommendation: Nov 2007

for use in: Chronic hepatitis C (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2010.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

5.3.1 - HIV Infection

Abacavir *(Ziagen®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Abacavir + dolutegravir + lamivudine *(Triumeq®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.
NHS England Policy: B06/P/b

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Abacavir and lamivudine *(Generics are available)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Antiretroviral therapy (ART) *(Various)* TAG recommendation: Sep 2015

for use in: Treatment as Prevention (TasP) - as per NHS England policy (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted F03/P/c (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment as Prevention (TasP) in HIV infected adults is use of antiretroviral therapy (ART) for people with diagnosed HIV with the aim of preventing HIV transmission to others rather than primarily for their own clinical benefit.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Atazanavir *(Reyataz®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Atazanavir and Cobicistat *(Evotaz®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA guidelines (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Cabotegravir *(Vocabria®)* TAG recommendation: Mar 2022

for use in: with rilpivirine for treating HIV-1 as per TA757 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2022.

Specific points: NHS England commissioned

Cidofovir *(Vistide®)* TAG recommendation: May 2018

for use in: Cytomegalovirus (CMV) infection (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Used in line with Trust Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Cobicistat ▼ *(Tybost® ▼)* TAG recommendation: Sep 2015

for use in: Use as a booster in treatment of HIV positive adults and adolescents - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted F03/P/b (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of HIV positive adults and adolescents:
* as part of the FDC of elvitegravir / cobicistat / emtricitabine / tenofovir (as set out in the policy F03/P/b), or
* used as single agent booster of protease inhibitors in adults and adolescents with HIV (as per its licence) and who have ritonavir intolerance, and
* when ritonavir intolerance has been discussed, agreed and recorded in the HIV specialist multidisciplinary team (MDT) meeting.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Darunavir *(Prezista®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Darunavir and Cobicistat (Rezolsta®) *(Rezolsta®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Didanosine *(Videx®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Dolutegravir ▼ *(Tivicay® ▼)* TAG recommendation: Jul 2015

for use in: (in combination with other antiretroviral drugs) Treatment of HIV-1 infection in adults and adolescents - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2015:
The TAG and the D&TCG noted NHS England Clinical Commissioning Policy B06/P/a (January 2015) - Dolutegravir (Tivicay®) for treatment of HIV-1 in adults and adolescents

NHS England SCG-commissioning responsibility

Efavirenz *(Sustiva®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Elvitegravir *(Part of Genvoya®; Stribild®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per NHS England Policy 16043/P (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England policy.
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Elvitegravir/cobicistat/emtricitabine/tenofovir ▼ *(Stribild® ▼)* TAG recommendation: Sep 2015

for use in: HIV infection - as per NHS England policy 16043/P (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted F03/P/a (July 2015) (NHS England) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

For treatment of HIV in adults who:
* are unable to take efavirenz due to toxicity, intolerance or adherence issues as agreed in the HIV specialist multidisciplinary team (MDT), or
* are unable to take other first or second line treatments due to toxicity, intolerance or adherence issues as agreed in the HIV specialist multidisciplinary team (MDT).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Emtricitabine *(Emtriva®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Emtricitabine and tenofovir *(Truvada®)* TAG recommendation: May 2018

for use in: (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Emtricitabine and Tenofovir alafenamide fumarate *(Descovy®)*

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Emtricitabine, Rilpivirine, tenofovir alafenamide *(Odefsey®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16043/P

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Enfuvirtide *(Fuzeon®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Etravirine *(Intelence)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Fosamprenavir *(Telzir®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs- with low-dose ritonavir (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Indinavir *(Crixivan)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Lamivudine *(Epivir, Zeffix (generic also available))* TAG recommendation: Jul 2013

for use in: Chronic hepatitis B (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2013.

Specific points: The TAG noted NICE CG 165 (June 2013) which updates and replaces 1.2 to 1.4 in NICE TA 96 regarding adefovir dipivoxil. NICE TAs 153, 154, 173 and 1.1 of NICE TA 96 have been incorporated into CG165 and remain extant.

April 2013: NHS England Specialised Commissioning responsibility.

July 2013: NICE CG 165 (June 2013) noted by the TAG and the D&TCG.

Lopinavir (with ritonavir) *(Kaletra®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Maraviroc *(Celsentri®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nelfinavir *(Viracept®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Nevirapine *(Viramune®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. BHIVA Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Raltegravir *(Isentress®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rilpivirine *(Edurant®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ritonavir *(Norvir®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Saquinavir *(Invirase)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Stavudine *(Zerit®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs when no suitable alternative available and when prescribed for shortest period possible (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility - as per BHIVA guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Tenofovir alafenamide fumarate *(Vemlidy®)* TAG recommendation: May 2018

for use in: HIV in combination with other anti-retroviral drugs - as per NHS England Policy 16043/P (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.1 - HIV Infection

Tenofovir disoproxil *(Viread®)* TAG recommendation: Sep 2009

for use in: Treatment of chronic hepatitis B (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2009.

Specific points: NHS England Specialised Cimmissioning responsibility from April 2013.

July 2013:
The TAG noted NICE CG 165 (June 2013) which updates and replaces 1.2 to 1.4 in NICE TA 96 regarding adefovir dipivoxil.
NICE Tas 153, 154, 173 and 1.1 of NICE TA 96 have been incorporated into CG165 and remain extant.

Tipranavir *(Aptivus®)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs - as per BHIVA Guidelines (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Zidovudine (also with lamivudine and Abacavir) *(Retrovir® / Combivir® / Trizivir® / Generics)* TAG recommendation: May 2018

for use in: HIV infection in combination with other antiretroviral drugs (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
These treatments are NHS England commissioning responsibility. As per BHIVA Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

5.3.2.2 - Cytomegalovirus infection

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.2.2 - Cytomegalovirus infection

Foscarnet *(Foscavir®)* TAG recommendation: May 2018

for use in: CMV infection (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ganciclovir sodium *(Cymevene)* TAG recommendation: May 2018

for use in: Cytomegalovirus infection (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Trust Guidelines

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Maribavir *(Livtencity®)* TAG recommendation: Mar 2023

for use in: refractory cytomegalovirus infection after transplant TA860 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.2.2 - Cytomegalovirus infection

Valganciclovir *(Valcyte®)* TAG recommendation: Jan 2008

for use in: Prevention of CMV disease following solid organ transplantation (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: Valganciclovir is provided by transplant centres under contract with the Department of Health and National Specialised Commissioning Services. Centres are contracted to provide medication for the first three months after transplantation or until the patient is stable. Patients require 100 days of prophylactic treatment against CMV infection with valganciclovir post transplant.

The TAG agreed that valganciclovir is not suitable for prescribing in primary care and that GPs should not be approached or be expected to prescribe it.

* On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group noted that recent guidance from the USA has resulted in the Addenbrooke's Hospital recommending that valganciclovir is used for 200 days CMV prophylaxis post transplantation (instead of 100 days as per the licensed indication). This has led to pressure on local Acute Hospital Trusts to provide the extra 100 days' treatment without funding being agreed. GPs have also been picking up prescribing, despite valganciclovir being an inappropriate drug for use in Primary Care.
* The D&TCG noted that extended use of valganciclovir was not highlighted under Horizon Scanning and that a Business Case to support use its use would be required.
* The D&TCG therefore confirmed that at present, valganciclovir for prevention of CMV disease post solid organ transplantation is funded under National Specialised Commissioning arrangements only for up to 100 days' use in hospital and is not funded for use in Primary Care.

NHS England Specialised Cimmissioning responsibility from April 2013.

5.3.3 - Viral hepatitis

Boceprevir *(Victrelis®)* TAG recommendation: Jul 2012

for use in: Treatment of genotype 1 chronic hepatitis C - as per NICE TA 253 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2012.

Specific points: NICE TA 253: Boceprevir is recommended as an option for the treatment of genotype 1 chronic hepatitis C in combination with peginterferon alfa and ribavirin.

NHS England Specialised Cimmissioning responsibility from April 2013.

Bulevirtide *(Hepcludex®)* TAG recommendation: Jul 2023

for use in: chronic hepatitis D TA896 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3 - Viral hepatitis

Entecavir *(Baraclude®)* TAG recommendation: Jul 2013

for use in: Chronic hepatitis B - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2013.

Specific points: NHS England Specialised Commissioning responsibility from April 2013.

NICE CG 165 (June 2013) updates and replaces 1.2 to 1.4 in NICE TA 96 regarding adefovir dipivoxil.
NICE Tas 153, 154, 173 and 1.1 of NICE TA 96 have been incorporated into CG165 and remain extant.

Telaprevir *(Incivo®)* TAG recommendation: Jul 2012

for use in: Treatment of genotype 1 chronic hepatitis C (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2012.

Specific points: NICE TA 252: Telaprevir is recommended as an option for the treatment of genotype 1 chronic hepatitis C in combination with peginterferon alfa and ribavirin.

NHS England Specialised Cimmissioning responsibility from April 2013..

5.3.3.2 - Chronic hepatitis C

Daclatasvir ▼ *(Daklinza® ▼)* TAG recommendation: Jan 2016

for use in: For treating chronic hepatitis C in adults (with sofosbuvir or peginterferon alfa, and with ribavirin) as per NICE TA 364 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2015.

Specific points: January 2016: The TAG noted NICE TA 364 (November 2015) for treating chronic hepatitis C as follows:
No previous treatment of hepatitis C:
Type 1 hepatitis, without cirrhosis - Daclatasvir plus sofosbuvir only for people with significant fibrosis - 12 weeks
Type 4 hepatitis - Daclatasvir plus peginterferon alfa and ribavirin, only for significant fibrosis or cirrhosis - 24 weeks
Previous treatment of hepatitis C:
Type 1 or 4 hepatitis without cirrhosis - Daclatasvir plus sofosbuvir, only for significant fibrosis - 12 weeks
Type 4 hepatitis - Daclatasvir plus peginterferon alfa and ribavirin, only for people with significant fibrosis or cirrhosis – 24 weeks
If unable to have interferon:
Types 1, 3 or 4 hepatitis without cirrhosis - Daclatasvir plus sofosbuvir, only for people with significant fibrosis - 12 weeks
Types 1 or 4 hepatitis with cirrhosis - Daclatasvir plus sofosbuvir, with or without ribavirin - 24 weeks
Type 3 hepatitis, with cirrhosis - Daclatasvir plus sofosbuvir and ribavirin - 24 weeks
and recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3.2 - Chronic hepatitis C

Elbasvir-grazoprevir ▼ *(Zepatier® ▼)* TAG recommendation: Nov 2016

for use in: Genotype 1 or 4 chronic hepatitis C in adults - as per NICE TA 413 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2016.

Specific points: November 2016:
The TAG noted NICE TA 413 (October 2016) recommended by NICE, within its marketing authorisation, as an option for treating chronic hepatitis C in adults, as specified in the guidance, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unitand and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Glecaprevir *(Maviret® (combi product with pibrentasvir))* TAG recommendation: May 2018

for use in: Chronic hepatitis C - as per NICE TA 499 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

Glecaprevir-pibrentasvir ▼ *(Maviret® ▼)* TAG recommendation: Mar 2018

for use in: Chronic hepatitis C (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 499 (January 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3.2 - Chronic hepatitis C

Ledipasvir-sofosbuvir ▼ *(Harvoni® ▼)* TAG recommendation: Jan 2016

for use in: For treating chronic hepatitis C as per NICE TA 363 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2015.

Specific points: January 2016: The TAG noted NICE TA 363 (November 2015) for treating chronic hepatitis C as follows:
No previous treatment of hepatitis C:
Type 1 hepatitis C, without cirrhosis - 8 weeks' treatment
Type 1 or 4 hepatitis C, with cirrhosis - 12 weeks' treatment
Inadequate response to previous treatment of hepatitis C:
Type 1 or 4 hepatitis C, without cirrhosis - 12 weeks' treatment
Type 1 or 4 hepatitis, with cirrhosis - 12 weeks' treatment, only if low risk of disease progression
and recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ombitasvir-paritaprevir-ritonavir ▼ *(Viekirax® ▼)* TAG recommendation: Jan 2016

for use in: Genotype 1 or 4 chronic hepatitis C in adults (with or without dasabuvir (Exviera®) as per NICE TA 365 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2015.

Specific points: January 2016: The TAG noted NICE TA 365 (November 2015) for treating chronic hepatitis C in adults (with or without dasabuvir (Exviera®)) as follows:
Type 1a hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 1a hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 24 weeks
Type 1b hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir - 12 weeks
Type 1b, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 4 hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 12 weeks
Type 4 hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 24 weeks
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3.2 - Chronic hepatitis C

Paritaprevir-ombitasvir-ritonavir ▼ *(Viekirax®)* TAG recommendation: Jan 2016

for use in: Genotype 1 or 4 chronic hepatitis C in adults (with or without dasabuvir (Exviera®) as per NICE TA 365 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2015.

Specific points: January 2016: The TAG noted NICE TA 365 (November 2015) for treating chronic hepatitis C in adults (with or without dasabuvir (Exviera®)) as follows:
Type 1a hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 1a hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 24 weeks
Type 1b hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir - 12 weeks
Type 1b, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 4 hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 12 weeks
Type 4 hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 24 weeks
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Pibrentasvir *(Maviret® (Combi product with glecaprevir))* TAG recommendation: May 2018

for use in: Chronic hepatitis C - as per NICE TA 499 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3.2 - Chronic hepatitis C

Ritonavir-paritaprevir-ombitasvir ▼ *(Viekirax®)* TAG recommendation: Jan 2016

for use in: Genotype 1 or 4 chronic hepatitis C in adults (with or without dasabuvir (Exviera®) as per NICE TA 365 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2016.

Specific points: January 2016: The TAG noted NICE TA 365 (November 2015) for treating chronic hepatitis C in adults (with or without dasabuvir (Exviera®)) as follows:
Type 1a hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 1a hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 24 weeks
Type 1b hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir - 12 weeks
Type 1b, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with dasabuvir and ribavirin - 12 weeks
Type 4 hepatitis, without cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 12 weeks
Type 4 hepatitis, with cirrhosis - Ombitasvir-paritaprevir-ritonavir with ribavirin - 24 weeks
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Simeprevir *(Olysio®)* TAG recommendation: Mar 2015

for use in: Treatment of genotypes 1 and 4 chronic hepatitis C (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: March 2015: The TAG acknowledged the NICE TA331 (February 2015), which recommends use of simeprevir in combination with peginterferon alfa and ribavirin, and recommended a classification of Red (Hospital/Specialist use only) for this NHS England SCG-commissioned drug.

The TAG also noted the NHS England Specialised Services Circular (SSC) 1467 (January 2015) - Clinical Commissioning Policy Statement A02/PS/C regarding simeprevir for treatment of genotype 1 chronic hepatitis C - interim policy to provide patients who do not meet the criteria for early access to sofosbuvir plus ledispavir with an alternative to current NICE-approved treatments.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted NICE TA 331 and the TAG's recommendation.

Sofosbuvir ▼ *(Sovaldi® ▼)* TAG recommendation: Mar 2015

for use in: Treatment of chronic hepatitis C in adults - as per NICE TA 330 and NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: March 2015: The TAG acknowledged the NICE TA 330 and recommended a classification of Red (Hospital/Specialist use only) for this NHS England SCG commissioned drug.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

5.3.3.2 - Chronic hepatitis C

Sofosbuvir-velpatasvir ▼ *(Epclusa® ▼)* TAG recommendation: Mar 2017

for use in: Chronic hepatitis C in adults - as pert NICE TA 430 and NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2017.

Specific points: March 2017: The TAG acknowledged NICE TA 430 (January 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Sofosbuvir-velpatasvir-voxilaprevir ▼ *(Vosevi® ▼)* TAG recommendation: Mar 2018

for use in: Chronic hepatitis C in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 507 (February 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

6.1.1 - Insulins

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.1.1 - Insulins

Insulin pump therapy *(Continuous Subcutaneous Insulin Infusion (CSII))* TAG recommendation: Nov 2004

for use in: Type 1 Diabetes under specified circumstances (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: July 2008.

Specific points: NICE guidance July 2008 states:
1. Continuous subcutaneous insulin infusion (CSII or "insulin pump") therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:
* attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. Disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life
Or
* HbA1c levels have remained high (that is, at 8.5% or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.
2. CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:
* MDI therapy is considered to be impractical or inappropriate, and
* children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.
3. It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.
4. Following initiation in adults and children
12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.
5. CSII therapy is not recommended for the
treatment of people with type 2 diabetes mellitus.

March 2013: The N&W Drugs & Therapeutics Commissioning Group (D&TCG) noted that from April 2013, commissioning responsibility for use of insulin pumps in children moves to the National Commissioning Board. Clinical Commissioning Groups (CCGs) will commission use in adolescents and adults.

September 2015: The TAG noted NICE NG 17 (August 2015) - Type 1 diabetes in adults: diagnosis and management, which covers the care and treatment of adults (aged 18 and over) with type 1 diabetes.
Contains several new recommendations for 2015.
NG 17 updates and replaces the sections for adults in NICE guideline CG15.

September 2015: The TAG noted NG 18 (August 2015) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management - which covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18 years. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

September 2016:
The TAG acknowledged NG 17 (update July 2016) which includes new recommendations on:
* Diagnosis
* Structured education
* Insulin therapy
* Blood glucose management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.1.1 - Insulins

* Impaired awareness of hypoglycaemia
* Managing complications of diabetes

Recommendation 1.15.1 was also reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

January 2017:
The TAG acknowledged NG 18 (updated November 2016) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management which includes recommendations on:
* diagnosis
* management of type 1 and type 2 diabetes
* diagnosis and management of diabetic ketoacidosis in children and young people with type 1 and type 2 diabetes
* service provision.

6.2.2 - Thyroid replacement drugs

Liothyronine / L-tri-iodothyronine sodium (T3) *(Cytomel, Triostat (U.S.))* TAG recommendation: Mar 2016

for use in: Niche, short-term use for up to three months in patients awaiting surgery pre-cancer therapy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2016:
The Norfolk & Waveney D&TCG decided that niche, short-term use of liothyronine for up to three months in patients awaiting surgery pre-cancer therapy is commissioned as Red (Hospital use only).

Liothyronine/L-tri-iodothyronine sodium (T3) *(Cytomel, Triostat (US))* TAG recommendation: Jul 2016

for use in: Patients with thyroid cancer following thyroid surgery, pre- and post radio iodine ablation (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2016:
The TAG was advised of the D&TCG's decision in June 2016 to include this patient group in the previously agreed classification of Red (Hospital use only) - Liothyronine (T3) being used for 6 weeks before and then for a further 3 weeks after radio iodine ablation, prior to conversion to maintenance treatment with thyroxine.

January 2019: The TAG considered guidance from the RMOC (November 2018) which confirmed previous recommendations regarding use of liothyronine for patients with thyroid cancer.

6.3.2 - Glucocorticoid therapy

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.3.2 - Glucocorticoid therapy

Dexamethasone *()* TAG recommendation: Jul 2020

for use in: To prevent prescribing in primary care as a treatment for covid-19 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2020 - Following publicity around some early trial results of dexamethasone in Covid-19 from the ongoing Recovery trial, the Norfolk and Waveney Drug and Therapeutics Group recommends that you should not prescribe dexamethasone to patients in primary care for the treatment of Covid-19. This statement is supported by the TAG and D+TC. It was agreed to add a traffic light classification of Red (Hospital / Specialist use only) for this specific indication to prevent inappropriate prescribing in primary care

Hydrocortisone *()* TAG recommendation: Sep 2020

for use in: To prevent prescribing in primary care as a treatment for covid-19 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Sept 2020 - The TAG acknowledged the guidance and agreed to recommend a traffic light classification of Red (Hospital/Specialist Only) for the specific covid indication. This was supported by the D+TC

6.4.1.2 - Progesterone receptor modulators

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.4.1.2 - Progesterone receptor modulators

Ulipristal ▼ (Esmya®) *(Esmya® ▼)* TAG recommendation: Sep 2018

for use in: First line option for treatment of symptoms of fibroids ≥ 3cm and with Hb ≤102g/L (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: March 2017:
The TAG considered a business application from a local acute trust and recommended a revised traffic light classification for the use of ulipristal as a first line option for treatment of symptoms of fibroids ≥ 3cm and with Hb ≤102g/L (as per NICE CG 44) of Red (Hospital/Specialist only) with a view to being revised to Amber (Option for GP prescribing under an approved Shared Care Agreement) once a shared care proposal is developed, and approved by the TAG.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG queried the likely patient numbers and costs for extended use of Esyma® where long term intermittent use is likely. GP practices would need to be advised on whether acute rather than repeat prescriptions are appropriate for such use, when a shared care agreement has been finalised and approved for local use.
The TAG's recommendations were otherwise noted and supported by the D&TCG.

September 2017: The TAG considered the shared care proposal which had been developed to clarify the GPs responsibilities regarding use of ulipristal for this indication.
The specialist would provide 3 months of treatment then review to assess its effectiveness, liaise with the GP. The treatment would be given intermittently depending of the patient's needs.
The TAG otherwise accepted the information provided and recommended that the re-classification be revised to Green (GP prescribing following specialist initiation) with the first 3 months of treatment being prescribed in hospital to assess effectiveness.
The shared care proposal to be modified to become GP prescribing guidance to be sent out with hospital letters for GPs and published on Knowledge Anglia for reference.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

March 2018: The TAG noted the MHRA safety notice advises against initiating treatment courses in new or previous patients.
Currently classified as Green - the TAG agreed to revise to Double Red (Not recommended for routine use) with no new patients or courses of treatment to be initiated, pending results of EU-wide evidence review.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation. The D&TC noted that this restriction does not apply to the other ulipristal-containing product, ellaOne®.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

September 2018:
The TAG noted that in August 2018 the MHRA had published updated guidance regarding new restrictions to licensed use and increased requirements for liver function monitoring before, during, and after treatment as follows:
Restricted indication and new contraindication:
* Esmya is now indicated for:
  * the intermittent treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age who are not eligible for surgery
  * one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
* Esmya treatment is to be initiated and supervised by physicians experienced in the diagnosis and treatment of uterine fibroids
* Esmya is contraindicated in women with underlying liver disorders
Liver function monitoring:
* Before initiation of each treatment course: perform liver function tests; do not initiate Esmya in women with baseline ALT or AST more than 2-times the upper limit of normal [ULN]
* During the first 2 treatment courses: perform liver function tests every month
* For further treatment courses: perform LFTs once before each new course and when clinically indicated

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.4.1.2 - Progesterone receptor modulators

* At the end of each treatment course: perform LFTs after 2-4 weeks
* Stop Esmya treatment and closely monitor women with ALT or AST more than 3-times ULN; consider the need for specialist hepatology referral

The TAG agreed that the classification should be revised to Red (Hospital / Specialist only) until such time as a shared care agreement could be developed.
The previously agreed GP Prescribing Guidance document could form the basis of a new shared care agreement.

September 2018:
The D&TC decided that in view of the safety issues and increased monitoring requirements, prescribing and monitoring responsibility should remain with the hospital for a period of at least 12 months before reconsidering whether a shared care approach was appropriate and that GPs should resume clinical responsibility for Esmya.
The D&TC therefore recommended that EPACT data should be checked to ensure that GPs were not continuing to prescribe, and that previously agreed GP prescribing guidance should be withdrawn for the time being.

October 2018:
The D&TC's recommendation to revise the classification of Esmya from Double Red to Red (Hospital only) for at least 12 months was supported by the N&W CCGs' JSCC.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.4.1.2 - Progesterone receptor modulators

Ulipristal acetate ▼ (Esmya®) *(Esmya® ▼)* TAG recommendation: Sep 2018

for use in: Pre-operative treatment of moderate to severe symptoms of uterine fibroids (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: September 2012:
Prescriber's Rating: Offers an advantage - "The product has some value but does not fundamentally change present therapeutic practice."

The NHS N&W D&TCG agreed to commission this treatment in-tariff only as per the NNUH business model. TAG recommendation overturned to Red (Hospital Only).

September 2016: The TAG acknowledged NICE CG 44 (August 2016) - update
The TAG noted new recommendation relating to treatment of women with fibroids ≥3cm with ulipristal which may result in longer term use of this treatment - (currently commissioned as (Red (Hospital only) for pre-operative use for moderate to severe symptoms of fibroids - September 2012).
The TAG would await interest and revised business applications from the Acute Trusts on this issue.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted NICE CG 44 (August 2016) - update and agreed that use of ulipristal (Esmya®) for treatment of women with fibroids ≥3cm is classified as Double Red (Not recommended for routine use/ not commissioned) pending submission of business applications to support its use locally.

March 2017: The TAG considered the local Trust's application and recommended that the current classification of Red (Hospital Only) for ulipristal as pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age as a second line option, prior to surgery or radiology, is maintained.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2017: The TAG considered the shared care proposal which had been developed to clarify the GPs responsibilities regarding use of ulipristal for this indication.
The specialist would provide 3 months of treatment then review to assess its effectiveness, liaise with the GP. The treatment would be given intermittently depending of the patient's needs.
The TAG otherwise accepted the information provided and recommended that the re-classification be revised to Green (GP prescribing following specialist initiation) with the first 3 months of treatment being prescribed in hospital to assess effectiveness.
The shared care proposal to be modified to become GP prescribing guidance to be sent out with hospital letters for GPs and published on Knowledge Anglia for reference.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

March 2018: The TAG noted the MHRA safety notice advises against initiating treatment courses in new or previous patients.
Currently classified as Green - the TAG agreed to revise to Double Red (Not recommended for routine use) with no new patients or courses of treatment to be initiated, pending results of EU-wide evidence review.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation. The D&TC noted that this restriction does not apply to the other ulipristal-containing product, ellaOne®.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

September 2018: The TAG noted the MHRA published guidance (Aug 18) and agreed that the classification should be revised to Red (Hospital / Specialist only) until such time as a shared care agreement could be developed.
The previously agreed GP Prescribing Guidance document could form the basis of a new shared care agreement.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.4.1.2 - Progesterone receptor modulators

September 2018:
The TAG noted that in August 2018 the MHRA had published updated guidance regarding new restrictions to licensed use and increased requirements for liver function monitoring before, during, and after treatment as follows:
Restricted indication and new contraindication:
* Esmya is now indicated for:
  * the intermittent treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age who are not eligible for surgery
  * one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
* Esmya treatment is to be initiated and supervised by physicians experienced in the diagnosis and treatment of uterine fibroids
* Esmya is contraindicated in women with underlying liver disorders
Liver function monitoring:
* Before initiation of each treatment course: perform liver function tests; do not initiate Esmya in women with baseline ALT or AST more than 2-times the upper limit of normal [ULN]
* During the first 2 treatment courses: perform liver function tests every month
* For further treatment courses: perform LFTs once before each new course and when clinically indicated
* At the end of each treatment course: perform LFTs after 2-4 weeks
* Stop Esmya treatment and closely monitor women with ALT or AST more than 3-times ULN; consider the need for specialist hepatology referral

The TAG agreed that the classification should be revised to Red (Hospital / Specialist only) until such time as a shared care agreement could be developed.
The previously agreed GP Prescribing Guidance document could form the basis of a new shared care agreement.

September 2018:
The D&TC decided that in view of the safety issues and increased monitoring requirements, prescribing and monitoring responsibility should remain with the hospital for a period of at least 12 months before reconsidering whether a shared care approach was appropriate and that GPs should resume clinical responsibility for Esmya.
The D&TC therefore recommended that EPACT data should be checked to ensure that GPs were not continuing to prescribe, and that previously agreed GP prescribing guidance should be withdrawn for the time being.

October 2018:
The D&TC's recommendation to revise the classification of Esmya from Double Red to Red (Hospital only) for at least 12 months was supported by the N&W CCGs' JSCC.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

6.5.1 - Hypothalamic and anterior pituitary hormones etc.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.5.1 - Hypothalamic and anterior pituitary hormones etc.

Infertility drugs *(Various)* TAG recommendation: Jan 1997

for use in: Infertility treatment (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: Norfolk LMC and Norfolk Health Authority recommend that GPs do not prescribe these drugs - even privately - as they are not in a position to monitor them. Norfolk PCT has a contract to provide infertility treatment - including all drugs - for people meeting certain criteria. It would not support their use in other circumstances.

September 2016: The TAG acknowledged NICE CG 156 (August 2016) - update.
The TAG also discussed the place of clomiphene and prescribing responsibility locally and whether this should be reviewed.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted NICE CG 156 (August 2016) - update and agreed that, for clarity, any GP prescribing of clomiphene for the treatment of ovulatory failure in women desiring pregnancy and for whom ovulatory dysfunction is demonstrated should be following specialist recommendation only
- i.e. Green (GP prescribing following consultant initiation / recommendation)

Somatrogon *(Ngenla®)* TAG recommendation: Mar 2023

for use in: growth disturbance in children and young people aged 3 years and over TA863 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Specific points: To confirm position in pathway

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.5.1 - Hypothalamic and anterior pituitary hormones etc.

Somatropin (Growth Hormone) *(Various - Omnitrope®, Genotropin®, Norditropin®)* TAG recommendation: Jul 2005

for use in: Growth disturbance in children born small for gestational age - as per NICE TA 188 and East of England PAC policy (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: July 2010.

Specific points: TAG subgroup re-considered decision made in November 2004 (Double Red) in the light of consultant recommendations and the technical report underpinning the NICE guidance on the use of growth hormone in short stature. Sub group discussions reported at TAG July 2005 and re-classification to Red agreed by TAG.

July 2010: The TAG noted revised guidance from NICE - TA 188 (May 2010):
This guidance replaced TA 42 (May 2002).
Human growth hormone (somatropin) is still recommended for the treatment of growth failure in children with growth hormone deficiency, Turner syndrome, Prader-Willi syndrome and chronic renal insufficiency. The guidance has been extended to include growth failure associated with :
* those born small for gestational age with subsequent growth failure at 4 years of age or later
* those with short stature homeobox-containing gene (SHOX) deficiency.

January 2011: The TAG noted guidance for GPs on the use of somatropin in the management of growth disorders developed by Dr Nandu Thalange (NNUH). Available via TAG information on the Knowledge Management website.

Janaury 2012: Guidance revised to reflect EMA recommendation that somatropin products should not be used above doses stated in the manufacturers' SPCs.

March 2017: The TAG considered the PAC recommendations for growth hormone devices in children (January 2016) with respect to local HGH guidance for GPs, last approved January 2012, and recommended that the newer PAC document be adopted to replace the previous guidance from the TAG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.5.1 - Hypothalamic and anterior pituitary hormones etc.

Somatropin (Growth hormone) *(Various - Omnitrope®, Genotropin®, Norditropin®)* TAG recommendation: Mar 2014

for use in: Children with growth failure with growth hormone deficiency, Turner syndrome, Prader-Willi syndrome and chronic renal insufficiency - as per NICE TA 188 and East of England PAC policy (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: July 2010.

Specific points: See also the the Red section for use in adults.

NICE guidance May 2002 - recommended for children with Turner syndrome (TS), pre-pubertal children with (CRI) providing nutritional status has been optimised, metabolic abnormalities have been optimised and steroid therapy has been reduced to a minimum, and for Prader-Willi syndrome. Treatment should be initiated and monitored by a specialist paediatrician. Continued treatment can be maintained under a shared-care protocol with a GP.
Various shared care protocols available from specialist centres. Agree with supervising consultant.

Local agreement of service provision states that for the present, prescribing responsibility will remain with Hospital specialists - Red.

July 2010: The TAG noted revised guidance from NICE - TA 188 (May 2010):
This guidance replaced TA 42 (May 2002).
Human growth hormone (somatropin) is still recommended for the treatment of growth failure in children with growth hormone deficiency, Turner syndrome, Prader-Willi syndrome and chronic renal insufficiency. The guidance has been extended to include growth failure associated with :
* those born small for gestational age with subsequent growth failure at 4 years of age or later
* those with short stature homeobox-containing gene (SHOX) deficiency.

January 2011: The TAG noted guidance for GPs on the use of somatropin in the management of growth disorders developed by Dr Nandu Thalannge (NNUH). Available via TAG information on the Knowledge Management website.

March 2015: The TAG noted the East Of England Priorities Advisory Committee's (PAC) Guidance Statement (March 2014) regarding recommendations for rationalisation of human growth hormone (somatroptin) products and was adivsed of local paeitrician's intention to feedback on its content to the PAC.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the PAC Guidance Statement from 2014 and was advised of the local paediatrician's intention to feedback on its content. The D&TCG was also advised that subsequent tendering arrangements regarding purchasing of growth hormone products have necessitated a further review of the PAC Guidance Statement.

Local use of somatropin is currently being monitored on behalf of commissioners.

March 2017: The TAG considered the PAC recommendations for growth hormone devices in children with respect to local HGH guidance for GPs, last approved January 2012, and recommended that the newer PAC document be adopted to replace the previous guidance from the TAG.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.5.1 - Hypothalamic and anterior pituitary hormones etc.

Somatropin (Growth hormone) *(Various (lowest cost preparation))* TAG recommendation: May 1998

for use in: Adults: Profound growth hormone deficiency (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2003.

Specific points: (See also Red and Double Red sections for use in children)

NICE Guidance (August 2003): Somatropin should be used in adults only if the following three criteria are fulfilled:
* Severe growth deficiency, established by an appropriate method (peak GH response of < 9mU/litre (3ng/ml) during an insulin tolerance test (cross-validated GH threshold in an equivalent test).
* Impaired quality of life, measured by means of a specific questionnaire.
* Already receiving treatment for another pituitary hormone deficiency.

Somatropin treatment should be discontinued if the quality of life has not improved sufficiently by 9 months.
Severe growth hormone deficiency developing after linear growth is complete but before the age of 25 years should be treated with growth hormone; treatment should continue until adult peak bone mass has been achieved. Treatment for adult-onset growth hormone deficiency should be stopped only when the patient and the physician consider it appropriate.
Treatment with somatropin should be initiated and managed by a physician with expertise in growth hormone disorders; maintenance treatment can be prescribed in the community under a shared-care protocol.
In November 2004 the TAG confirmed that until such time as an agreed Shared Care Protocol is available, prescribing of growth hormone in adults will remain as Hospital Only.

6.5.2 - Posterior pituitary hormones and antagonists

Tolvaptan *(Jinarc®, Samsca®)* TAG recommendation: May 2018

for use in: Hyponatraemia in cancer - as per NHS England Policy 16051/P (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16051/P - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.5.2 - Posterior pituitary hormones and antagonists

Tolvaptan ▼ *(Jinarc®, Samsca® ▼)* TAG recommendation: Nov 2015

for use in: Autosomal dominant polycystic kidney disease in adults - NICE TA 358 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2015.

Specific points: November 2015: The TAG noted NICE TA 358 (October 2015) for treating autosomal dominant polycystic kidney disease in adults where
* the patient has chronic kidney disease stage 2 or 3 at the start of treatment and
* there is evidence of rapidly progressing disease
and recommended a classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

September 2017: The TAG considered a shared care proposal for this treatment. The TAG acknowledged that GPs are generally happy to provide phlebotomy services (for which they are remunerated) but that the specialist must be responsible for monitoring the treatment where they retain prescribing responsibility.
The document was therefore declined as a shared care agreement but was agreed to provide useful information for GPs regarding tolvaptan. The content could therefore be used in-Trust and also be communicated to GPs when their patients are initiated on treatment.

The TAG therefore decided to maintain the current classification of Red (Hospital/Specialist only), with blood sampling possibly being carried out in primary care but responsibility for monitoring the results to remain with the specialist.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation that Tolvaptan (Jinarc®) for use in Autosomal Dominant Polycystic Kidney Disease - as per NICE TA 358 to remain as Red (Hospital / Specialist use only) with the specialist responsible for prescribing and monitoring the treatment.

6.6.1 - Calcitonin and parathyroid hormone

Parathyroid hormone *(Natpar®)* TAG recommendation: May 2018

for use in: Specialist endocrinology conditions (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Trust guidelines apply.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.6.1 - Calcitonin and parathyroid hormone

Teriparatide *(Forsteo®)* TAG recommendation: Jan 2009

for use in: Secondary prevention of osteoporotic fragility fractures in postmenopausal women (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.161 October 2008: Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

Teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to take alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (see below)), or who have a contraindication to, or are intolerant of strontium ranelate (see below)), or who have had an unsatisfactory response (see below) to treatment with alendronate, risedronate or etidronate and
* who are 65 years or older and have a T-score of -4.0 SD or below, or a T-score of -3.5 SD or below plus more than two fractures, or who are aged 55 to 64 years and have a T-score of
-4 SD or below plus more than two fractures.

NICE Guidance defines intolerance of alendronate, risedronate or etidronate as persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.

NICE Guidance defines intolerance of strontium ranelate as persistent nausea or diarrhoea, either of which warrants discontinuation of treatment.

NICE Guidance defines an unsatisfactory response as occurring when a woman has another fragility fracture despite adhering fully to treatment for 1 year and there is evidence of a decline in BMD below her pre-treatment baseline.

6.6.2 - Bisphosphonates - drugs affecting bone metabolism

Denosumab ▼ *(XGEVA® ▼)* TAG recommendation: Nov 2012

for use in: Prevention of skeletal-related events in adults with bone metastases from solid tumours (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2012.

Specific points: November 2012: The TAG agreed to reconfirm its recommendation on this guidance when a business case had been received. The MHRA October 2012 Drug Safety Update bulletin reports cautions about the use of denosumab and the need to monitor calcium levels in high risk patients.

January 2013: The Drugs & Therapeutics Commissioning Group (D&TCG) considered the NNUH's business case for this monthly subcutaneous injection. MHRA's safety alert noted. This is an in-tariff treatment which will be responsibility of the National Specialised Commissioning Group (SCG) from April 2013. Extra hospital attendance costs are an issue. GPs could give under a Local Enhanced Service or possibly Shared Care, which would need LMC support. However the SCG is likely to transfer any shared care to Homecare providers.
Decision: Commissioned as Red (Hospital Only) on the Out Patient National Tariff for 3 months leading up to transfer to the SCG in April 2013.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.6.2 - Bisphosphonates - drugs affecting bone metabolism

Ibandronic acid *(Bonviva® Injection)* TAG recommendation: Nov 2007

for use in: Treatment of osteoporosis in postmenopausal women (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: Recommendation applies to intravenous administration. For use in a cohort of patients who fail or who are intolerant of standard oral bisphosphonate therapy.

NICE Technology Appraisal Guidance 161 October 2008 does not cover use of ibandronic acid which became available after commencement of the appraisal process.

September 2017:
The TAG acknowledged NICE TA 464 (August 2017) - Bisphosphonates (alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid) for treating osteoporosis in adults which states:
Intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended as options for treating osteoporosis in adults only if:
* the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis and
* the 10-year probability of osteoporotic fragility fracture is at least 10% or
* the 10-year probability of osteoporotic fragility fracture is at least 1% and the person has difficulty taking oral bisphosphonates (alendronic acid, ibandronic acid or risedronate sodium) or these drugs are contraindicated or not tolerated
- and recommended that the Prescribing Reference Group be requested to consider the implications of this guidance which recommends a lower treatment threshold, for a wider patient group than previously recommended.
The TAG also considered that there should be no case-finding or screening to identify suitable patients outside the terms of the guidance.

November 2017:
The TAG and the D&TCG noted and supported the revised Key Message Bulletins for (oral) bisphosphonates in osteoporosis which has been upadted in line with NICE TA 464 - available on Knowledge Anglia via
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/prescribing_sitemap.htm#keymessages

Zoledronic acid *(Various)* TAG recommendation: May 2017

for use in: 6-monthly infusions for 2 years to improve survival in post-menopausal women with breast cancer receiving chemotherapy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2017:
The TAG considered the QEH's application alongside the key reference and agreed to support the application.
The TAG recommended traffic light classifications of Green (GP prescribable following consultant recommendation) for daily oral ibandronate and Red (Hospital use only) for 6-monthly IV zoledronic acid infusions (4 doses) as adjuvant treatment to improve survival in post-menopausal women with breast cancer receiving chemotherapy for 2 years.

May 2017:
The D&TCG noted and supported the TAG's recommendations and decided to commission adjuvant use of 2 years of either 6-monthly IV zoledronic acid infusions (4 doses), or daily oral ibandronate, to improve survival in post-menopausal women with breast cancer receiving chemotherapy as Red (Hospital use only) and Green (GP prescribable following consultant recommendation) respectively.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

6.6.2 - Bisphosphonates - drugs affecting bone metabolism

Zoledronic Acid *(Various)* TAG recommendation: Mar 2011

for use in: To prolong survival and prevent skeletal-related events (SREs) in patients with plasma cell myeloma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2011:
The TAG agreed that the drug is cost-effective. However it is for commissioners to agree the service costs and to decide whether to commission this treatment. Total "in-chair" administration time is around 45 minutes.
Prescriber's Rating: 2. A real advance - The product is an important therapeutic innovation but has certain limitations.
17th March 2011- NHS Norfolk D&TCG noted the TAG's clinical recommendation for an In-Tariff drug, the significant service costs for which must be considered separately by NHS Norfolk's Central Delivery Unit.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management.

6.7.3 -

Metyrapone *(Metopirone)* TAG recommendation: Sep 2020

for use in: Cushing's syndrome (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Sept 2020 - BNF suggests specialist supervision in hospital, so PRG recommended awarding a Red (Hospital/Specialist Only) classification. This was supported by the TAG and D+TC

7.4.5 - Drugs for erectile dysfunction in SLS list

Erectile dysfunction drugs *(Various)* TAG recommendation: Aug 1999

for use in: Severe distress from erectile dysfunction seeking treatment on the NHS (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Drugs affected include Alprostadil, branded Sildenafil (but not generic sildenafil as from August 2014), Tadalalfil, Vardenafil.
The Department of Health issued recommendation that drug treatments for erectile dysfunction may only be prescribed on the NHS under certain circumstances. Drug treatment when the condition is causing severe distress should be provided by specialist services commissioned by local PCTs. Currently there are no such services agreed in the Norwich area. This issue was most recently referred by the TAG to Specialised Services Commissioners in March 2004.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

7.4.5 - Drugs for erectile dysfunction in SLS list

Vacuum pumps / devices for erectile dysfunction *(Various)* TAG recommendation: Jul 2003

for use in: Erectile dysfunction (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG orginally recommended Hospital supply due to historical funding and since patients should receive the device they are trained to use.

In-tariff treatment for which hospitals have funds to supply. Confirmed via contracting process during 2010-11.

8.1 - Cytotoxics - monoclonal antibodies

Inotuzumab ozogamicin *(Besponsa®)* TAG recommendation: Nov 2018

for use in: Relapsed or refractory B-cell acute lymphoblastic leukaemia - as per NICE TA 541 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2018.

Specific points: November 2018: The TAG noted NICE TA 541 (September 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Olaparib *(Lynparza®)* TAG recommendation: Nov 2019

for use in: Maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA598 - August 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Olaparib *(Lynparza®)* TAG recommendation: May 2021

for use in: plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer as per TA693 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2021.

Specific points: Red (Hospital / Specialist use only)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Olaparib ▼ *(Lynparza® ▼)* TAG recommendation: Mar 2016

for use in: Maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The NICE TA 381 (January 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Pembrolizumab *(Keytruda®)* TAG recommendation: Jan 2019

for use in: Adjuvant treatment of resected melanoma with high risk of recurrence - stage III melanoma with lymph node involvement in adults who have had complete resection - as per NICE TA 553 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 553 (December 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHS England commissioning responsibility treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Pembrolizumab *(Keytruda®)* TAG recommendation: Mar 2019

for use in: Untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK)-positive mutations - as per NICE TA 557 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE TA 557 (January 2019) which recommended use within the Cancer Drugs Fund, only if the company provides pembrolizumab according to the managed access agreement for patients with untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR)- or anaplastic lymphoma kinase (ALK)-positive mutations, only if:
* pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if disease progresses

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Pembrolizumab *(Keytruda®)* TAG recommendation: Jun 2023

for use in: plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer TA885 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

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Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2018

for use in: Relapsed or refractory classical Hodgkin lymphoma in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant - as per NICE TA 540 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2018.

Specific points: November 2018: The TAG noted NICE TA 540 (Recommended for treating relapsed or refractory classical Hodgkin lymphoma in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant, only if pembrolizumab is stopped after 2 years of treatment or earlier if the person has a stem cell transplant or the disease progresses)
and recommended a traffic light classification of Double Red (Not recommended for routine use) in adults who have had autologous stem cell transplant and brentuximab vedotin, and Red (Hospital / Specialist use only) in adults who have had brentuximab vedotin and cannot have autologous stem cell transplant as per criteria specified by NICE, for this NHSE-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Pembrolizumab *(Keytruda®)* TAG recommendation: Jan 2023

for use in: neoadjuvant and adjuvant treatment of triple-negative early or locally advanced breast cancer TA851 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2022.

Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2021

for use in: with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer as per TA737 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2022

for use in: adjuvant treatment of resected stage 2B or 2C melanoma as per TA837 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2022

for use in: adjuvant treatment of renal cell carcinoma as per TA830 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Pembrolizumab *(Keytruda®)* TAG recommendation: May 2018

for use in: Locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy - as per NICE TA 519 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 519 (April 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendation

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Pembrolizumab *(Keytruda®)* TAG recommendation: Jul 2023

for use in: with lenvatinib for previously treated advanced or recurrent endometrial cancer TA904 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Pembrolizumab *(Keytruda®)* TAG recommendation: Sep 2018

for use in: Untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable - as per NICE TA 522 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 522 (June 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

September 2018: The TAG noted NICE TA 522 (Update July 2018) wich recommended use of pembrolizumab as an option within the Cancer Drugs Fund. The TAG reaffirmed a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Pembrolizumab *(Keytruda®)* TAG recommendation: Apr 2021

for use in: pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer as per TA683 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: April 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Pembrolizumab *(Keytruda®)* TAG recommendation: Jul 2021

for use in: untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency as per TA709 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

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Pembrolizumab *(Keytruda®)* TAG recommendation: Nov 2019

for use in: With carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA600 - September 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Pembrolizumab ▼ *(Keytruda® ▼)* TAG recommendation: Nov 2017

for use in: Locally advanced or metastatic PD-L1-positive non-small-cell lung cancer after chemotherapy - as per NICE TA 428 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: March 2017: The TAG acknowledged NICE TA 428 (January 2017) which states:
Recommended by NICE as an option for adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK] positive tumour), only if:
* pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression, and
* the company provides pembrolizumab with discount agreed under PAS revised in the context of this appraisal.

The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

November 2017:
The TAG acknowledged NICE TA 428 (Sept 17) and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Pembrolizumab ▼ *(Keytruda®)* TAG recommendation: Sep 2018

for use in: untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations - as per

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2018.

Specific points: September 2018:
The TAG noted NICE TA 531 (July 2018) which recommended pembrolizumab (Keytruda®) as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations, only if:
* pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier in the event of disease progression and
* the company provides pembrolizumab according to the commercial access agreement.

The TAG recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Pembrolizumab ▼ *(Keytruda® ▼)* TAG recommendation: Nov 2017

for use in: Advanced (unresectable or metastatic) melanoma in adults not previously treated with ipilimumab as per NICE TA 366 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: January 2016: The TAG noted NICE TA 366 (November 2015) for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab, in adults, and only if the company provides pembrolizumab with the discount agreed in the patient access scheme and recommended a classification of Red (Hospital/Specialist only) for this SCG commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCG's D&TC noted the TAG recommendation.

November 2017:
The TAG acknowledged NICE update of TA 366 (Sept 17) and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Noted by the D&TCG.

Pembrolizumab ▼ *(Keytruda® ▼)* TAG recommendation: Jul 2017

for use in: Untreated PD-L1-positive metastatic non-small-cell lung cancer - as per NICE TA 447 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 447 (June 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1 - Cytotoxics - monoclonal antibodies

Pembrolizumab ▼ *(Keytruda® ▼)* TAG recommendation: Nov 2017

for use in: Advanced melanoma after disease progression with ipilimumab in adults - as per NICE TA 357 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: November 2015: The TAG noted NICE TA 357 (October 2015) for advanced melanoma after disease progression with ipilimumab in adults with melanoma that:
* can't be completely removed by surgery or has spread to other parts of the body
* has been treated with ipilimumab (melanoma that is BRAF V600 mutation-positive must also have had treatment with vemurafenib, dabrafenib, or trametinib).
And recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

November 2017:
The TAG acknowledged the NICE update of TA 357 (Sept 17) and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Noted by the D&TCG.

Trifluridine-tipiracil ▼ *(Lonsurf® ▼)* TAG recommendation: Sep 2016

for use in: For previously treated metastatic colorectal cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: September 2016: The TAG acknowledged NICE TA 405 (August 2016) for previously treated metastatic colorectal cancer in adults who have had previous treatment with available therapies including fluoropyrimidine-, oxaliplatin- or irinotecan-based chemotherapies, anti-vascular endothelial growth factor (VEGF) agents and anti-epidermal growth factor receptor (EGFR) agents, or when these therapies are not suitable and recommended a classification of Red (Hospital only use) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

8.1.1 - Alkylating drugs

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.1 - Alkylating drugs

Bendamustine *(Levact®)* TAG recommendation: Nov 2010

for use in: Treatment of indolent (low grade) non-Hodgkin's lymphoma that is refractory to rituximab - as per NICE TA 206 / NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2010.

Specific points: November 2010:
NICE terminated technology appraisal 206 on use of bendamustine for indolent NHL (i.e. Follicular Lymphoma).

November 2010: Not commissioned by the NHS Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG).

NHS England Specialised Commissioning responsibility from April 2013.

November 2013: Updated in line with NHS England SCG Cancer Drug Fund List Sept 2013 which supports use: http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Bendamustine *(Levact®)* TAG recommendation: May 2011

for use in: First-line treatment of chronic lymphocytic leukaemia (binet stage B or C) - as per NICE TA 216 / NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: The TAG noted NICE Technology Appraisal Guidance 216 which states:
Bendamustine is recommended as an option for the first-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.1 - Alkylating drugs

Busulfan *(Myleran®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Chlorambucil *(Leukeran®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Cyclophosphamide *(Endoxana®)* TAG recommendation: Mar 2008

for use in: Use in Cancer (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Estramustine phosphate *(Estracyt®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.1 - Alkylating drugs

Lomustine *(CCNU®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Melphalan *(Alkeran®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Polatuzumab vedotin *(Polivy)* TAG recommendation: Oct 2020

for use in: with rituximab and bendamustine - relapsed or refractory diffuse large B-cell lymphoma as per TA649 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Treosulfan *(Trecondi)* TAG recommendation: Sep 2020

for use in: with fludarabine for malignant disease before allogeneic stem cell transplant as per TA640 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2020.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.1 - Alkylating drugs

Treosulfan *()* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

8.1.2 - Anthracyclines and other cytotoxic drugs

Idarubicin HCl *(Zavedos®)* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.2 - Anthracyclines and other cytotoxic drugs

Pixantrone ▼ *(Pixuvri® ▼)* TAG recommendation: Mar 2014

for use in: Monotherapy treatment of multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2014.

Specific points: March 2014:
The TAG noted NICE TA 306 (Feb 2014) which stated that pixantrone monotherapy is recommended as an option for treating adults with multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma only if:
* the person has previously been treated with rituximab and
* the person is receiving third- or fourth-line treatment and
* the manufacturer provides pixantrone with the discount agreed in the patient access scheme.

NHS England SCG-commissioning responsibility: Specialised Services Circular SSC1411 states that this teatment would be commissioned from 27th February 2014, providing that Trusts had signed the appropriate PAS agreement.

TAG recommendation noted and supported by the D&TCG.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

8.1.3 - Antimetabolites

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Azacitidine *(Vidaza®)* TAG recommendation: May 2011

for use in: Myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia - as per NICE 218 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2011.

Specific points: NICE Technology Appraisal Guidance 218 states:
1.1 Azacitidine is recommended as a treatment option for adults who are not eligible for haematopoietic stem cell transplantation and have:
- intermediate-2 and high-risk myelodysplastic syndromes according to the International Prognostic Scoring System (IPSS) or
- chronic myelomonocytic leukaemia with 10-29% marrow blasts without myeloproliferative disorder or
- acute myeloid leukaemia with 20-30% blasts and multilineage dysplasia, according to the World Health Organization classification
and
- if the manufacturer provides azacitidine with the discount agreed as part of the patient access scheme.

NHS England Specialised Commissioning responsibility from April 2013.

Azacitidine (oral) *(Onureg®)* TAG recommendation: Nov 2022

for use in: maintenance treatment of acute myeloid leukaemia after induction therapy as per TA827 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Capecitabine *(Xeloda®)* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: April 2006.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

September 2010: The TAG noted NICE TA Guidance 191: Capecitabine for the treatment of advanced gastric cancer.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Cladribine *(Mavenclad®)* TAG recommendation: Jan 2018

for use in: Relapsing-remitting multiple sclerosis - as per NICE TA 493 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 493 (Dec 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

The TAG also agreed that it would be prudent to monitor for any inappropriate prescribing of this oral treatment in primary care.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Cladribine *(Mavenclad®)* TAG recommendation: Jan 2020

for use in: Relapsing-remitting multiple sclerosis - as per NICE TA616 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2019.

Specific points: January 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Red (Hospital/Specialist only) was afforded for this NHS England commissioning responsibility treatment.

Clofarabine *(Evoltra®)* TAG recommendation: May 2018

for use in: Cancer (Various indications).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Cancer Drug Fund / SACT Policy

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Fludarabine *(Fludara®)* TAG recommendation: Jul 2003

for use in: B-cell Chronic Lymphocytic Leukaemia - 2nd line treatment - as per NICE TA 29 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2001.

Specific points: NICE September 2001: Oral fludarabine is recommended as second line therapy for B-cell chronic lymphocytic leukaemia (CLL) for patients who have either failed, or are intolerant of, first line chemotherapy, and who would otherwise have received combination chemotherapy of either: a) cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP); b) cyclophosphamide, doxorubicin and prednisolone (CAP) or c) cyclophosphamide, vincristine and prednisolone (CVP).

March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

NHS England Specialised Commissioning responsibility from April 2013.

Gemcitabine *(Gemzar®)* TAG recommendation: Nov 2013

for use in: Non-small cell lung carcinoma (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: November 2013.

Specific points: NHS England Specialised Commissioning responsibility from April 2013.

November 2013: NICE treatment pathway for lung cancer: http://pathways.nice.org.uk/pathways/lung-cancer

Gemcitabine *(Gemzar®)* TAG recommendation: May 1998

for use in: Pancreatic cancer (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: May 2001.

Specific points: NICE: Gemcitabine may be considered as a treatment option for patients with advanced or metastatic adenocarcinoma of the pancreas and a Karnofsky performance score of 50 or more, where first line chemotherapy is to be used.
Gemcitabine is not recommended for patients who are suitable for potentially curative surgery, or patients with a Karnofsky (see Appendix D) score of less than 50.
There is insufficient evidence to support the use of gemcitabine as a second line treatment in patients with pancreatic adenocarcinoma.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Liposomal cytarabine-daunorubicin *(Vyxeos®)* TAG recommendation: Jan 2019

for use in: Untreated therapy-related acute myeloid leukaemia or acute myeloid leukaemia with myelodysplasia-related changes in adults - as per NICE TA 552 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 552 (December 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHS England commissioning responsibility treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Mercaptopurine *(Puri-Nethol®)* TAG recommendation: Mar 2008

for use in: Acute leukaemias and chronic myeloid leukaemia (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

In July 2007, the TAG agreed to support an Amber (option for shared care) classification and a shared care protocol for use of mercaptopurine to provide a steroid-sparing effect in patients with inflammatory bowel disease - see separate entry. Available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/mercaptopurine_for_ibd.pdf

April 2013: NHS England SCG took over commissioning responsibility.

Methotrexate (Oral and injectable)) *()* TAG recommendation: May 2008

for use in: High doses used in malignant disease (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

April 2013: NHS England SCG took over commissionin responsibility.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Nelarabine *(Atriance®)* TAG recommendation: May 2018

for use in: Cancer - lymphoblastic leukaemia - as per Cancer Drug Fund policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Cancer Drug Fund policy applies.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pemetrexed *(Alimta®)* TAG recommendation: Mar 2008

for use in: Treatment of malignant pleural mesothelioma (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: January 2008.

Specific points: NICE TAG No. 135:
1. Pemetrexed is recommended as a treatment option for malignant pleural mesothelioma only in people who have a World Health Organization (WHO) performance status of 0 or 1, who are considered to have advanced disease and for whom surgical resection is considered inappropriate.
2. Patients currently receiving pemetrexed who do not fall into the patient population defined in section 1. should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

January 2013: Commissioned in line with Cancer Network regimens

Pemetrexed *(Alimta®)* TAG recommendation: Jul 2010

for use in: Maintenance treatment of non-small-cell lung cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2010.

Specific points: NICE TA 190 (June 2010): Pemetrexed is recommended as an option for the maintenance treatment of people with locally advanced or metastatic non-small-cell lung cancer other than predominantly squamous cell histology if disease has not progressed immediately following platinum-based chemotherapy in combination with gemcitabine, paclitaxel or docetaxel.

January 2013: Commissioned in line with Cancer Network regimens.

Commissioning responsibility of NHS England SCG from April 2013.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Pemetrexed *(Alimta®)* TAG recommendation: Nov 2009

for use in: First-line treatment of non-small-cell lung cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2009.

Specific points: NICE TA 181 recommends pemetrexed in combination with cisplatin as an option for the first-line treatment of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC)

March 2010: Proposal for use of pemetrexed in combination with carboplatin instead of cisplatin supported by the NHS Norfolk Drugs & Therapeutics Commissioning Programme Board on 21st April 2010.

January 2013: Commissioned in line with Cancer network regimens.

Commissioning responsibility of NHS England SCG from April 2013.

Pemetrexed *(Alimta®)* TAG recommendation: Sep 2007

for use in: Non-small-cell lung cancer - patients who have had prior chemotherapy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2007.

Specific points: NICE TAG (124) August 2007: NICE does not recommend use of pemetrexed for the treatment of locally advanced or metastatic non-small-cell lung cancer in patients who have had prior chemotherapy.
People currently receiving pemetrexed should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

September 2009: NICE TAG 181 provides guidance on the use of pemetrexed as a first-line treatment in patients with NSCLC.

Commissioning responsibility of NHS England SCG from April 2013.
Recommendation update to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.3 - Antimetabolites

Pemetrexed *(Alimta®)* TAG recommendation: Sep 2016

for use in: Maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) following induction therapy with pemetrexed and cisplatin (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: NICE TA 309 (April 2014) states that:
Pemetrexed is not recommended for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) in people whose disease has not progressed immediately following induction therapy with pemetrexed and cisplatin.

People currently receiving treatment initiated within the NHS with pemetrexed that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

This treatment is the commissioning responsibility of NHS England SCG.

TAG recommendation noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

September 2016: The TAG acknowledged NICE TA 402 (August 2016) which replaces NICE TA 309, and recommended a classification of Red (Hospital only use) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Tegafur with uracil *(Uftoral®)* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: May 2003.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Commissioning responsibility of NHS England SCG from April 2013.

Tioguanine *(Lanvis®)* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Commissioning responsibility of NHS England SCG from April 2013.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.4 - Vinca alkaloids and etoposide

Etoposide *(Vepesid®)* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Commissioning responsibility of NHS England SCG from April 2013.

Vinorelbine *(Navelbine®, Navelbine® Capsules ▼)* TAG recommendation: Mar 2009

for use in: Advanced breast cancer - as per NICE 81 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2009.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

March 2009: NICE Clinical Guideline 81 Advanced Breast Cancer, states that for patients with advanced breast cancer who are not suitable for anthracyclines (because they are contraindicated or because of prior anthracycline treatment either in the adjuvant or metastatic setting), systemic chemotherapy should be offered in the following sequence:
* First line: single-agent docetaxel
* Second line: single-agent vinorelbine or capecitabine
* Third line: single-agent capecitabine or vinorelbine (whichever was not used as second-line treatment)

Commissioning responsibility of NHS England SCG from April 2013.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.4 - Vinca alkaloids and etoposide

Vinorelbine *(Navelbine®, Navelbine® Capsules ▼)* TAG recommendation: May 1998

for use in: Non-small cell lung cancer (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2001.

Specific points: NICE: Chemotherapy for non-small cell lung cancer (NSCLC) should be considered as an option in patients who are unsuitable for, or considered unlikely to respond to an attempt at curative treatment.
Gemcitabine, paclitaxel, and vinorelbine should each be considered as part of first-line chemotherapy options for advanced (stage III and IV) NSCLC patients. Combination of these three agents individually with platinum-based chemotherapy, where tolerated, is likely to be the most effective approach.

March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Commissioning responsibility of NHS England SCG from April 2013.

8.1.5 - Other antineoplastic drugs

Abemaciclib *(Verzenios ®)* TAG recommendation: Mar 2019

for use in: Locally advanced or metastic hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer as first endocrine-based therapy in adults - as per NICE TA 563 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 563 (February 2019) which recommends use only if the company provides it according to the commercial arrangement.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Abemaciclib *(Verzenios®)* TAG recommendation: Aug 2022

for use in: ®) with endocrine therapy for adjuvant treatment of hormone receptor-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence as per TA810 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Abemaciclib with fulvestrant *(Verzenios®)* TAG recommendation: Oct 2021

for use in: hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy as per TA725 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment

Acalabrutinib *(Calquence®)* TAG recommendation: May 2021

for use in: chronic lymphocytic leukaemia as per TA689 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2021.

Specific points: Red (Hospital / Specialist use only)

Afatinib ▼ *(Giotrif® ▼)* TAG recommendation: May 2014

for use in: Treatment of epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer - as per NICE TA 310 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2014.

Specific points: NICE TA 310 (April 2014) states:
Afatinib is recommended as an option, within its marketing authorisation, for treating adults with locally advanced or metastatic non-small-cell lung cancer only if:

* the tumour tests positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and
* the person has not previously had an EGFR-TK inhibitor and
* the manufacturer provides afatinib with the discount agreed in the patient access scheme.

Commissioning responsibility of NHS England SCG.

May 2014: TAG recommendation noted and supported by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Alectinib *(Alecensa®)* TAG recommendation: Sep 2018

for use in: Untreated ALK-positive advanced non-small-cell lung cancer - as per NICE TA 536 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018: The TAG noted NICE TA 536 (August 2018) and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Alpelisib *(Piqray®)* TAG recommendation: Sep 2022

for use in: with fulvestrant for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced breast cancer as per TA816 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Arsenic trioxide *(Trisenox®)* TAG recommendation: Jul 2018

for use in: Acute promyelocytic leukaemia (characterised by the presence of the t[15;17] translocation or the PML/RAR-alpha gene) in adults - as per NICE TA 526 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 526 (June 2018)) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Asciminib *(Scemblix®)* TAG recommendation: Sep 2022

for use in: chronic myeloid leukaemia after 2 or more tyrosine kinase inhibitors as per TA813 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Atezolimumab ▼ *(Tecentriq® ▼)* TAG recommendation: Nov 2021

for use in: Untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable - as per NICE TA739 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Specific points: January 2018: The TAG acknowledged NICE TA 492 (Dec 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE-commissioning responsibility treatment.

January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

September 2018: The TAG noted NICE TA 492 (Update July 2018) which acknowledged that the European Medicines Agency has restricted the use of atezolizumab for untreated urothelial carcinoma. It should now only be used in adults with high levels of PD-L1. The TAG reaffirmed a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Nov 2021 - TA492 replaced by TA739. Recommendation remains the same

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Atezolizumab *(Tecentriq®)* TAG recommendation: Jul 2021

for use in: monotherapy for untreated advanced non-small-cell lung cancer as per TA705 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

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Atezolizumab *(Tecentriq®)* TAG recommendation: Jan 2021

for use in: with bevacizumab for treating advanced or unresectable hepatocellular carcinoma as per TA666 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Specific points: Jan 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by the D+TC and ratified by CCG Governing Body

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Atezolizumab *(Tecentriq®)* TAG recommendation: Jul 2018

for use in: Locally advanced or metastatic non-small-cell lung cancer after chemotherapy - as per NICE TA 520 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 520 (May 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Atezolizumab *(Tecentriq®)* TAG recommendation: Jul 2018

for use in: Locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy - as per NICE TA 525 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 525 (June 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Atezolizumab *(Tecentriq®)* TAG recommendation: Aug 2020

for use in: with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2020.

Specific points: August 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by Norfolk and Waveney CCG Governing Body

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Atezolizumab *(Tecentriq®)* TAG recommendation: Aug 2020

for use in: with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer as per TA638 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2020. There is a shared care protocol approved by TAG.

Specific points: August 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by Norfolk and Waveney CCG Governing Body

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Atezolizumab *(Tecentriq®)* TAG recommendation: Nov 2022

for use in: adjuvant treatment of resected non-small-cell lung cancer as per TA823 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Atezolizumab▼ *(Tecentriq® ▼)* TAG recommendation: May 2018

for use in: Cancer - various (Various indications).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2017.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility / Cancer Drug Fund.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Avelumab *(Bavencio®)* TAG recommendation: Jun 2022

for use in: for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy as per TA788 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Avelumab *(Bavencio)* TAG recommendation: Oct 2020

for use in: with axitinib for untreated advanced renal cell carcinoma as per TA645 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2020.

Specific points: Oct 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Avelumab *(Bavencio®)* TAG recommendation: May 2018

for use in: Metastatic Merkel cell carcinoma - as per NICE TA 517 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 517 (April 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation

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Avelumab *(Bavencio®)* TAG recommendation: May 2021

for use in: untreated metastatic Merkel cell carcinoma as per TA691 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2021.

Specific points: Red (Hospital / Specialist use only)

Axitinib *(Inlyta®)* TAG recommendation: Mar 2015

for use in: Advanced renal cell carcinoma after failure of prior systemic treatment - as per NICE TA 331 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2015.

Specific points: NICE Final Appraisal Determination guidance (March 2013) -
Not recommended by NICE.

May 2013: The N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) noted that the NICE FAD is currently under appeal and that the treatment is the commissioning responsibility of the NHS England SCG.

March 2 015: The TAG acknowledged the NICE TA331 and recommended a classification of Red (Hospital/Specialist use only) for this NHS England SCG commissioned drug.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bevacizumab *(Avastin®)* TAG recommendation: Nov 2019

for use in: Radiation retinopathy macular oedema (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. The business case was noted and ra traffic light classification of Red (Hospital/Specialist only) was afforded.

Bevacizumab *(Avastin®)* TAG recommendation: Mar 2012

for use in: Treatment of metastatic colorectal cancer after 1st-line chemotherapy - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2012.

Specific points: NICE TA 242 states that bevacizumab in combination with non-oxaliplatin (fluoropyrimide-based) chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.
People currently receiving bevacizumab in combination with non-oxaliplatin chemotherapy for the treatment of metastatic colorectal cancer that has progressed after first-line chemotherapy should have the option to continue treatment until they and their clinician consider it appropriate to stop.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2015: The TAG noted NICE CG 131 for the diagnosis and management of colorectal cancer but did not make any specific "traffic light" recommendations for this SCG commissioned treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted the NICE CG 131.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bevacizumab *(Avastin®)* TAG recommendation: Jul 2013

for use in: (with gemcitabine & carboplatin) - treatment of the first recurrence of platinum-sensitive advanced ovarian cancer - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2013.

Specific points: NICE TA 285 (May 2013) states that Bevacizumab in combination with gemcitabine and carboplatin is not recommended within its marketing authorisation, that is, for treating people with the first recurrence of platinum-sensitive advanced ovarian cancer (including fallopian tube and primary peritoneal cancer) who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents.

July 2013: The Norfolk and Waveney Drugs & Therapeutics Commissioning Groups noted NICE TA 285.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Bevacizumab *(Avastin®)* TAG recommendation: May 2011

for use in: First-line treatment of metastatic breast cancer (in combination with a taxane) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: The TAG noted NICE Technology Appraisal Guidance 214 which does not recommend use.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bevacizumab *(Avastin®)* TAG recommendation: Jan 2011

for use in: With oxaliplatin and either 5-FU plus folinic acid or capecitabine for metastatic colorectal cancer - as NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2010.

Specific points: January 2011: The TAG noted NICE TA Guidance 212 which does not recommend use.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2015: The TAG noted NICE CG 131 (December 2014) - the diagnosis and management of colorectal cancer.
Noted by the N&W CCGs' D&TCG.
Commissioning responsibility of the NHS England SCG.

Bevacizumab *(Avastin®)* TAG recommendation: May 2018

for use in: Neurofibromatosis (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Bevacizumab *(Avastin®)* TAG recommendation: May 2014

for use in: Choroidal neovascularisation (CNV) secondary to conditions other than age-related macular degeneration (AMD) or pathological myopia (PM) - as per local agreement during 2014-15 (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2014: The TAG considered a draft Policy produced by Public Health on behalf of the N&W CCGs Individual Funding Request (Drugs) Panel.

Supported in principle by the TAG subject to recommended amendments to emphasise the low quality of available evidence for this small group of patients.
Business application and proforma to be developed to advice and support commissioning process.
The clinicians are asked to maintain a register and carry out a prospective study of the cases coming through as a result of the policy.
Information on outcomes to be reported back after 12 months' use.

Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) meeting May 2014:

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bevacizumab *(Avastin®)* TAG recommendation: Jul 2013

for use in: (with paclitaxel & carboplatin) 1st-line for advanced ovarian cancer - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2013.

Specific points: April 2013: NHS England SCG took over commissioning responsibility.

July 2013: the TAG noted final NICE Technology Appraisal guidance 284 (May 2013) which confirmed that the treatment is not recommended by NICE.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

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Bevacizumab *(Avastin®)* TAG recommendation: Jun 2022

for use in: pre-treatment before vitrectomy for proliferative diabetic retinopathy (neovascular) (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Bevacizumab *(Avastin®)* TAG recommendation: Jul 2016

for use in: (Short term) treatment of neovascular glaucoma in rubeosis iridis - as per locally commissioned agreement (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2016: The TAG noted the evidence and summary appraisal provided and agreed to support the NNUH's business application and recommended a traffic light classification of Red (Hospital/Specialist only) in line with the specified criteria for starting and stopping treatment stated in the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation and agreed to commission the treatment as Red (Hospital/Specialist only) in line with the specified criteria for starting and stopping treatment stated in the business application.

November 2017:
The TAG acknowledged NICE NG 81 - Glaucoma: diagnosis and management (October 2017) and noted that it states that generic eye drop options should be used first-line in the treatment of glaucoma and that preservative-free products should be reserved for use where there is known allergy or high risk of conversion to chronic open angle glaucoma (COAG).

Noted by the D&TCG.

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bexarotene *(Targretin®)* TAG recommendation: Mar 2008

for use in: All indications (x).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

Commissioning responsibility of NHS England SCG from April 2013.

Binimetinib *(Mektovi®)* TAG recommendation: Mar 2019

for use in: (with encorafenib (Braftovi®)) for treating unresectable or metastatic BRAF V600 mutation-positive melanoma in adults - as per NICE TA 562 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 562 (February 2019) which recommended use as an option, only if the company provides encorafenib and binimetinib according to the commercial arrangements.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibliity treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Bortezomib *(Velcade®)* TAG recommendation: May 2014

for use in: Induction therapy in multiple myeloma before high-dose chemotherapy and autologous stem cell transplantation - as per NICE TA 311 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2014.

Specific points: NICE TA 311 (April 2014) states:
Bortezomib is recommended as an option within its marketing authorisation, that is, in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adults with previously untreated multiple myeloma, who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Commissioning responsibility of NHS England SCG.

May 2014: TAG recommendation noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bortezomib *(Velcade®)* TAG recommendation: Jan 2016

for use in: Previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable as per NICE TA 370 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: January 2016: The TAG noted NICE TA 370 (December 2015) for the treatment of previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Bortezomib *(Velcade®)* TAG recommendation: Sep 2011

for use in: Multiple myeloma (first line) - as per NICE 228 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2011.

Specific points: NICE TA 228 (http://guidance.nice.org.uk/TA228) states:
Bortezomib in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma if:
* high-dose chemotherapy with stem cell transplantation is considered inappropriate and
* the person is unable to tolerate or has contraindications to thalidomide.

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and agreed to commission and fund bortezomib (and thalidomide) for the first-line treatment of multiple myeloma as per NICE TA 228 (July 2011) subject to confirmation that the treatments were included on the Anglia Cancer Network's current list of approved regimens.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Bosutinib *(Bosulif®)* TAG recommendation: Sep 2016

for use in: Previously treated chronic myeloid leukaemia - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: NICE TA 299 (Nov 2013)
Not recommended by NICE.

NHS England SCG-commissioning responsibility.

January 2014: N&W CCGs' D&TCG noted the TAG recommendation

September 2016: The TAG acknowledged NICE TA 401 (August 2016) and recommended a revised classification of Red (Hospital only use) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recoemmendation.

Brentuximab vedotin *(Adcetris)* TAG recommendation: Sep 2020

for use in: in combination for untreated systemic anaplastic large cell lymphoma as per TA641 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2020.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Brentuximab vedotin *(Adcetris®)* TAG recommendation: May 2019

for use in: Treating CD30-positive cutaneous T-cell lymphoma (CTCL) after at least 1 systemic therapy in adults, only if they have mycosis fungoides stage IIB or over, primary cutaneous anaplastic large cell lymphoma or Sézary syndrome - as per NICE TA 577 (NHSE

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2019.

Specific points: Recommended by NICE as an option, only if the company provides it according to the commercial arrangement.

May 2019: The TAG noted NICE TA 577 (April 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

May 2019: Noted by the D&TC.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Brentuximab vedotin *(Adcetris®)* TAG recommendation: Jul 2018

for use in: CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease - as per NICE TA 524 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 524 (June 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Brentuximab vedotin ▼ *(Adcetris® ▼)* TAG recommendation: Jul 2017

for use in: CD30-positive Hodgkin lymphoma - as per NICE TA 446 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 446 (June 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Brentuximab vedotin ▼ *(Adcetris® ▼)* TAG recommendation: Nov 2017

for use in: For treating relapsed or refractory systemic anaplastic large cell lymphoma in adults, only if they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 - as per NICE TA 478 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
Recommended as an option by NICE.
The TAG acknowledged NICE TA 478 (Oct 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Noted by the D&TCG

Brexucabtagene autoleucel *(Tecartus®)* TAG recommendation: Jul 2023

for use in: relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over TA893 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Brigatinib *(Alunbrig®)* TAG recommendation: May 2019

for use in: For treating ALK-positive advanced non-small-cell lung cancer in adults, after crizotinib - as per NICE TA 571 (NHSE commissioning responsibility) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2019.

Specific points: May 2019:
Recommended by NICE only if the company provides it according to the commercial arrangement.
The TAG noted NICE TA 571 (March 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE commissioning responsibility treatment.

May 2019: Noted by the D&TC

Brigatinib *(Alunbrig®)* TAG recommendation: Mar 2021

for use in: ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor as per TA670 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Cabazitaxel *(Jevtana®)* TAG recommendation: Sep 2016

for use in: Metastatic hormone relapsed prostate cancer in people whose disease has progressed during or after docetaxel chemotherapy - as per NICE TA 391 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: September 2016: NICE TA 391 states that:
Cabazitaxel (Jevtana®) for hormone-relapsed metastatic prostate cancer treated with docetaxel is an option if:
* ECOG performance status is 0 or 1
* 225 mg/m2 or more of docetaxel has been given
* cabazitaxel is stopped when the disease progresses or after max 10 cycles, whichever occurs first
* cabazitaxel is purchased in pre prepared intravenous infusion bags, not in vials, and
* is provided with the discount agreed under PAS.
The TAG noted NICE TA 391(update) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Cabozantinib *(Cabometyx®)* TAG recommendation: Jan 2023

for use in: previously treated advanced hepatocellular carcinoma TA849 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2022.

Specific points: Replaces TA582

Cabozantinib *(Cabometyx®)* TAG recommendation: Nov 2018

for use in: Untreated advanced renal cell carcinoma in adults under defined circumstances - as per NICE TA 541 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2018.

Specific points: November 2018: The TAG noted NICE TA 542 (October 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Cabozantinib ▼ *(Cabometyx® ▼)* TAG recommendation: Sep 2017

for use in: Previously treated advanced renal cell carcinoma in adults after vascular endothelial growth factor (VEGF)-targeted therapy - as per NICe TA 463 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 463 (August 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Carfilzomib *(Kyprolis®)* TAG recommendation: Dec 2020

for use in: previously treated multiple myeloma as per TA657 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Carfilzomib *(Kyprolis®)* TAG recommendation: May 2021

for use in: (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2021.

Specific points: Red (Hospital / Specialist use only)

Carfilzomib ▼ *(Kyprolis® ▼)* TAG recommendation: Sep 2017

for use in: (with dexamethasone) for previously treated multiple myeloma where the patient has had only 1 previous therapy, which did not include bortezomib - as per NICE 457 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 457 (July 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Cemiplimab *(Libtayo®)* TAG recommendation: Jul 2022

for use in: advanced cutaneous squamous cell carcinoma as per TA802 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Ceritinib *(Zykadia®)* TAG recommendation: Jul 2016

for use in: Anaplastic lymphoma kinase positive non-small-cell lung cancer in adults previously treated with crizotinib - as per NICE TA 395 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2016.

Specific points: July 2016: The TAG noted NICE TA 395 (June 2016) for adults previously treated with crizotinib and only if it is provided with the discount agreed under PAS and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs; D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ceritinib ▼ *(Zykadia® ▼)* TAG recommendation: Mar 2018

for use in: Untreated ALK-positive non-small-cell lung cancer in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 500 (January 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Cetuximab *(Erbitux®)* TAG recommendation: May 2017

for use in: First-line treatment of metastatic colorectal cancer under specified circumstances - as per NICE TA 176 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2017.

Specific points: August 2009 - NICE Technology Appraisal Guidance 176 - Cetuximab for the first-line treatment of metastatic colorectal cancer - recommends use of cetuximab as part of the FOLFOX and the FOLFIRI treatment regimens under specified circumstances.

April 2013: NHS England SCG took over commissioning responsibility.

January 2015: The TAG noted NICE CG 131for the diagnosis and management of colorectal cancer but did not make any specific "traffic light" recommendations for this SCG commissioned treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted the NICE CG 131.

May 2017: The TAG acknowledged NICE TA 439 (March 2017) for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults:
Cetuximab is recommended as an option in combination with:
* 5 fluorouracil, folinic acid and oxaliplatin (FOLFOX) or
* 5 fluorouracil, folinic acid and irinotecan (FOLFIRI)
and recommended traffic light classifications of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Cetuximab *(Erbitux®)* TAG recommendation: Nov 2017

for use in: Recurrent or metastatic squamous cell head and neck cancer in adults only if started in the mouth - as per NICE TA 473 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: July 2009 - the acknowledged NICE Technology Appraisal Guidance No. 172 - cetuximab not supported by NICE for this indication.
Cetuximab is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the MHRA Yellow Card scheme.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

November 2017:
The TAG acknowledged NICE TA 473 (Aug 17) and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

This guidance is a Cancer Drugs Fund reconsideration of cetuximab which replaces TA172.

Noted by the D&TCG.

Cetuximab *(Erbitux®)* TAG recommendation: Mar 2012

for use in: Treatment of metastatic colorectal cancer after 1st-line chemotherapy - as per NICE TA 242 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2012.

Specific points: NICE TA 242 states that cetuximab monotherapy or combination chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.
People currently receiving cetuximab monotherapy or combination chemotherapy for the treatment of metastatic colorectal cancer that has progressed after first-line chemotherapy should have the option to continue treatment until they and their clinician consider it appropriate to stop.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated in line with the Cancer Drug Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2015: The TAG noted NICE CG 131for the diagnosis and management of colorectal cancer but did not make any specific "traffic light" recommendations for this SCG commissioned treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted the NICE CG 131.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Cetuximab *(Erbitux®)* TAG recommendation: Jul 2008

for use in: Locally advanced squamous cell cancer of the head and neck - as per NICE TA 145 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2008.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No. 145 June 2008 which recommended use. Prescriber's Rating of 2. - a real advance - the product is an important therapeutic innovation but has certain limitations.

April 2013: NHS England SCG took over commissioning responsibility.

Crizotinib *(Xalkori®)* TAG recommendation: Sep 2018

for use in: ROS1-positive advanced non-small-cell lung cancer - as per NICE TA 529 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2018.

Specific points: September 2018: The TAG noted NICE TA 529 (July 2018) which recommended use of crizotinib as an option within the Cancer Drugs Fund. The TAG recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Crizotinib ▼ *(Xalkori® ▼)* TAG recommendation: Jan 2017

for use in: Previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene - as per NICE TA 422 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: November 2013: The TAG noted that NICE TA 296 did not recommend the use of this treatment. The TAG also noted that this is a treatment which is currently the commissioning responsibility of NHS England SCG.

January 2017: The TAG acknowledged NICE TA 422 (December 2016) and recommended a revised traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Crizotinib ▼ *(Xalkori® ▼)* TAG recommendation: Nov 2016

for use in: Untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer - as per NICE TA 406 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 406 (September 2016) recommended by NICE as an option, only if the company provides it with the discount agreed in the patient access scheme and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.,

Dabrafenib *((Tafinlar®))* TAG recommendation: Jul 2023

for use in: plus trametinib for treating BRAF V600 mutation-positive advanced non-small-cell lung cancer TA898 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Dabrafenib ▼ *(Tafinlar® ▼)* TAG recommendation: Nov 2014

for use in: Treatment of unresectable or metastatic BRAF V600 mutation-positive melanoma (alone or with trametinib) - as per NICE TA 321 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2014.

Specific points: Dabrafenib is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the MHRA Yellow Card scheme.

November 2014: The TAG acknowledged NICE TA 321 recommending the treatment as an option if discounted under PAS and recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioned treatment.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG's recommendation.

September 2015: The TAG noted NG 14 (July 2015) - Assessment and management of melanoma in children, young people and adults which includes recommendations on:
* Assessing and staging melanoma
* Treating stages 0-II melanoma
* Treating stage III melanoma
* Treating stage IV melanoma
* Follow up after treatment
* Managing suboptimal vitamin D levels

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

July 2016: The TAG noted NICE TA 396 (June 2016) Trametinib (Mekinist®) in combination with Dabrafenib (Tafinlar®) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Dabrafenib with trametinib *(Tafinlar® with Mekinist®)* TAG recommendation: Nov 2018

for use in: Adjuvant treatment of resected BRAF V600 mutation-positive melanoma - as per NICE TA 544 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2018.

Specific points: November 2018: The TAG noted NICE TA 544 (October 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for these NHSE-commissioning responsibility treatments.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

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- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Dacomitinib *(Vizimpro®)* TAG recommendation: Sep 2019

for use in: Untreated EGFR mutation-positive non-small-cell lung cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA595 - August 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Daratumumab *((Darzalex®))* TAG recommendation: Jul 2023

for use in: with bortezomib and dexamethasone for previously treated multiple myeloma TA897 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Daratumumab *(Darzalex®)* TAG recommendation: Mar 2022

for use in: in combination for untreated multiple myeloma when a stem cell transplant is suitable as per TA763 - Feb 2022 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: NHS England

Daratumumab *(Darzalex®)* TAG recommendation: May 2022

for use in: As monotherapy for treating relapsed and refractory multiple myeloma - as per NICE TA783 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 510 (March 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

May 2022 - TA510 replaced by TA783

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Daratumumab (with bortezomib and dexamethasone) *(Darzalex®)* TAG recommendation: May 2019

for use in: Previously treated multiple myeloma •in people who have had 1 previous treatment - as per NICE TA 573 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2019.

Specific points: Recommended by NICE as an option within the Cancer Drugs Fund and •only if the conditions in the managed access agreement for daratumumab plus bortezomib plus dexamethasone are followed.

May 2019: The TAG noted NICE TA 573 (April 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE- commissioning responsibility treatment.

May 2019: Noted by the D&TC

Dasatinib *(Sprycel®)* TAG recommendation: Jan 2017

for use in: Untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults - as per NICE TA 426 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2017: The TAG acknowledged NICE TA 426 (December 2016) for dasatinib, nilotinib and imatinib for untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, and recommended traffic light classifications of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Dasatinib *(Sprycel®)* TAG recommendation: Jan 2017

for use in: Chronic myeloid leukaemia (CML) - as per NHS England policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2012:
NICE TA 241 states that dasatinib is not recommended across all CML indications.
(patients already on treatment may continue as appropriate in consultation with their specialist).

April 2012:
NICE TA 251 states that dasatinib is not recommended for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML.
http://guidance.nice.org.uk/TA251

19th July 2012: The NHS Norfolk & Waveney Drug & Therapeutics Commissioning Group confirmed that dasatinib for CML is decommissioned.

November 2013:
Commissioning responsibility of NHS England SCG from April 2013.

Recommendation revised to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf which includes use of dasatinib for CML under specified criteria.

January 2017:
NICE TA 425 (December 2016) replaces TA 241 (January 2012), and partially updates NICE TA 70 (last update January 2016) on imatinib for chronic myeloid leukaemia.

The TAG acknowledged NICE TA 425 (December 2016) for dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia. Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:
* they cannot have imatinib, or their disease is imatinib-resistant
* High-dose imatinib (i.e. 600mg in the chronic phase or 800mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant
and recommended traffic light classifications of:
Red (Hospital/Specialist only) for recommended uses of dasatinib and nilotinib
and
Double Red (Not recommended for routine use) for use of high-dose imatininb

for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Dinutuximab beta *(Qarziba®)* TAG recommendation: Sep 2018

for use in: High-risk neuroblastoma in people aged 12 months and over - as per NICE TA538 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018: The TAG noted NICE TA 538 (August 2018) which states:
Dinutuximab beta (Qarziba®) is recommended as an option by NICE for treating high-risk neuroblastoma in people aged 12 months and over whose disease has at least partially responded to induction chemotherapy, followed by myeloablative therapy and stem cell transplant, only if:
* they have not already had anti-GD2 immunotherapy and
* the company provides dinutuximab beta according to the commercial arrangement.

The TAG recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Docetaxel *(Taxotere®)* TAG recommendation: Nov 2013

for use in: Non-small cell lung cancer - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts Enter period.

NICE issued Guidance in: November 2013.

Specific points: April 2013: NHS England SCG took over commissioning responsibility.

November 2013: NICE treatemnet pathway for NSCLC - http://pathways.nice.org.uk/pathways/lung-cancer

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Docetaxel *(Taxotere®)* TAG recommendation: Mar 2009

for use in: Advanced breast cancer - as per NICE CG 80 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: February 2009.

Specific points: March 2009: The TAG acknowledged NICE Clinical Guideline 80 - Early and locally advanced breast cancer (Feb 2009), which specifies the place of docetaxel as part of adjuvant chemotherapy regimen for lymph node positive breast cancer.

March 2009: TAG acknowledged NICE Clinical Guideline 81 Advanced Breast Cancer, which states that for patients with advanced breast cancer who are not suitable for anthracyclines (because they are contraindicated or because of prior anthracycline treatment either in the adjuvant or metastatic setting), systemic chemotherapy should be offered in the following sequence:
* First line: single-agent docetaxel
* Second line: single-agent vinorelbine or capecitabine
* Third line: single-agent capecitabine or vinorelbine (whichever was not used as second-line treatment)

Commissioning responsibility of NHS England SCG from April 2013.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Docetaxel *(Taxotere®)* TAG recommendation: Nov 2008

for use in: Substitute for paclitaxel causing peripheral neuropathy in ovarian cancer - as per NHS England policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Commissioning responsibility of NHS England SCG from April 2013.

Doxorubicin HCl (pegylated liposomal) (PLDH) *(Caelyx)* TAG recommendation: May 2016

for use in: As monotherapy or with platinum for treatment of advanced recurrent ovarian cancer - as per NICE TA 389 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2016.

Specific points: May 2016: The TAG noted NICE TA 389 (April 2016) review of TA91 & TA 222 (ID468) Topotecan (Hycamtin®), pegylated liposomal doxorubicin hydrochloride (Caelyx®), paclitaxel, trabectedin (Yondelis®) and gemcitabine for advanced recurrent ovarian cancer:
* Paclitaxel in combination with platinum or as monotherapy is recommended as an option.
* Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended as an option.
* PLDH in combination with platinum is recommended as an option.
The following are not recommended for treating the first recurrence of platinum sensitive ovarian cancer:
* gemcitabine in combination with carboplatin
* trabectedin in combination with PLDH
* topotecan
The appraisal committee was unable to recommend use of these technologies to treat platinum sensitive ovarian cancer beyond the first recurrence.
*Topotecan is not recommended for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

The TAG recommended a classification of Red (Hospital/Specialist only) for the treatments recommended by NICEand Double Red (Not recommended for routine use/Not commissioned) for those treatments not recommended by NICE.
It was noted that these are SCG-commissioning responsibility treatments.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Encorafenib *(Braftovi®)* TAG recommendation: Mar 2019

for use in: (with binimetinib (Mektovi®)) for treating unresectable or metastatic BRAF V600 mutation-positive melanoma in adults - as per NICE TA 562 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 562 (February 2019) which recommended use as an option, only if the company provides encorafenib and binimetinib according to the commercial arrangements.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibliity treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Encorafenib *(Braftovi®)* TAG recommendation: Mar 2021

for use in: plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer as per TA668 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Entrectinib *(Rozlytrek)* TAG recommendation: Sep 2020

for use in: treating ROS1-positive advanced non-small-cell lung cancer as per TA643 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2020.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Entrectinib *(Rozlytrek)* TAG recommendation: Sep 2020

for use in: treating NTRK fusion-positive solid tumours as per TA644 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2020.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Eribulin *(Halaven®)* TAG recommendation: Jan 2017

for use in: Locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens only when it has progressed after at least 2 chemotherapy regimens (which may include an anthracycline or a taxane, and capecitabine) - as per NICE TA 423 (A licensed

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2017: The TAG noted NICE TA 423 (December 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Eribulin *(Halaven®)* TAG recommendation: Jan 2017

for use in: Treatment of locally advanced or metastatic breast cancer - as per NICE TA 423 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: 3rd May 2012:
Not recommended by NICE for this indication.
http://guidance.nice.org.uk/TA250

17th May 2012: The NHS Norfolk & Waveney Drug & Therapeutics Commissioning Group decided not to fund use of eribulin as per NICE TA 250.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

January 2017: The TAG noted NICE TA 423 (December 2016) which replaced NICE TA 250 and re-affirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Everolimus *(Afinitor®)* TAG recommendation: Jul 2017

for use in: Unresectable or metastatic neuroendocrine tumours in people with progressive disease in adults - as per NICE TA 449 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 449 (June 2017) and recommended traffic light classifications of Red (Hospital/Specialist only) for everolimus and sunitinib (SCG-commissioning responsibility treatments).

July 2017: Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Everolimus *(Afinitor tablets® ▼)* TAG recommendation: Mar 2017

for use in: 2nd line for advanced renal cell carcinoma - as per NICE TA 432 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2017.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 219 which does not recommend use for this indication.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

March 2017: The TAG acknowledged NICE TA 432 (February 2017) for advanced renal cell carcinoma that has progressed during or after treatment with vascular endothelial growth factor targeted therapy, and recommended a revised traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Everolimus *(Afinitor®)* TAG recommendation: Jan 2017

for use in: (with exemestane) for advanced HER2-negative, hormone-receptor-positive breast cancer in postmenopausal women - as per NICE TA 421 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: September 2013: The TAG noted NICE TA 295. Everolimus (with exemestane) - for advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy was not recommended.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) therefore did not commission the treatment.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

January 2017: The TAG acknowledged NICE TA 421 (December 2016) which replaced TA 295 and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Fedratinib *(Inrebic®)* TAG recommendation: Jan 2022

for use in: disease-related splenomegaly or symptoms in myelofibrosis as per TA756 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Filgotinib *(Jyseleca®)* TAG recommendation: Jan 2023

for use in: moderately to severely active ulcerative colitis as per TA792 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Jan 2023 - application accepted and amended to red

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Gefitinib *(Iressa®)* TAG recommendation: Sep 2010

for use in: First-line treatment of locally advanced or metastatic non-small-cell lung cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2010.

Specific points: The TAG noted NICE TA 192 which states: Gefitinib is recommended as an option for the first line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if:
* they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and
* the manufacturer provides gefitinib at the fixed price agreed under the patient access scheme.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Gefitinib *(Iressa®)* TAG recommendation: Jan 2016

for use in: Treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) that has progressed after prior non-targeted chemotherapy because of delayed confirmation of epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation status (as

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: January 2016:
The TAG noted NICE TA 374 (which supersedes NICE TA 162) which recommends use of Erlotinib (Tarceva®) and gefitinib (Iressa®) as options for treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) that has progressed after prior non-targeted chemotherapy because of delayed confirmation of epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation status, if
* the cancer tests positive for the EGFR TK mutation or
* it is not known if the cancer is EGFR TK mutation positive because of problems with the test, and
  the cancer is very likely to be EGFR TK mutation positive
  it responds to the first 2 cycles of treatment with erlotinib

January 2016:
The Norfolk & Waveney CCGs' D&TCG noted NICE TA 374 for these NHS England SCG-commissioning responsibility treatments and the TAG's recommendations.

Gemtuzumab ozogamicin *(Mylotarg®)* TAG recommendation: Jan 2019

for use in: Untreated de novo CD33-positive acute myeloid leukaemia in people aged ≥15 years - as per NICE TA 545 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2018.

Specific points: January 2019: The TAG noted NICE TA 545 (November 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHS England commissioning responsibility treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Gilteritinib *(Xospata)* TAG recommendation: Sep 2020

for use in: treating relapsed or refractory acute myeloid leukaemia as per TA642 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2020.

Specific points: Sept 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This was supported by the D+TC

Ibrutinib *(Imbruvica®)* TAG recommendation: Jul 2023

for use in: with venetoclax for untreated chronic lymphocytic leukaemia TA891 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Ibrutinib ▼ *(Imbruvica® ▼)* TAG recommendation: Jan 2018

for use in: Waldenstrom's macroglubulinaemia (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 491 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ibrutinib ▼ *(Imbruvica® ▼)* TAG recommendation: Mar 2017

for use in: Previously treated adults with chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation - as per NICE TA 429 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2017.

Specific points: March 2017: The TAG acknowledged NICE TA 429 (January 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ibrutinib ▼ *(Imbruvica® ▼)* TAG recommendation: Mar 2018

for use in: Relapsed or refractory mantle cell lymphoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 502 (January 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Idelalisib ▼ *(Zydelig® ▼)* TAG recommendation: Nov 2015

for use in: Chronic lymphocytic leukaemia for adults (in combination with rituximab) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2015.

Specific points: November 2015: The TAG noted NICE TA 359 (October 2015) for chronic lymphocytic leukaemia for adults when:
* untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation or
* for previously treated adults with chronic lymphocytic leukaemia who have relapsed within 24 months.
And recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Imatinib ▼ *(Glivec® ▼)* TAG recommendation: Jan 2011

for use in: Kit-positive unresectable and /or metastatic GIST (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: November 2010.

Specific points: January 2011: The TAG acknowledged NICE Technology Appraisal 209 (partial update of TA 86) as follows:
Imatinib at 600 or 800 mg/day is not recommended for people with unresectable
and/or metastatic gastrointestinal stromal tumours whose disease has progressed after treatment with 400 mg/day imatinib.
People who are currently receiving 600 or
800 mg/day imatinib for unresectable and/or metastatic gastrointestinal stromal tumours should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Imatinib ▼ *(Glivec® ▼)* TAG recommendation: Sep 2010

for use in: Adjuvant treatment of gastrointestinal stromal tumours (GIST) after surgery (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2014.

Specific points: The TAG noted NICE TA Guidance 196: Imatinib for adjuvant treatment of gastrointestinal stromal tumours - not recommended by NICE.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2015: The TAG noted NICE TA 326 (review of NICE TA 196) Recommended by NICE as an option as adjuvant treatment for up to three years for patients who are at high risk of relapse after surgery, under specified criteria, and recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility drug.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

March 2015: The TAG noted the NHS England SSC 1568 (January 2015). (Commissioning document to advise Local Area Team of the budget impact for 2015/16.)

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the NHSE SSC 1568 (January 2015).

Imatinib mesylate ▼ *(Glivec® ▼)* TAG recommendation: Jan 2017

for use in: Untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2017:
NICE TA 426 updates and replaces NICE TA 251 (April 2012) - Dasatinib, nilotinib and standard-dose imatinib for the first-line treatment of chronic myeloid leukaemia.

The TAG acknowledged NICE TA 426 (December 2016) for dasatinib, nilotinib and imatinib for untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, and recommended traffic light classifications of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Imatinib mesylate ▼(standard dose) *(Glivec® ▼)* TAG recommendation: Mar 2016

for use in: Chronic myeloid leukaemia (CML) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: See Red (Hospital Only) section also for use in GIST and the Double Red (Not recommended for routine use) section for unlicensed indications and high-dose imatinib in CML..

NICE TA 241 also outlines current recommendations for treatment of imatinib-resistant CML. http://guidance.nice.org.uk/TA241

April 2012: NICE TA 251 states that Standard-dose imatinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML). http://guidance.nice.org.uk/TA251

Commisioned as provided via Homecare.

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

March 2016:
The TAG noted the partial update to NICE TA 70 regarding use of imatinib for CML.

January 2017:
NICE TA 425 (December 2016) replaces TA 241 (January 2012), and partially updates NICE TA 70 (last update January 2016) on imatinib for chronic myeloid leukaemia.

The TAG acknowledged NICE TA 425 (December 2016) for dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia. Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:
* they cannot have imatinib, or their disease is imatinib-resistant
* High-dose imatinib (i.e. 600mg in the chronic phase or 800mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant
and recommended traffic light classifications of:
Red (Hospital/Specialist only) for recommended uses of dasatinib and nilotinib
and
Double Red (Not recommended for routine use) for use of high-dose imatininb

for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ipilimumab *(Yervoy®)* TAG recommendation: Sep 2014

for use in: Previously untreated advanced (unresectable or metastatic) melanoma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2014.

Specific points: NICE TA 319 (July 2014):
Recommended by NICE as an option for previously untreated people with advanced (unresectable or metastatic) melanoma, if discounted under PAS.

September 2014: The TAG noted NICE TA 319 and recommended a classification of Red (Hospital/Specialist only).

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

SCG commissioning responsibility.

September 2015: The TAG noted NG 14 (July 2015) - Assessment and management of melanoma in children, young people and adults which includes recommendations on:
* Assessing and staging melanoma
* Treating stages 0-II melanoma
* Treating stage III melanoma
* Treating stage IV melanoma
* Follow up after treatment
* Managing suboptimal vitamin D levels

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ipilimumab *(Yervoy®)* TAG recommendation: Jan 2013

for use in: Previously treated advanced (unresectable or metastatic) melanoma (stage III or IV) in previously treated people (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2012.

Specific points: December 2012:
NICE TA 268 recommends Ipilimumab as an option for treating advanced (unresectable or metastatic) melanoma in people who have received prior therapy, only if the manufacturer provides ipilimumab with the discount agreed in the Patient Access Scheme.
Noted to be a high cost treatment: £75k-£100k per treatment course.

January 2013: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) commissioned use as per NICE TA 268 (http://guidance.nice.org.uk/TA268)

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

September 2015: The TAG noted NG 14 (July 2015) - Assessment and management of melanoma in children, young people and adults which includes recommendations on:
* Assessing and staging melanoma
* Treating stages 0-II melanoma
* Treating stage III melanoma
* Treating stage IV melanoma
* Follow up after treatment
* Managing suboptimal vitamin D levels

Irinotecan *(Campto®)*

for use in: Colorectal cancer 2nd line (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2005.

Specific points: NICE TA 93 (August 2005):
Irinotecan and oxaliplatin are recommended as possible treatments for people with advanced colorectal cancer, if they are used in these ways:
Irinotecan is given with 5-fluorouracil and folinic acid to people who have not had chemotherapy for advanced colorectal cancer before, or given on its own to people who have already had chemotherapy.
Oxaliplatin is always given with 5-fluorouracil and folinic acid.
Raltitrexed is not recommended for people with advanced colorectal cancer, unless they are taking part in a clinical trial.

April 2013: NHS Engalnd SCG took over commissioning responsibility for this treatment.

January 2015: The TAG noted NICE CG 131for the diagnosis and management of colorectal cancer but did not make any specific "traffic light" recommendations for this SCG commissioned treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted the NICE CG 131.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Isatuximab *(Sarclisa®)* TAG recommendation: Dec 2020

for use in: with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma as per TA658 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

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Ixazomib *(Ninlaro®)* TAG recommendation: Mar 2023

for use in: with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma TA870 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Ixazomib ▼ (with lenalidomide and dexamethasone) *(Ninlaro® ▼)* TAG recommendation: Mar 2018

for use in: Relapsed or refractory multiple myeloma - as per NICE TA 505 - CDF list (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 505 (February 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

May 2018: Noted to be listed by NHS England as per the Cancer Drugs Fund

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Larotrectinib *(Vitrakvi)* TAG recommendation: Jul 2020

for use in: treating NTRK fusion-positive solid tumours as per TA630 (May 2020) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Lenvatinib *(Lenvima®)* TAG recommendation: Jan 2019

for use in: Untreated advanced, unresectable hepatocellular carcinoma in adults - as per NICE TA 551 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2018.

Specific points: January 2019: The TAG noted NICE TA 551 (December 2018) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHS England commissioning responsiblilty treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Lenvatinib *(Kisplyx®)* TAG recommendation: Mar 2023

for use in: with pembrolizumab (Keytruda®) for untreated advanced renal cell carcinoma TA858 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Lenvatinib (with sorafenib) *(Lenvima® (used with Nexavar®))* TAG recommendation: Sep 2018

for use in: Progressive, locally advanced or metastatic differentiated thyroid cancer - as per NICE TA 535 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018: The TAG noted NICE TA 535 (August 2018) which stated:
Lenvatinib (Lenvima®) and sorafenib (Nexavar®) are recommended by NICE as options for treating progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults whose disease does not respond to radioactive iodine, only if:
* they have not had a tyrosine kinase inhibitor before or
* they have had to stop taking a tyrosine kinase inhibitor within 3 months of starting it because of toxicity (specifically, toxicity that cannot be managed by dose delay or dose modification).
* Lenvatinib and sorafenib are recommended only if the companies provide them according to the commercial arrangements

and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Lenvatinib ▼ (with everolimus) *(Kisplyx® ▼)* TAG recommendation: Mar 2018

for use in: Previously treated advanced renal cell carcinoma in adults who have had 1 previous vascular endothelial growth factor (VEGF)-targeted therapy - as per NICE TA 498 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2018.

Specific points: March 2018: The TAG acknowledged NICE TA 498 (January 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Lorlatinib *(Lorviqua)* TAG recommendation: Jul 2020

for use in: previously treated ALK-positive advanced non-small-cell lung cancer as per TA628 (May 2020) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC

Midostaurin *(Rydapt®)* TAG recommendation: Jul 2018

for use in: Untreated FLT3-mutation-positive acute myeloid leukaemia in adults - as per NICE TA 523 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 523 (June 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Midostaurin *(Rydapt®)* TAG recommendation: Oct 2021

for use in: advanced systemic mastocytosis as per TA728 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Mitotane *(Lysodren®)* TAG recommendation: Mar 2008

for use in: Adrenocortical carcinoma (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

April 2013: NHS Engalnd SCG took over commissioning responsibility for this treatment.

Mobocertinib *(EXKIVITY®)* TAG recommendation: Mar 2023

for use in: EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy TA855 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Neratinib *(Nerlynx®)* TAG recommendation: Jan 2020

for use in: Extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2019.

Specific points: February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Red (Hospital/Specialist only) was afforded for this NHS England Commissioning responsibility treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nilotinib *(Tasigna®)* TAG recommendation: Jan 2017

for use in: Untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults - as per NICE TA 426 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: April 2012: NICE TA 251 states that nilotinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme. http://guidance.nice.org.uk/TA251

17th May 2012: The NHS Norfolk and Waveney Drug & Therapeutics Commissioning Group decided to fund standard-dose imatinib as per NICE TA 251.

19th July 2012: The NHS Norfolk and Waveney Drug & Therapeutics Commissioning Group commisioned use of nilotinib for all acute trust providers as per the NICE TA 251 Costing template, and provided that the treatment is supplied via Homecare (as for imatinib).

Use of dasatinib was decommissioned.

January 2017:
The TAG acknowledged NICE TA 426 (December 2016) for dasatinib, nilotinib and imatinib for untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, and recommended traffic light classifications of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nilotinib ▼ *(Tasigna® ▼)* TAG recommendation: Jan 2017

for use in: Chronic myeloid leukaemia in adults resistant or intolerant to imatinib as per NICE TA 425 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2009:
For individual patients with chronic myeloid leukaemia (chronic phase) who are intolerant to standard doses of imatinib (having experienced grade 3 or 4 adverse events), treatment with nilotinib should be considered under Prior Approval.

March 2012: The TAG acknowledged NICE TA 241 which states that nilotinib is recommended for all CML indications where there is resistance or intolerance to standard-dose imatinib, via a Patient Access Scheme.

April 2012: NICE TA 251 states that nilotinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme.
http://guidance.nice.org.uk/TA251

17th May 2012: The NHS Norfolk and Waveney Drug & Therapeutics Commissioning Group decided to fund standard-dose imatinib as per NICE TA 251.

19th July 2012: The NHS Norfolk and Waveney Drug & Therapeutics Commissioning Group commisioned use of nilotinib for all acute trust providers as per the NICE TA 251 Costing template, and provided that the treatment is supplied via Homecare (as for imatinib).

Use of dasatinib was decommissioned.

April 2013: NHS Engalnd SCG took over commissioning responsibility for this treatment.

January 2017:
NICE TA 425 (December 2016) replaces TA 241 (January 2012), and partially updates NICE TA 70 (last update January 2016) on imatinib for chronic myeloid leukaemia.

The TAG acknowledged NICE TA 425 (December 2016) for dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia. Dasatinib and nilotinib are recommended as options for treating only chronic- or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:
* they cannot have imatinib, or their disease is imatinib-resistant
* High-dose imatinib (i.e. 600mg in the chronic phase or 800mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant
and recommended traffic light classifications of:
Red (Hospital/Specialist only) for recommended uses of dasatinib and nilotinib
and
Double Red (Not recommended for routine use) for use of high-dose imatininb

for these SCG-commissioning responsibility treatments.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nintedanib *(Ofev®)* TAG recommendation: Dec 2021

for use in: progressive fibrosing interstitial lung diseases as per TA747 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Nintedanib *(Ofev®)* TAG recommendation: Mar 2023

for use in: idiopathic pulmonary fibrosis when forced vital capacity is above 80% predicted TA864 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Nintedanib ▼ *(Ofev® ▼)* TAG recommendation: Mar 2016

for use in: Idiopathic pulmonary fibrosis - as per NICE TA 379 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG noted NICE TA 379 (January 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Nintedanib ▼ *(Vargatef® ▼)* TAG recommendation: Sep 2015

for use in: Previously treated locally advanced, metastatic, or locally recurrent non small cell lung cancer - as per NICE TA 347 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2015.

Specific points: September 2015: The TAG noted NICE TA 347 (July 2015) for nintedanib in combination with docetaxel, as an option for treating locally advanced, metastatic or locally recurrent non small cell lung cancer of adenocarcinoma histology that has progressed after first line chemotherapy, only if provided with discount agreed under the PAS. The TAG recommended a traffic light classification of Red (Hospital only) for this SCG-commissioning responsibility treatment.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted the TAG's recommendation regarding this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Niraparib *(Zejula®)* TAG recommendation: Mar 2021

for use in: maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemo as per TA673 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Niraparib *(Zejula®)* TAG recommendation: May 2022

for use in: Maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer - as per NICE TA784 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2022.

Specific points: September 2018: The TAG noted NICE TA 528 (July 2018) for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer only if:
* they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy or
* they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy
and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

Recommended by NICE as an option within the Cancer Drugs Fund.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

May 2022 - TA784 replaced TA528

Nivolumab *(Opdivo®)* TAG recommendation: Aug 2021

for use in: advanced non-squamous non-small-cell lung cancer after chemotherapy as per TA713 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: NHS England commissioned treatment

Nivolumab *(Opdivo®)* TAG recommendation: Nov 2021

for use in: recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy as per TA736 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nivolumab *(Opdivo®)* TAG recommendation: Jul 2021

for use in: previously treated unresectable advanced or recurrent oesophageal cancer as per TA707 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

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Nivolumab *(Opdivo®)* TAG recommendation: Dec 2021

for use in: adjuvant treatment of resected oesophageal or gastro-oesophageal junction cancer as per TA746 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Nivolumab *(Opdivo®)* TAG recommendation: Mar 2023

for use in: with fluoropyrimidine- and platinum-based chemotherapy for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma TA865 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Nivolumab *(Opdivo®)* TAG recommendation: Apr 2021

for use in: adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease as per TA684 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: April 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Nivolumab *(Opdivo®)* TAG recommendation: Mar 2023

for use in: with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma TA857 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nivolumab *(Opdivo®)* TAG recommendation: Mar 2019

for use in: Adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metstatic disease - as per NICE TA 558 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE TA 558 (January 2019) which recommended use only if the conditions in the managed access agreement are followed.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Nivolumab *(Opdivo®)* TAG recommendation: Nov 2020

for use in: advanced squamous non-small-cell lung cancer after chemotherapy as per TA655 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2020.

Specific points: Nov 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

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Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Mar 2016

for use in: Advanced (unresectable or metastatic) melanoma - as per NICE TA 384 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: March 2016: The TAG noted NICE TA 384 (February 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Jan 2018

for use in: Squamous cell carcinoma of the head and neck after platinum-based chemotherapy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 490 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Nov 2017

for use in: For previously treated local advanced or metastatic squamous non-small-cell lung cancer in adults after chemotherapy only if nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression - as per NICE TA 483 (A

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 483 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
Nivolumab will continue to be available through the Cancer Drug Fund while the guidance is being updated, as part of the managed access agreement.

Noted by the D&TCG.

Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Nov 2017

for use in: For previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer in adults after chemotherapy, only if their tumours are PD L1 positive and nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 484 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
Nivolumab will continue to be available through the Cancer Drug Fund while the guidance is being updated, as part of the managed access agreement.

Noted by the D&TCG.

Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Sep 2017

for use in: Relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin - as per NICE TA 462 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 462 (July 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Nivolumab ▼ *(Opdivo® ▼)* TAG recommendation: Jan 2017

for use in: Previously treated advanced renal cell carcinoma in adults - as per NICE TA 417 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2016.

Specific points: January 2017: The TAG acknowledged NICE TA 417 (November 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Nivolumab ▼ in combination with Ipilimumab *(Opdivo® ▼ in combination with Yervoy®)* TAG recommendation: Sep 2016

for use in: Advanced (unresectable or metastatic) melanoma in adults, only when the company provides ipilimumab with discount agreed under PAS - as per NICE TA 400 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2016.

Specific points: September 2016: The TAG acknowledged NICE TA 400 (July 2016) and recommended a classification of Red (Hospital only use) for these SCG-commissioning responsibility treatments.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Nivolumab with ipilimumab *(Opdivo and Yervoy®)* TAG recommendation: Sep 2021

for use in: previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency as per TA716 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2021.

Specific points: NHS England commissioned treatment

Olaparib *(LYNPARZA®)* TAG recommendation: Mar 2020

for use in: for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer as per NICE TA620 - Jan 2020 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2020.

Specific points: March 2020 - The TAG recommended a traffic light classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Olaparib *(Lynparza®)* TAG recommendation: Jun 2023

for use in: previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer TA887 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Olaparib *(Lynparza®)* TAG recommendation: Jun 2023

for use in: adjuvant treatment of BRCA mutation-positive HER2-negative high-risk early breast cancer after chemotherapy TA886 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Olaratumab ▼ *(Lartruvo® ▼)* TAG recommendation: Sep 2017

for use in: (in combination with duxorubicin) for treating advanced soft tissue sarcoma in adults - as per NICE TA 465 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 465 (August 2017) for treating advanced soft tissue sarcoma in adults only if:
•they have not had any previous systemic chemotherapy for this indication
•they cannot have curative treatment with surgery, or their disease does not respond to radiotherapy
and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the recommendation.

Osimertinib *(Tagrisso®)* TAG recommendation: Mar 2022

for use in: adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection as per TA761 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2022.

Specific points: NHS England commissioning

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Osimertinib *(TAGRISSO®)* TAG recommendation: Nov 2020

for use in: for untreated EGFR mutation-positive nonsmall-cell lung cancer as per TA654 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2020.

Specific points: March 2020 - Osimertinib does not meet NICE's criteria to be considered a life-extending treatment at the end of life. The most plausible cost-effectiveness estimates are above what NICE normally considers an acceptable use of NHS resources. So osimertinib is not recommended. The TAG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned). This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Nov 2020 - The TAG acknowledged the updated guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

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Osimertinib *(Tagrisso®)* TAG recommendation: Nov 2020

for use in: treating EGFR T790M mutation-positive advanced non-small-cell lung cancer as per TA653 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2020.

Specific points: Nov 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

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Oxaliplatin *(Eloxatin®)* TAG recommendation: Sep 2005

for use in: Colorectal cancer (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2005.

Specific points: NICE No.93 August 2005:
Irinotecan and oxaliplatin are recommended as possible treatments for people with advanced colorectal cancer, if they are used in these ways:
Irinotecan is given with 5-fluorouracil and folinic acid to people who have not had chemotherapy for advanced colorectal cancer before, or given on its own to people who have already had chemotherapy.
Oxaliplatin is always given with 5-fluorouracil and folinic acid.
Raltitrexed is not recommended for people with advanced colorectal cancer, unless they are taking part in a clinical trial.

April 2013: NHS Engalnd SCG took over commissioning responsibility for this treatment.

January 2015: The TAG noted NICE CG 131 for the diagnosis and management of colorectal cancer but did not make any specific "traffic light" recommendations for this SCG commissioned treatment.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted the NICE CG 131.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Paclitaxel *(Taxol®)* TAG recommendation: Nov 2013

for use in: Non-small cell lung cancer (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: November 2013.

Specific points: Commissioning responsibility of NHS England SCG from April 2013.

November 2013: NICE treatment pathway for lung cancer: http://pathways.nice.org.uk/pathways/lung-cancer

Paclitaxel *(Abraxane®)* TAG recommendation: Nov 2017

for use in: As albumin-bound nanoparticles in combination with gemcitabine (Gemzar®) for previously untreated metastatic adenocarcinoma of the pancreas in adults - as per NICE TA 476 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: November 2015: The TAG noted NICE TA 360 (October 2015) (Not recommended by NICE) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioning responsibility treatment.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

November 2017:
The TAG acknowledged NICE TA 476 (Sept 17) and recommended a revised traffic light classification - currently Double Red (Nov 2015) - of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

This guidance replaces NICE TA 360 which previously recommended against use.
Recommended as an option by NICE.

Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Paclitaxel *(Taxol®)* TAG recommendation: May 2016

for use in: In combination with platinum or as monotherapy for treatment of advanced recurrent ovarian cancer (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: April 2016.

Specific points: May 2016: The TAG noted NICE TA 389 (April 2016) review of TA91 & TA 222 (ID468) Topotecan (Hycamtin®), pegylated liposomal doxorubicin hydrochloride (Caelyx®), paclitaxel, trabectedin (Yondelis®) and gemcitabine for advanced recurrent ovarian cancer:
* Paclitaxel in combination with platinum or as monotherapy is recommended as an option.
* Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended as an option.
* PLDH in combination with platinum is recommended as an option.
The following are not recommended for treating the first recurrence of platinum sensitive ovarian cancer:
* gemcitabine in combination with carboplatin
* trabectedin in combination with PLDH
* topotecan
The appraisal committee was unable to recommend use of these technologies to treat platinum sensitive ovarian cancer beyond the first recurrence.
*Topotecan is not recommended for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

The TAG recommended a classification of Red (Hospital/Specialist only) for the treatments recommended by NICEand Double Red (Not recommended for routine use/Not commissioned) for those treatments not recommended by NICE.
It was noted that these are SCG-commissioning responsibility treatments.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendations.

Paclitaxel albumin *(Abraxane®)* TAG recommendation: Sep 2010

for use in: As monotherapy for metastatic breast cancer in patients who have not or are unlikely to tolerate first-line treatment with standard taxanes (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2013: Commissioning responsibility of NHS England SCG from April 2013.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Palbociclib *(IBRANCE®)* TAG recommendation: Mar 2020

for use in: with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer as per NICE TA619 - Jan 2020 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2020.

Specific points: March 2020 - The TAG recommended a traffic light classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Palbociclib *(Ibrance®)* TAG recommendation: Nov 2022

for use in: with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy as per TA836 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Palbociclib ▼ (with an aromatase inhibitor) *(Ibrance® ▼)* TAG recommendation: Jan 2018

for use in: Previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 495 (2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation. The D&TCG also recommended for any inappropriate prescribing of this oral treatment in primary care.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Panitumumab *(Vectibix®)* TAG recommendation: May 2017

for use in: Previously untreated metastatic colorectal cancer (with chemo) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2017.

Specific points: January 2012:
NICE TA Guidance 240 (December 2011 http://guidance.nice.org.uk/TA240) Panitumumab (with chemo) for metastatic colorectal cancer (terminated appraisal)
states that NICE is unable to recommend the use in the NHS of panitumumab in combination with chemotherapy for the treatment of metastatic colorectal cancer because no evidence submission was received from the manufacturer or sponsor of the technology.
This appraisal relates to the treatment of wild-type KRAS metastatic colorectal cancer for first-line treatment in combination with FOLFOX, and for second-line treatment in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan).

Not commissioned by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (January 2012).

November 2013: Commissioning responsibility of NHS England SCG from April 2013.
Not commissioned for third-line monotherapy of patients with metastatic rectal adenocarcinoma.

May 17: The TAG acknowledged NICE TA 439 (March 2017) For previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults Panitumumab is recommended as an option in combination with:
* FOLFOX or
* FOLFIRI:
and recommended traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Pazopanib *(Votrient®)* TAG recommendation: May 2011

for use in: First-line treatment of advanced renal cell carcinoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: The TAG noted NICE Technology Appraisal Guidance 215 which states:
1.1 Pazopanib is recommended as a first-line treatment option for people with advanced renal cell carcinoma:
- who have not received prior cytokine therapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and
- if the manufacturer provides pazopanib with a 12.5% discount on the list price, and provides a possible future rebate linked to the outcome of the head-to-head COMPARZ trial, as agreed under the terms of the patient access scheme and to be confirmed when the COMPARZ trial data are made available.
1.2 When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate.
1.3 People who are currently being treated with pazopanib for advanced metastatic renal cell carcinoma but who do not meet the criteria in 1.1 should have the option to continue their therapy until they and their clinicians consider it appropriate to stop.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Pegaspargase ▼ *(Oncaspar® ▼)* TAG recommendation: Nov 2016

for use in: Acute lymphoblastic leukaemia in children, young people and adults only when they have untreated newly diagnosed disease (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 408 (September 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Pegylated liposomal doxorubicin *()* TAG recommendation: May 2018

for use in: Cancer - as per NHS England / Cancer Drug Fund policy (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pembrolizumab *(Keytruda®)* TAG recommendation: Dec 2020

for use in: untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma as per TA661 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only).
Supported by D+TC and ratified by CCG Governing Body

Pemigatinib *(Pemaryze®)* TAG recommendation: Oct 2021

for use in: relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement as per TA722 (x).

Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Pertuzumab *(Perjeta®)* TAG recommendation: May 2018

for use in: (with trastuzumab and docetaxel) for treating HER2-positive breast cancer - as per NICE TA 509 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 509 (March 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Pertuzumab *(Perjeta®)* TAG recommendation: May 2019

for use in: For adjuvant treatment of HER2-positive early stage breast cancer in adults, only if they have lymph node-positive disease - as per NICE TA 569 (NHSE commissioning responsibility) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2019.

Specific points: May 2019:
The TAG noted NICE TA 569 (March 2019) and recommended a traffic light classification of Red (Hospital / Specialist use only) for this NHSE-commissioning responsibility treatment.

May 2019: Noted by the D&TC

Pertuzumab *(Perjeta®)* TAG recommendation: Jan 2017

for use in: In combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory or early-stage breast cancer at high risk of recurrence (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2017: The TAG noted NICE TA 424 (December 2016) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Polatuzumab vedotin *(Polivy®)* TAG recommendation: Jun 2023

for use in: combination for untreated diffuse large B-cell lymphoma TA874 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ponatinib ▼ *(Iclusig® ▼)* TAG recommendation: Jul 2017

for use in: Chronic myeloid leukaemia and acute lymphoblastic leukaemia in adults - as per NICE TA 451 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 451 (June 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Procarbazine *()* TAG recommendation: Mar 2008

for use in: All indications (x).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Ravulizumab *(Ultomiris®)* TAG recommendation: Jun 2021

for use in: paroxysmal nocturnal haemoglobinuria as per TA698 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2021.

Specific points: Ravulizumab is recommended, within its marketing authorisation, as an option
for treating paroxysmal nocturnal haemoglobinuria in adults with haemolysis with clinical symptoms suggesting high disease activity, or whose disease is clinically stable after having eculizumab for at least 6 months

Ravulizumab *(Ultomiris®)* TAG recommendation: Jul 2021

for use in: atypical haemolytic uraemic syndrome as per TA710 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Regorafenib *(Stivarga®)* TAG recommendation: Mar 2023

for use in: previously treated metastatic colorectal cancer TA866 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Regorafenib *(Stivarga®)* TAG recommendation: Mar 2019

for use in: Advanced unresectable hepatocellular carcinoma in adults who have had sorafenib - as per NICE TA 555 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2019.

Specific points: March 2019: The TAG noted NICE TA 555 (January 2019) which recommends use of regorafenib for treating advanced unresectable hepatocellular carcinoma in adults who have had sorafenib, only if:
* they have Child-Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
and the company provides regorafenib (Stivarga®) according to the commercial arrangement.
The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Regorafenib ▼ *(Stivarga® ▼)* TAG recommendation: Jan 2018

for use in: Previously treated unresectable or metastatic gastrointestinal stromal tumours (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 488 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
January 2018: The NHS Norfolk & Waveney CCGs' noted the TAG recommendation.

Ribociclib *(Kisqali®)* TAG recommendation: May 2021

for use in: with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy as per TA687 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: Red (Hospital / Specialist use only)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Ribociclib with fulvestrant *(Kisqali®)* TAG recommendation: Sep 2019

for use in: Hormone receptor-positive, HER2-negative, advanced breast cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA593 - August 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Ribociclib▼(with an aromatase inhibitor) *(Kisqali® ▼)* TAG recommendation: Jan 2018

for use in: Previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 496 (2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Rucaparib *(Rubraca®)* TAG recommendation: Jan 2020

for use in: Maintenance of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2019.

Specific points: January 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. A traffic light classification of Red (Hospital/Specialist only) was afforded for this NHS England commissioning responsibility treatment.

Ruxolitinib *(Jakavi®)* TAG recommendation: May 2016

for use in: Disease-related splenomegaly or symptoms in adults with myelofibrosis - as per NICE TA 386 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2016.

Specific points: May 2016: The TAG noted NICE TA 386 (March 2016) which supersedes NICE TA 289 (June 2013) for treatment:
* in people with intermediate 2 or high-risk disease, and
* if the company provides ruxolitinib with the discount agreed in the patient access scheme.
(Includes use in primary myelofibrosis (aka chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation for this SCG-commissioning responsibility treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Sacituzumab govitecan *(Trodelvy®)* TAG recommendation: Sep 2022

for use in: unresectable triple-negative advanced breast cancer after 2 or more therapies as per TA819 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Selpercatinib *(Retsevmo®)* TAG recommendation: Dec 2021

for use in: advanced thyroid cancer with RET alterations as per TA742 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Selpercatinib *(Retsevmo®)* TAG recommendation: Mar 2022

for use in: previously treated RET fusion-positive advanced non-small-cell lung cancer as per TA760 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2022.

Specific points: NHS England commissioning

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Sorafenib *(Nexavar®)* TAG recommendation: Nov 2017

for use in: Treatment of advanced hepatocellular carcinoma as per NICE TA 474 / treatment of papillary or follicular thyroid cancer (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).
However use of sorafenib is currently not routinely funded by Norfolk PCT in view of the lack of outcome data therefore it is not recommended for routine use at present. (Refn: Notes of the TAG Horizon Scanning Group 25/1/08, item B)5.)

August 2009: NICE Technology Appraisal guidance does NOT recommend sorafenib for first- or second-line use in advanced and/or metastatic renal cell carcinoma.

July 2010: NICE TA 189 (May 2010) does not recommend use of sorafenib in advanced hepatocellular carcinoma.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

November 2017:
The TAG acknowledged NICE TA 474 (Sept 17) and reaffirmed a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

This guidance is a Cancer Drugs Fund reconsideration of sorafenib which replaces TA189.
Recommended as an option by NICE.

Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Sorafenib (with lenvatinib) ▼ *(Nexavar® (with Lenvima®) ▼)* TAG recommendation: Sep 2018

for use in: Treatment of progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults whose disease does not respond to radioactive iodine - as per NICE TA 535 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018:
The TAG noted NICE TA 535 (August 2018) which stated:
Lenvatinib (Lenvima®) and sorafenib (Nexavar®) are recommended as options for treating progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults whose disease does not respond to radioactive iodine, only if:
* they have not had a tyrosine kinase inhibitor before or
* they have had to stop taking a tyrosine kinase inhibitor within 3 months of starting it because of toxicity (specifically, toxicity that cannot be managed by dose delay or dose modification).
* Lenvatinib and sorafenib are recommended only if the companies provide them according to the commercial arrangements.

The TAG recommended a traffic light classification of Red (Specialist only) for these NHSE-commissioning responsibility treatments.

September 2018:
The N&W CCGs' Drugs & Therapeutics Committee (D&TC) noted the TAG's recommendation.

Sotorasib *(Lumykras®)* TAG recommendation: Apr 2022

for use in: previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer as per TA781 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2022.

Sunitinib *(Sutent®)* TAG recommendation: Jul 2017

for use in: Unresectable or metastatic neuroendocrine tumours in people with progressive disease in adults - as per NICE TA 449 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 449 (June 2017) and recommended traffic light classifications of Red (Hospital/Specialist only) for everolimus and sunitinib (SCG-commissioning responsibility treatments).

July 2017: Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Sunitinib *(Sutent®)* TAG recommendation: Nov 2009

for use in: Treatment of gastrointestinal stromal tumours (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2009.

Specific points: NICE TA 179 recommends sunitinib, within its licensed indication, as a treatment option for people with unresectable and / or metastatic malignant gastrointestinal stromal tumours if,
- imatinib treatment has failed because of resistance or intolerance,
- and the drug cost for the first treatment cycle will be met by the manufacturer.

April 2013: NHS England SCG took over commissioning responsibility.
Commissioned for treatment of pancreatic neuroendocrine carcinomas.

Sunitinib *(Sutent®)* TAG recommendation: May 2009

for use in: First-line for advanced and/or metastatic renal cell carcinoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2009.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

May 2009: NICE TA 169 - Sunitinib is recommended as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma who are suitable for immunotherapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

April 2013: NHS England SCG took over commissioning responsibility.
Commissioned for treatment of pancreatic neuroendocrine carcinomas.

Temozolomide *(Temodal®)* TAG recommendation: Jul 2007

for use in: Malignant glioma (brain cancer) (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2007.

Specific points: NICE TA 23 April 2001: Patients with recurrent malignant glioma (brain cancer) who have failed first-line chemotherapy treatment with other agents (either because of lack of efficacy or because of side effects) may be considered for treatment with temozolomide. See fuller guidance.

NICE TA No.121 June 2007: (Carmustine implants and) temozolomide for the treatment of newly diagnosed high-grade glioma. Temozolomide, within its licensed indications, is recommended as an option for treatment of newly diagnosed glioblastoma multiforme (GBM) in patients with a WHO performance status of 0 or 1. See full guidance for detail.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Temsirolimus *(Torisel®)* TAG recommendation: Sep 2009

for use in: First-line treatment of advanced and/or metastatic renal cell carcinoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2009.

Specific points: Refn: NICE Technology Appraisal 178

April 2013: NHS England took over commissioning responsibility.

November 2013: Recommendation updated to "Red" in line with the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Tepotinib *(Tepmetko®)* TAG recommendation: Jun 2022

for use in: advanced non-small-cell lung cancer with MET gene alterations as per TA789 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2022.

Tivozanib *(Fotivda®)* TAG recommendation: May 2018

for use in: Advanced renal cell carcinoma - as per NICE TA 512 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 512 (March 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Topotecan *(Hycamtin®)* TAG recommendation: Jul 2005

for use in: Advanced ovarian cancer (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: May 2005.

Specific points: May 2005: NICE reviewed Technology Appraisal guidance No's 28, 45 and 55, topotecan, pegylated liposomal doxorubicin HCl and paclitaxel for second-line or subsequent treatment of advanced ovarian cancer issuing TA 91
* Topotecan is now only recommended for the treatment of women with platinum-refractory or platinum-resistant ovarian cancer if PLDH and paclitaxel are considered unsuitable.
* Paclitaxel in combination with platinum-based therapy is now recommended as a treatment option for women whose disease relapses after 6 months of first-line platinum-based therapy.
* Within these recommendations, women who have received paclitaxel as part of their first-line treatment may receive paclitaxel as part of their second-line (or subsequent) treatment.
* PLDH is now recommended as a treatment option for women whose disease does not respond to, and those women whose disease relapses within 12 months from, initial platinum-based therapy.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Topotecan *(Hycamtin®)* TAG recommendation: Nov 2009

for use in: Treatment of recurrent and stage IVB cervical cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2009.

Specific points: NICE TA 183 recommends topotecan in combination with cisplatin as a treatment option for women with recurrent or stage IVB cervical cancer only if they have not previously received cisplatin.
Women who have previously received cisplatin and are currently being treated with topotecan in combination with cisplatin for recurrent and stage IVB cervical cancer should have the option to continue their therapy until they and their clinicians consider it appropriate to stop.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Topotecan (oral) *(Hycamtin®)* TAG recommendation: Mar 2010

for use in: Treatment of relapsed small-cell lung cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2009.

Specific points: NICE TA 184: Oral topotecan is recommended as an option for treatment in patients with relapsed small-cell lung cancer only if re-treatment with the first-line regimen is not considered appropriate, and the combination of cyclophosphamide, doxorubicin and vincristine (CAV) is contra-indicated. Intravenous topotecan is not recommended for people with relapsed small-cell lung cancer.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Trabectedin *(Yondelis®)* TAG recommendation: Mar 2010

for use in: Treatment of advanced soft tissue sarcoma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2010.

Specific points: NICE Technology Appraisal Guidance 185: Trabectedin is recommended as a treatment option for people with advanced soft tissue sarcoma if:
Treatment with anthracyclines and ifosfamide has failed or
They are intolerant of or have contraindications for treatment with anthracyclines and ifosfamide
and
The acquisition cost of trabectedin for treatment needed after the 5th cycle is met by the manufacturer.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Trametinib ▼ *(Mekinist® ▼)* TAG recommendation: Jul 2016

for use in: Unresectable or metastatic melanoma in adults with a BRAF V600 mutation (with dabrafenib) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2016.

Specific points: July 2016: The TAG noted NICE TA 396 (June 2016) Trametinib (Mekinist®) in combination with Dabrafenib (Tafinlar®)and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation,

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Trastuzumab *(Herceptin®)* TAG recommendation: Mar 2009

for use in: Advanced breast cancer (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: February 2009.

Specific points: March 2002 NICE TA 34:
Trastuzumab in combination with paclitaxel (combination trastuzumab is currently only licensed for use with paclitaxel) is recommended as an option for people with tumours expressing human epidermal growth factor receptor 2 (HER2) scored at levels of 3+ who have not received chemotherapy for metastatic breast cancer and in whom anthracycline treatment is inappropriate.
Trastuzumab monotherapy is recommended as an option for people with tumours expressing HER2 scored at levels of 3+ who have received at least two chemotherapy regimens for metastatic breast cancer. Prior chemotherapy must have included at least an anthracycline and a taxane where these treatments are appropriate. It should also have included hormonal therapy in suitable oestrogen receptor positive patients.
(NICE TA 34 is due to be updated by NICE)

March 2009: The TAG noted NICE Clinical Guideline No.81 Advanced Breast Cancer, which states that for patients who are receiving trastuzumab for advanced breast cancer, treatment with trastuzumab should be discontinued at the time of disease progression outside the central nervous system. Trastuzumab should not be discontinued if disease progression is within the central nervous system alone.

For patients who are HER2 +ve who have previously been treated with trastuzumab, NICE recommends that more research be done to invesigate whether patients who have received adjuvant trastuzumab should receive further biological response modifiers.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Trastuzumab *(Herceptin®)* TAG recommendation: Jan 2011

for use in: HER2-positive metastatic gastric cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2010.

Specific points: NICE Technology Appraisal 208 states:
1.1 Trastuzumab, in combination with cisplatin and capecitabine or
5-fluorouracil, is recommended as an option for the treatment of people with human epidermal growth factor receptor 2 (HER2)-positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who:
have not received prior treatment for their metastatic disease and
have tumours expressing high levels of HER2 as defined by a positive immunohistochemistry score of 3 (IHC3 positive).
1.2 People who are currently receiving treatment with trastuzumab for HER2-positive metastatic gastric cancer who do not meet the criteria in 1.1 should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Trastuzumab *(Herceptin®)* TAG recommendation: Sep 2006

for use in: Adjuvant treatment of early-stage HER2-positive breast cancer (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: February 2009.

Specific points: NICE Guidance TA 107 August 2006:
Trastuzumab treatment should be offered as an option for women with early-stage HER2-positive breast cancer after they have had surgery and chemotherapy (and sometimes radiotherapy).

Trastuzumab should be given once every 3 weeks for 12 months, or until the breast cancer comes back, whichever is sooner.

Trastuzumab treatment has been associated with heart problems. Before trastuzumab is prescribed a woman should have tests to check how well her heart is working. The tests should be repeated every 3 months during treatment. If a woman develops heart problems while taking trastuzumab her treatment will be stopped.

Trastuzumab should not be offered to women with certain heart problems or with high blood pressure that is not well controlled with drugs or other treatment.

TAG September 2007: Awaiting clarity regarding the starting and stopping criteria for use of trastuzumab as recommended by the local cancer network.

March 2009: The TAG acknowledged NICE Clinical Guideline 80: Early and locally advanced breast cancer, which replaces NICE TA Guidance 107. For patients with HER2-positive early invasive breast cancer following surgery, chemotherapy, and radiotherapy when applicable -
* Offer trastuzumab, given at 3-week intervals for 1 year or until disease recurrence (whichever is shortest).
* Assess cardiac function before starting treatment with trastuzumab. Do not offer if any of the following are present: LVEF ≤ 55%; history of documented congestive heart failure; high-risk uncontrolled arrhythmias; angina pectoris requiring medication; clinically significant valvular disease; evidence of transmural infarction on ECG; poorly controlled hypertension
* Repeat cardiac functional assessments every 3 months during trastuzumab treatment.
If LVEF drops by ≥ 10 percentage (ejection) points from baseline and to < 50%, stop trastuzumab. Restart trastuzumab only after further cardiac asessment and fully informed discussion with the patient about the risks and benefits.

Trastuzumab deruxtecan *(Enhertu®)* TAG recommendation: Mar 2023

for use in: HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments TA862 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Trastuzumab deruxtecan *(Enhertu®)* TAG recommendation: Jun 2021

for use in: HER2-positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies as per TA704 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2021.

Specific points: Trastuzumab deruxtecan is recommended for use within the Cancer Drugs Fund as an option for treating HER2-positive unresectable or metastatic breast cancer in adults after 2 or more anti-HER2 therapies

Red - 'Hospital / Specialist only'

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Trastuzumab emtansine *(Kadcyla)* TAG recommendation: Jul 2020

for use in: adjuvant treatment of HER2-positive early breast cancer as per TA632 (June 2020) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC

Trastuzumab emtansine ▼ *(Kadcyla® ▼)* TAG recommendation: Sep 2017

for use in: HER2-positive, unresectable locally advanced or metastatic breast cancer, after treatment with trastuzumab and a taxane (paclitaxel or docetaxel) as per NICE TA 458 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: January 2016: The TAG noted NICE TA 371 (December 2015) for the treatment of HER2-positive, unresectable locally advanced or metastatic breast cancer, after treatment with trastuzumab and a taxane (paclitaxel or docetaxel) and recommended a classification of Double Red (Not recommended for routine use/not commissioned) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

September 2017: The TAG acknowledged NICE TA 458 (July 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Trifluridine–tipiracil *(Lonsurf®)* TAG recommendation: Jan 2023

for use in: metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more therapies TA852 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2022.

Specific points: March 2021 - NICE do not recommend

Jan 2023 - TA852 replaced TA669. Trifluridine–tipiracil is recommended, within its marketing authorisation, as an option for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma in adults who have had 2 or more treatment regimens

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Tucatinib *(TUKYSA®)* TAG recommendation: May 2022

for use in: with trastuzumab and capecitabine for treating HER2-positive advanced breast cancer after 2 or more anti-HER2 therapies as per TA786 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

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8.1.5 - Other antineoplastic drugs

Vemurafenib *(Zelboraf®)* TAG recommendation: Jan 2013

for use in: Melanoma (BRAF V600 mutation positive, unresectable metastatic) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2013.

Specific points: December 2012: NICE recommends vemurafenib as an option for treating BRAF V600 mutation-positive unresectable or metastatic melanoma only if the manufacturer provides vemurafenib with the discount agreed in the Patient Access Scheme.

January 2013: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) commissioned use as per NICE TA 269 (http://guidance.nice.org.uk/TA269)

April 2013: NHS England Specialised Commissioning took over commissioning responsibility for this treatment.

September 2015: The TAG noted NG 14 (July 2015) - Assessment and management of melanoma in children, young people and adults which includes recommendations on:
* Assessing and staging melanoma
* Treating stages 0-II melanoma
* Treating stage III melanoma
* Treating stage IV melanoma
* Follow up after treatment
* Managing suboptimal vitamin D levels

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Venetoclax *(Venclyxto®)* TAG recommendation: Jul 2022

for use in: chronic lymphocytic leukaemia as per TA796 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Venetoclax *(Venclyxto®)* TAG recommendation: May 2022

for use in: with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable as per TA787 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Venetoclax *(Venclyxto®)* TAG recommendation: Mar 2022

for use in: with azacitidine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable as per TA765 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: NHS England

Venetoclax *(Venclyxto®)* TAG recommendation: Mar 2019

for use in: (with rituximab) for treating chronic lymphocytic leukaemia in adults who have had at least 1 previous therapy - as per NICE TA 561 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2019.

Specific points: March 2019: The TAG noted NICE TA 561 (February 2019) which recommended use as an option, only if the company provides it according to the commercial arrangement.

The TAG recommended a traffic light classification of Red (Hospital/Specialist use only) for this NHS England commissioning responsibility treatment.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG recommendation.

Venetoclax *(Venclyxto®)* TAG recommendation: Jan 2021

for use in: with obinutuzumab for untreated chronic lymphocytic leukaemia as per TA663 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: Jan 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Venetoclax ▼ *(Venclyxto® ▼)* TAG recommendation: Jan 2018

for use in: Chronic lymphocytic leukaemia (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: January 2018: The TAG acknowledged NICE TA 487 (Nov 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.
January 2018: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.1.5 - Other antineoplastic drugs

Zanubrutinib *(Brukinsa®)* TAG recommendation: Nov 2022

for use in: Waldenstrom's macroglobulinaemia as per TA833 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

8.2 - Drugs affecting the immune response

Teriflunomide ▼ *(Aubagio® ▼)* TAG recommendation: Mar 2014

for use in: Relapsing remitting multiple sclerosis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2014.

Specific points: March 2014: The TAG noted NICE TA 303 (Jan 2014) which recommends use of teriflunomide for treating adults with active relapsing-remitting multiple sclerosis (normally defined as 2 clinically significant relapses in the previous 2 years), only if they do not have highly active or rapidly evolving severe relapsing-remitting multiple sclerosis and the manufacturer provides teriflunomide with the discount agreed in the patient access scheme.

NHS England SCG-commissioning responsibility.

TAG recommendation of Red (Hospital/Specialist only) noted and supported by the D&TCG.

8.2.2 - Corticosteroids and other immunosuppressants

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.2 - Corticosteroids and other immunosuppressants

Basiliximab *(Simulect®)* TAG recommendation: Nov 2017

for use in: Option for induction therapy in the prophylaxis of acute organ rejection in adults, children and adolescents undergoing renal transplantation - as per NICE TAs 481 and 482 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: January 2005: The TAG acknowledged NICE No. 85 which stated that:
1.1 Basiliximab or daclizumab (the latter has since withdrawn from market), used as part of a calcineurin-inhibitor-based immunosuppressive regimen, are recommended as options for induction therapy in the prophylaxis of acute organ rejection in adults undergoing renal transplantation. The induction therapy (basiliximab or daclizumab (since withdrawn from market)) with the lowest acquisition cost should be used.
1.5 These recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Clinicians prescribing these drugs should ensure that patients are aware of this, and that they consent to their use in such circumstances.

April 2006 NICE No. 99:
NICE made the following recommendations about the use of immunosuppressive drugs in children and adolescents receiving kidney transplants: Doctors should consider using basiliximab or daclizumab (since withdrawn from market) for induction therapy. These drugs should only be used with a combination of other drugs that includes ciclosporin.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

November 2017:
The TAG acknowledged NICE TAs 481 and 482 (Oct 17) and re-affirmed a traffic light classification of Red (Hospital/Specialist only) for use of basiliximab as an initial option for use To prevent organ rejection in kidney transplant in patients of all ages.

Basiliximab is a SCG-commissioning responsibility treatment.

Noted by the D&TCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.2 - Corticosteroids and other immunosuppressants

Budesonide orodispersible tablets *(Jorveza®)* TAG recommendation: May 2019

for use in: Eosinophilic oesophagitis in adults (first treatment with follow-up assessment of effectiveness by the hospital) as per TA708 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: January 2019: The TAG supported the PRG recommendation of applying a Double Red (Not recommended for routine use) classification for this product as an interim measure, until a formal application for its use is submitted via usual processes.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

March 2019:
The TAG considered the QEH's application for use of this treatment. The TAG noted that Jorveza® is a newly licensed option for a rare condition that occurs in a small number of people, which has been treated to date using budesonide nebules, off-label, mixed to form a slurry to coat the oesophagus.
The Trusts consider that it is necessary to use a licensed product, where available. The TAG considered that the evidence presented indicated that Jorveza® was as effective as the current treatment option and debated whether a more expensive licensed option should necessarily be used. It was noted that there are occasions where treatments of lower cost and equivalent effectiveness have continued to be used off-label instead of a more expensive licensed option.
The TAG acknowledged that the evidence provided indicated higher patient preference for using Jorveza® compared with the slurry prepared from the nebules.
The TAG also debated how the 6-week treatment course for Jorveza® might be managed if an additional 6-week course was deemed necessary as confirmed by histology. In order to avoid patients having to return to hospital, the TAG agreed it was reasonable to recommend a traffic light classification of Red (Hospital/Specialist use only) for the first six weeks of treatment, and Green (GP prescribing following Specialist initiation/recommendation) if an additional six weeks of treatment is required. This would be a one-off, acute prescription from the GP.
The TAG noted the price differential between the current and the proposed treatment options.

March 2019:
The D&TC acknowledged that the proposed treatment schedule would mean that a GPs would be asked to prescribe only a single (follow-up) 6-week treatment course per patient, for a very small number of cases. The D&TC therefore requested sight of the QEH Trust's planned GP communication letter regarding use of Jorveza® before agreeing to recommend that it is commissioned as per the TAG's recommendations. Once approved the letter would have to be used across all the Acute Trusts to ensure a consistent approach.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC considered the QEH's proposed template letter and agreed to support its use and recommended a classification of Red (Hospital/Specialist use only) for the first six weeks of treatment, , and Green (GP prescribing following Specialist initiation/recommendation) only if an additional six weeks of treatment is required. This would be a one-off, acute prescription from the GP.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

June 2021 - NICE TA published. Supports existing recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.2 - Corticosteroids and other immunosuppressants

Imlifidase *(Idefirix®)* TAG recommendation: Aug 2022

for use in: desensitisation treatment before kidney transplant in people with chronic kidney disease as per TA809 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Tacrolimus (oral) - immediate release *(Various)* TAG recommendation: Nov 2017

for use in: Immunosuppressive therapy to prevent organ rejection in kidney transplant in children and young people - as per NICE TA 482 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: April 2006 NICE TAG No.99:
NICE made the following recommendations about the use of immunosuppressive drugs in children and adolescents receiving kidney transplants: Tacrolimus is a calcineurin inhibitor and can be used instead of ciclosporin when a person needs a calcineurin inhibitor as part of their initial therapy or maintenance therapy.

July 2012: The TAG noted Commission on Human Medicines letter:
Oral tacrolimus prescribed/ dispensed by brand to avoid medication errors regarding the importance of ensuring that the same brand is correctly and consistently provided in order to prevent toxicity and rejection.

November 2017:
The TAG acknowledged NICE TA 482 (Oct 17) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Voclosporin *(Lupkynis®)* TAG recommendation: Jun 2023

for use in: with mycophenolate mofetil for treating lupus nephritis TA882 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

8.2.3 - Anti-lymphocyte monoclonal antibodies

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Alemtuzumab *(MabCampath®)* TAG recommendation: Jan 2011

for use in: Chronic lymphocytic leukaemia (CLL) - as per NHS England policy 2013 (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2011:
The BNF states that "Alemtuzumab (MabCampath) is no longer licensed but is available through a patient access programme for oncological and transplant indications".

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: TAG recommendation revised from Double Red to Red (Hospital only) in line with NHS England SCG Cancer Drug Fund List - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

Alemtuzumab *(Lemtrada®)* TAG recommendation: May 2018

for use in: Behcet's syndrome (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.
Specialist centre only. Highly specialised criteria.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Alemtuzumab *(Lemtrada®)* TAG recommendation: May 2018

for use in: Pre-transplant immunosuppression (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.
Specialist centre only. Highly specialised criteria.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Alemtuzumab ▼ *(Lemtrada® ▼)* TAG recommendation: Jul 2014

for use in: Treatment of adults with relapsing-remitting multiple sclerosis (RRMS) - as per NICE TA 312 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2014.

Specific points: NICE TA 312 (May 2014):
Recommended by NICE as an option. Stated to be CCG-commissioning responsibility (according to TA 312 Costing Report) however responsibility commissioning and funding treatment of MS currently rests with NHSE SCG.

July 2014: The TAG noted NICE TA 312 and recommended a classification of Red (Hospital Only) awaiting guidance from the NHSE SCG regarding commissioned use.

This treatment has significant long-term monitoring requirements.

July 2014: TAG recommendation noted and supported by the Norfolk and Waveney CCGs D&TCG.

January 2015: The TAG noted and supported NICE CG 186 regarding the following drug treatment recommendations under Section 1.5 - MS symptom management and rehabilitation:
For spasticity:
First- line: Use baclofen or gabapentin. If not tolerated consider switching to the other drug. Consider combining baclofen and gabapentin if individual drugs do not provide adequate relief, or side effects from individual drugs prevent the dose being increased.
Second-line: Consider tizanidine or dantrolene.
Third-line: Consider benzodiazepines; be aware of their potential benefit in treating nocturnal spasms. DO NOT offer Sativex® for spasticity in MS.
For oscillopsia:
First-line: Gabapentin.
Second-line: Consider memantine. Refer for specialist advice if there is no improvement after treatment with gabapentin and memantine, or side effects prevent continued use.
Lack of mobility in MS:
DO NOT use fampridine as it is not cost-effective. Fatigue in MS:
Offer amantadine. DO NOT use vitamin B12 injections for fatigue.
Relapse and exacerbation: Offer oral methylprednisolone 0.5 g daily for 5 days. Do not use lower doses, nor provide a rescue course to treat next relapse.
The TAG noted that the full NICE Clinical Guideline 186 also states that "modafanil should not be used to treat fatigue in MS."

Other treatments:
Consider amitriptyline to treat emotional lability.
DO NOT offer vitamin D solely for MS.
DO NOT offer omega-3 or -6 fatty acids.
Although the TAG decided not to assign new "Traffic Light" recommendations to any of the above-listed treatments, it was agreed that previous Double Red (Not recommended for routine use) recommendations for Sativex® for spasticity and for fampridine for reduced mobility were in line with NICE CG 186 and should be maintained.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations regarding NICE CG 186 with particular reference to the treatments which are not recommended which will be drawn to the attention of local prescribers.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Blinatumomab ▼ *(Blincyto® ▼)* TAG recommendation: Jul 2017

for use in: Philadelphia-chromosome-negative relapsed or refractory precursor B-cell acute lymphoblastic leukaemia in adults - as per NICE TA 450 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 450 (June 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Chlormethine gel *(Ledaga®)* TAG recommendation: Sep 2021

for use in: mycosis fungoides-type cutaneous T-cell lymphoma as per TA720 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2021.

Specific points: NHS England commissioned treatment

Dostarlimab *(Jemperli®)* TAG recommendation: Apr 2022

for use in: previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency as per TA779 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2022.

Durvalumab *(Imfinzi®)* TAG recommendation: Jul 2022

for use in: maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation as per TA798 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Mogamulizumab *(Poteligeo®)* TAG recommendation: Jan 2022

for use in: previously treated mycosis fungoides and Sézary syndrome as per TA754 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Nivolumab *(Opdivo®)* TAG recommendation: Apr 2022

for use in: with ipilimumab for untreated advanced renal cell carcinoma as per TA780 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2022.

Nivolumab *(Opdivo®)* TAG recommendation: Sep 2022

for use in: adjuvant treatment of invasive urothelial cancer at high risk of recurrence as per TA817 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Nivolumab *(Opdivo®)* TAG recommendation: Sep 2022

for use in: with ipilimumab for untreated unresectable malignant pleural mesothelioma as per TA818 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Obinutuzumab *(Gazyvaro®)* TAG recommendation: May 2018

for use in: Untreated advanced follicular lymphoma - as per NICE TA 513 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 513 (March 2018) and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHSE--commissioning responsibility treatment.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted the TAG's recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Obinutuzumab ▼ *(Gazyvaro® ▼)* TAG recommendation: Jul 2015

for use in: For untreated chronic lymphocytic leukaemia for adults who have comorbidities that make full-dose fludarabine based therapy unsuitable for them - as per NICE TA 343 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: May 2015: The TAG noted the NICE FAD and agreed to recommend that a future classification for Obinutuzumab (Gazyvaro®) in combination with chlorambucil for untreated chronic lymphocytic leukaemia in adults who have comorbidities that make full-dose fludarabine based therapy unsuitable for them, only if bendamustine-based therapy is not suitable and discount is provided under PAS, would be Red (Hospital use only) pending publication of the NICE TA guidance for this SCG-commissioned treatment.

May 2015: The D&TCG noted the TAG's recommendation and decided that the treatment is Not Commissioned - i.e. Double Red (Not recommended for routine use), pending publication of the related NICE Technology Appraisal Guidance.

July 2015: The TAG acknowledged the NICE TA 343 (June 2015) and recommended a classification of Red (Hospital only) for this SCG-commissioning responsibility treatment.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Obinutuzumab ▼ *(Gazyvaro® ▼)* TAG recommendation: Jul 2020

for use in: (with bendamustine, then as maintenance) for follicular lymphoma in adults that did not respond or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen - as per NICE TA 472 - updated to TA629 (May 2020) (A

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2020.

Specific points: September 2017: The TAG acknowledged NICE TA 472 (August 2017) Obinutuzumab (Gazyvaro®) with bendamustine, then obinutuzumab as maintenance and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

July 2020 - NICE guidance updated to TA629 (May 2020). Recommendation remains the same

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Ocrelizumab ▼ *(Ocrevus® ▼)* TAG recommendation: Sep 2018

for use in: Relapsing-remitting multiple sclerosis in adults in line with NICE TA 533 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2018.

Specific points: September 2018: The TAG noted NICE TA 533 (July 2018) and recommended a traffic light classification of Red (Specialist only) for this NHSE-commissioning responsibility treatment.

For treating relapsing-remitting multiple sclerosis in adults, only if:
* alemtuzumab is contraindicated or otherwise unsuitable and
* the company provides ocrelizumab according to the commercial arrangement.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

Ofatumumab *(Arzerra®)* TAG recommendation: Jul 2015

for use in: For untreated chronic lymphocytic leukaemia in combination with chlorambucil or bendamustine - as per NICE TA 344 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: May 2015: The TAG noted the NICE FAD and agreed to recommend that a future classification for Ofatumumab (Arzerra®) in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia when the person is ineligible for fludarabine-based therapy;
bendamustine is not suitable and
discount is provided under PAS would be Red (Hospital use only) pending publication of the NICE TA guidance for this SCG-commissioned treatment.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and decided that the treatment is Not Commissioned - i.e. Double Red (Not recommended for routine use), pending publication of the related NICE Technology Appraisal Guidance.

July 2015: The TAG acknowledged the NICE TA 344 (June 2015) and recommended a classification of Red (Hospital only) for this SCG-commissioning responsibility treatment.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ofatumumab *(Kesimpta®)* TAG recommendation: Jun 2021

for use in: relapsing multiple sclerosis as per TA699 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2021.

Specific points: Ofatumumab is recommended as an option for treating relapsing–remitting multiple sclerosis in adults with active disease defined by clinical or imaging features

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Ofatumumab ▼ *(Arzerra® ▼)* TAG recommendation: Nov 2010

for use in: Treatment of chronic lymphocytic leukaemia refractory to fludarabine and alemtuzumab (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2010.

Specific points: NICE TA 202 does not recommend use for this indication.

April 2013: NHS England toook over commissioning responsibility.

TAG Double Red entry revised to Red (Hospital only) in line with Cancer Drug Fund List - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

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Pembrolizumab *(Keytruda®)* TAG recommendation: Mar 2022

for use in: adjuvant treatment of completely resected stage 3 melanoma as per TA766 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: NHS England

Pembrolizumab *(Keytruda®)* TAG recommendation: Mar 2022

for use in: relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies as per TA772 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Pembrolizumab *(Keytruda®)* TAG recommendation: Mar 2022

for use in: with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer as per TA770 (replaces TA600) (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Pembrolizumab *(Keytruda®)* TAG recommendation: Jul 2022

for use in: ®) plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer as per TA801 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®)* TAG recommendation: Mar 2008

for use in: Relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: February 2008.

Specific points: NICE TAG No. 137 February 2008 (supersedes NICE guidance March 2002):
1. Rituximab, within its marketing authorisation, in combination with chemotherapy, is recommended as an option for the induction of remission in people with relapsed stage III or IV follicular non-Hodgkin's lymphoma.
2. Rituximab monotherapy as maintenance therapy, within its marketing authorisation, is recommended as an option for the treatment of people with relapsed stage III or IV follicular non-Hodgkin's lymphoma in remission induced with chemotherapy with or without rituximab.
3. Rituximab monotherapy, within its marketing authorisation, is recommended as an option for the treatment of people with relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma, when all alternative treatment options have been exhausted (that is, if there is resistance to or intolerance of chemotherapy).

April 2013: NHS England SCG took over commissioning responsibility.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®, Rixathon®, Truxima®)* TAG recommendation: Jan 2018

for use in: Option for treatment of Immune (Idiopathic) Thromboctyopenic Purpura (ITP) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2018: The TAG noted and supported a revised local policy (adapted fo local use from a version from the EoE PAC). Developed to formalise a long-standing agreement between commissioners and local acute trusts as an option for use instead of eltromboag or romiplostim.

January 2018: The policy was supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) providing that the most cost-effective biosimilar option was used.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TCG's recommendation.

March 2020 - This was previously considered by the TAG, but the policy is now out of date. It was recommended that the treatment be recommissioned as Red (Hospital/Specialist use only). This was supporte by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Rituximab *(MabThera®)* TAG recommendation: Jul 2011

for use in: 1st-line maintenance treatment of follicular non-Hodgkin's lymphoma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 226 which recommended the following:
1.1 Rituximab maintenance therapy is recommended as an option for the treatment of people with follicular non Hodgkin's lymphoma that has responded to first-line induction therapy with rituximab in combination with chemotherapy.
This guidance supersedes the previous TAG recommendation not to support use.

April 2013: NHS England SCG took over commissioning responsibility.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®)* TAG recommendation: Sep 2015

for use in: Treatment of Steroid Resistant Nephrotic Syndrome (SRNS) in paediatric patients (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted E03/P/c (July 2015) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Applies to treatment of Steroid Resistant Nephrotic Syndrome (SRNS) in paediatric patients including:
* Patients with SRNS, after formal exclusion of other forms of glomerulonephritis, and of genetic causes using UKGTN approved Next Generation Sequencing test (www.nbt.nhs.uk/genetics)
* Patients with SRNS in whom trial of CNI +/- MMF therapy has failed or unacceptable side effects.

1. Patients 1 - 18 years of age.
2. Patients must be referred to and reviewed by a Consultant Paediatric Nephrologist before treatment is initiated. Rituximab will be given at the specialist centre.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Rituximab *(MabThera®)* TAG recommendation: Sep 2015

for use in: Treatment for relapsing Steroid Sensitive Nephrotic Syndrome (SSNS) in children (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted E03/P/b (E03X02) (July 2015) (NHS England policy) and recommended classification of Red (Specialist use only) for the SCG-commissioning responsibility treatment.

Applies to treatment for relapsing Steroid Sensitive Nephrotic Syndrome (SSNS) in children with:
* frequently relapsing or steroid dependent SSNS refractory to conventional therapy, with ongoing disease relapses, despite prior or ongoing treatment with alternate day prednisolone, levamisole, alkylating agents (cyclophosphamide or chlorambucil), calcineurin inhibitors (ciclosporin or tacrolimus) and mycophenolate mofetil, alone or in combination.
* unacceptable adverse effects of corticosteroids as evidenced by severe end-organ damage such as osteoporosis, cataracts, obesity, behavioural problem.
* ciclosporin-dependent nephrotic syndrome

1. Patients are 1-18 years old
2. Patients must be referred to and reviewed by a Consultant Paediatric Nephrologist before treatment is initiated. Rituximab will be given at the specialist centre.
3. Rituximab should not be considered as a first line treatment for a patient with nephrotic syndrome.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera & biosimilars)* TAG recommendation: May 2018

for use in: Steroid sensitive nephrotic syndrome - as per NHS England policy E03/P/c and b (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab *(Mabthera®)* TAG recommendation: May 2009

for use in: Splenic B cell non Hodgkin's lymphoma (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Supported as an alternative to first-line use of splenectomy which carries immediate (post-operative complications) and long term (i.e. infection) risks, and can be difficult depending on the size of the spleen.

April 2013: NHS England SCG took over commissioning responsibility.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®)* TAG recommendation: Sep 2009

for use in: Option for first-line treatment of chronic lymphocytic leukaemia (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2009.

Specific points: NICE Technology appraisal guidance 174, July 2009, details use of rituximab for this indication.

September 2010:
The TAG noted NICE TA Guidance 193 Rituximab for the treatment of relapsed or refractory chronic lymphocytic leukaemia

April 2013: NHS England SCG took over commissioning responsibility.

Rituximab *(MabThera®)* TAG recommendation: Sep 2010

for use in: Treatment of relapsed or refractory chronic lymphocytic leukaemia (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2010.

Specific points: The TAG noted NICE TA 193 which states: Rituximab in combination with fludarabine and cyclophosphamide is recommended as a treatment option for people with relapsed or refractory chronic lymphocytic leukaemia except when the condition:
* is refractory to fludarabine (that is, it has not responded to fludarabine or has relapsed within 6 months of treatment) or
* has previously been treated with rituximab, unless:
- in the context of a clinical trial, at a dose lower than the dose currently licensed for chronic lymphocytic leukaemia or
- in the context of a clinical trial, in combination with chemotherapy other than fludarabine and cyclophosphamide.

April 2013: NHS England SCG took over commissioning responsibility.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®)* TAG recommendation: Mar 2012

for use in: 1st-line treatment of stage III-IV follicular lymphoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2012.

Specific points: NICE TA 243 states that Rituximab, in combination with:
* cyclophosphamide, vincristine and prednisolone (CVP) or
* cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) or
* mitoxantrone, chlorambucil and prednisolone (MCP) or
* cyclophosphamide, doxorubicin, etoposide, prednisolone and interferon-α (CHVPi) or
* chlorambucil

is recommended as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated people.

Noted by the NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group and commissioned in line with the Cancer Network list of approved treatment regimens.

April 2013: NHS England SCG took over commissioning responsibility.

Rituximab *(MabThera)* TAG recommendation: May 2010

for use in: Splenic marginal zone (B cell non Hodgkin) lymphoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Approved for funding by the NHS Norfolk Drugs & Therapeutics Commissioning Programme Board, May 2010.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab *(MabThera®)* TAG recommendation: May 2006

for use in: Connective tissue disease (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Routine use not recommended for connective tissue diseases including lupus, lupus nephritis, Wegener's, and dermatomyositis / polymyositis.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: TAG database entry revised to Red (Hospital only) in line with NHS England SCG commissioning policy A13
http://www.england.nhs.uk/wp-content/uploads/2013/10/a13-ps-a.pdf

Rituximab *(MabThera®)*

for use in: Aggressive non-Hodgkin's lymphoma (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2003.

Specific points: NICE has recommended that rituximab, in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone, for first-line treatment of CD20-positive diffuse large-B-cell lymphoma at clinical stage II, III or IV. The use of rituximab for localised (stage I) disease should be limited to clinical trials.

April 2013: NHS England SCG took over commissioning responsibility.

September 2016:
The TAG acknowledged NG 52 (July 2016) Non-Hodgkin's lymphoma: diagnosis and management in people aged 16 years and over which includes recommendations on:
* Diagnosis
* Staging and end of treatment assessment using fluorodeoxyglucose-positron emission tomography-CT
* Managing:
  o Follicular lymphoma
  o MALT lymphoma
  o Mantle cell lymphoma
  o Diffuse large B-cell lymphoma
  o Burkitt lymphoma
  o Peripheral T-cell lymphoma
* Information and support
* Survivorship

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab - subcutaneous injection *(MabThera®)* TAG recommendation: May 2018

for use in: Follicular Lymphoma maintenance - NHS England policy Lymphoma maintenance (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2018

for use in: Cytopenia complicating primary immunodeficiency - as per NHS England policy 16044/P (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy 16044/P - Specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *()* TAG recommendation: Jul 2020

for use in: treatment of autoimmune haemolytic anaemia (AIHA) in adults (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2020 - The TAG heard how this is a one-off treatment for approximately 5 patients per year in this area. There is a biosimilar available and it has a reasonable cost. Business case was supported by the TAG and a traffic light classification of Red (Hospital / Specialist use only) was awarded. This recommendation was supported by the D+TC

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: Immunoglobin G4 related disease - as per NHS England policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: Pemphigus Vulgaris - as per NHS England policy 16035/P (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy 16035/P.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: Sep 2011

for use in: ANCA associated vasculitis - as per NICE TA 308 and NHS England policy A13/P/a (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG considered aand supported a proposal from the NNUH for use in
* Patients with systemic disease with contraindications to cyclophosphamide
* Patients with refractory disease
* Relapsing disease, previously treated with cyclophosphamide

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided to commission and fund use of rituximab for ANCA associated vasculitis as per the NNUH's proposed business case.

April 2013: NHS England SCG took over commissioning responsibility.
http://www.england.nhs.uk/wp-content/uploads/2013/04/a13-p-a.pdf

May 2018: Entry updated to reflect preferred use cost -effective biosimilar products - as per the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: Neuromyelitis optica (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per specification - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: Graft versus host disease -as per Policy NHS England Policy 16069/P (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16069/P - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: Myositis - as per NHS England Policy 16035/P (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy 16035/P

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: Sep 2010

for use in: Rheumatoid arthritis - with MTX after DMARDs including a TNF inhibitor (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA 195: which states that Rituximab in combination with methotrexate is recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or are intolerant of, other disease-modifying anti-rheumatic drugs (DMARDs), including at least one tumour necrosis factor (TNF) inhibitor. Treatment with rituximab should be given no more frequently than every 6 months.
Treatment with rituximab in combination with methotrexate should be continued only if there is an adequate response following initiation of therapy and if an adequate response is maintained following retreatment with a dosing interval of at least 6 months. An adequate response is defined as an improvement in disease activity score (DAS28) of 1.2 points or more.

September 2010: The TAG supported a business case from the NNUH for use of Rituximab for rheumatoid arthritis (DAS28 >5.1, AND failure of two DMARDs including methotrexate, AND contraindication to anti-TNF therapy. This was approved by the NHS Norfolk Drug & Therapeutics Commissioning Programme Board in September 2010.

January 2011: The TAG noted NICE's algorithm (November 2010) on biologic drugs for rheumatoid arthritis.

May 2018: Entry updated to reflect preferred use cost -effective biosimilar products - as per the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truxima®, Rithaxon®)* TAG recommendation: Sep 2015

for use in: RhF +ve Poly-Articular Juvenile Idiopathic Arthritis (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

Regarding use of rituximab in JIA:
NICE guidance in adults with Rheumatoid Arthritis, of which RhF +ve Poly-Articular JIA is usually considered to be analogous, suggests Rituximab should be used after failure of any anti-TNF treatment. Usual practice in other forms of JIA would be a trial of an alternative Anti-TNF before proceeding further along the pathway.

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

May 2018: Entry updated to reflect preferred use cost -effective biosimilar products - as per the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: Sep 2015

for use in: Eradication of inhibitors in patients with Acquired Haemophilia (2nd line option) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015:
The TAG noted F02/P/a (July 2015) (NHS England policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Rituximab is given only as second line treatment for patients who fail first line immunosuppressive treatment for AHA, and who have no clinical contraindication to rituximab (e.g. allergic reaction, history of cardiovascular disease).

Rituximab will be routinely commissioned for patients with confirmed AHA where
* All patients should have undergone a 3-5 week trial of first line treatment before rituximab is considered, and
* Treatment is provided in specialised haemophilia centres, as defined by the NHS England service specification for specialised haemophilia services.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

May 2018: Entry updated to reflect preferred use cost -effective biosimilar products - as per the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truximab®, Rithaxon®)*

for use in: Systemic Lupus Erythematosus (SLE) - as per NHS England Policy A13/PS/a (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy A13/PS/a

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.3 - Anti-lymphocyte monoclonal antibodies

Rituximab (biosimilar) *(Truximab®, Rithaxon®)* TAG recommendation: May 2018

for use in: ABO-incompatible kidney transplants - as per specification - Specialist centres only (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Rituximab (biosimilar) *(Truxima®, Rixathon®)* TAG recommendation: May 2014

for use in: Anti-neutrophil cytoplasmic antibody-associated (ANCA) vasculitis (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2014.

Specific points: NICE TA 308 (March 2014) states:
Rituximab, in combination with glucocorticoids, is recommended as an option for inducing remission in adults with anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis (severely active granulomatosis with polyangiitis [Wegener's] and microscopic polyangiitis), only if:
* further cyclophosphamide treatment would exceed the maximum cumulative cyclophosphamide dose or
* cyclophosphamide is contraindicated or not tolerated or
*the person has not completed their family and treatment with cyclophosphamide may materially affect their fertility or
* the disease has remained active or progressed despite a course of cyclophosphamide lasting 3 to 6 months or
* the person has had uroepithelial malignancy.

NHSE SCG-commissioning policy: http://www.england.nhs.uk/wp-content/uploads/2013/04/a13-p-a.pdf

TAG recommendation noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group.

May 2018: Entry updated to reflect preferred use cost -effective biosimilar products - as per the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) -
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

8.2.4 - Other immunomodulating drugs

Axicabtagene ciloleucel *((Yescarta®))* TAG recommendation: Jul 2023

for use in: relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy TA895 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Axicabtagene ciloleucel *(Yescarta®)* TAG recommendation: Jun 2023

for use in: diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies TA872 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Replaced TA559

Blinatumomab *(Blincyto®)* TAG recommendation: Sep 2019

for use in: Acute lymphoblastic leukaemia in remission with minimal residual disease activity (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA589 - July 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Cemiplimab *(Libtayo®)* TAG recommendation: Sep 2019

for use in: Metastatic or locally advanced cutaneous squamous cell carcinoma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA592 - August 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Dimethyl fumarate (Skilarence®) *(Skilarence®)* TAG recommendation: Mar 2018

for use in: Treatment of moderate to severe plaque psoriasis in adults - as per NICE TA 475 and locally commissioned pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 475 (Sept 17) which states:
Recommended as an option by NICE For treating moderate to severe plaque psoriasis in adults, only if the disease:
* is severe, as defined by a total Psoriasis Area and Severity Index of 10 or more and a Dermatology Life Quality Index of more than 10 and
* has not responded to other systemic therapies, including, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.

The TAG's recommendation was noted and supported by the D&TCG.

March 2018: The TAG considered and supported the QEH's application, along with the proposed treatment pathway, for use of Dimethyl fumarate (Skilarence®) for severe psoriasis which has not responded to other non-biological therapies, or when biological therapies cannot be taken.
The TAG was advised that dimethyl fumarate would be used instead of (not added to) apremilast.
The TAG agreed to recommend a revised classification of Red (Hospital use only).

March 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC's recommendation - teatment commissioned

May 2018: The TAG considered the NNUH's application and discussed how dimethyl fumarate would be placed in the psoriasis treatment pathway with respect apremilast. Apremilast is more effective for nail treatment whereas dimethyl fumarate is more effective in hand and foot psoriasis. Both drugs would be positioned ahead of biologics.
Patients will be selected according to NICE criteria which places DMF alongside apremilast. There may also be a small subgroup of patients (that transfer from apremilast) where the use of a biologic agent is contraindicated.
The TAG agreed to support the NNUH's application and reaffirmed the previous recommendation of Red (Hospital only).
The treatment pathway to be sent to the D&TC for confirmation.

May 2018: The D&TC was advised that since local dermatology specialists also wish to switch between different treatment options for psoriasis, the treatment pathway was not finalised and would be brought to the June 2018 D&TC meeting.
The D&TC therefore did not make any decision regarding the NNUH's application and the TAG's recommendation from the May 2018 meeting.

July 2018:
July 2018:
The D&TC was advised that the psoriasis treatment pathway had been updated and published on Knowledge Anglia in May 2018 for dimethyl fumarate to be used as a non-biosimilar option, as an alternative to apremilast before biologics, in line with NICE TA 475 and the QEH and the NNUH's applications.
Already classified as Red (Hospital only) following the JSCC's decision in April 2018.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

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Dimethyl Fumarate (Tecfidera®) *(Tecfidera®)* TAG recommendation: Sep 2014

for use in: For treatment of adults with active relapsing-remitting multiple sclerosis (RRMS) - as per NICE TA 320 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2014.

Specific points: NICE TA 320 (August 2014):
Recommended by NICE as an option only if:
The patients do not have highly active or rapidly evolving severe RRMS and the manufacturer provides discount under PAS.

September 2014: The TAG noted NICE TA 320 and recommended a classification of Red (Hospital/Specialist only).

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

SCG commissioning responsibility.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Fingolimod ▼ *(Gilenya® ▼)* TAG recommendation: Nov 2012

for use in: Highly active, or rapidly evolving severe, relapsing-remitting multiple sclerosis outside NICE TA 254 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2012.

Specific points: September 2012:
The TAG recommended that patients with severe MS who meet the criteria for treatment with natalizumab but do not respond, or who are at risk of PML after two years' treatment with natalizumab due to positive JC Virus status could be treated with fingolimod. Patients being treated with copolymer-1 (glatiramer) who fulfil the same criteria as beta-interferon (at least one more relapse within a year) could also be treated with fingolimod.

Oct 2012 - The D&TCG agreed that for patients outside NICE TA 254:
* Fingolimod is commissioned on safety grounds for patients at risk of PML (proven by testing) who would have been considered for natalizumab or who have previously been treated with natalizumab.
* Prior approval is required.
* MS treatment pathway to be reviewed and returned to D&TCG.

November 2012:
Regarding patients who fail on glatiramer but who wouldn't have natalizumab, the TAG had recommended (Sept 2012) use of fingolimod since treating these patients with beta-interferon (a less effective treatment) in order to fulfil NICE criteria for use of fingolimod, was felt to be unethical. However the D&TCG had decided not to fund fingolimod in this group of patients as there was no evidence that they would have a better response.
The TAG agreed to investigate how other areas are commissioning fingolimod and to seek evidence for use in glatiramer patients to further advise the D&TCG.
NNUH neurologists' current views on the treatment pathway to be sought.

The D&TCG has noted the information and advice received from around the East of England area and supported the TAG's recommendation providing that there is:
1. agreement on a patient / treatment pathway across all local provider trusts (including Addenbrooke and Hinchingbrooke hospitals)
and
2. clarification regarding patient numbers and additional service cost regarding ECG monitoring
and
3. that fingolimod is provided via a Homecare service to ensure VAT savings in Primary Care

January 2013: The D&TCG agreed to commission use of fingolimod for patients outside NICE as discussed previously in line with an agreed treatment pathway.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Fingolimod ▼ *(Gilenya® ▼)* TAG recommendation: Sep 2012

for use in: Highly active relapsing remitting multiple sclerosis as per NICE TA 254 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2012.

Specific points: April 2012:
NICE TA 254 states that fingolimod is recommended as an option for the treatment of highly active relapsing remitting multiple sclerosis in adults, only if:
they have an unchanged or increased relapse rate or on-going severe relapses compared with the previous year despite treatment with beta interferon,
and
the manufacturer provides fingolimod with the discount agreed as part of the patient access scheme.
http://guidance.nice.org.uk/TA254

August 2012: The NHS Norfolk & Waveney Drug & Therapeutics Commissioning Group decided to fund use of fingolimod in line with NICE TA 254.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

Glatiramer *(Copaxone®)* TAG recommendation: Jul 2018

for use in: Multiple Sclerosis - as per NICE TA 527 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

July 2018:
The TAG acknowledged NICE TA 527: Beta interferons (Avonex®, Betaferon®, Extavia®, Rebif®) and glatiramer acetate (Copaxone®) for treating multiple sclerosis, which stated:
1.1 Interferon beta 1a is recommended as an option for multiple sclerosis only if:
* the person has relapsing-remitting multiple sclerosis and
* the companies provide it according to commercial arrangements.
1.2 Interferon beta 1b (Extavia) is recommended as an option for treating multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or
* the person has secondary progressive multiple sclerosis with continuing relapses and
* the company provides it according to the commercial arrangement.
1.3 Glatiramer acetate is recommended as an option for multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and
* the company provides it according to the commercial arrangement.
1.4 Interferon beta 1b (Betaferon) is not recommended as an option for treating multiple sclerosis.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Interferon alfa *(Roferon-A®, Viraferon®)* TAG recommendation: Mar 2006

for use in: Metastatic renal cell carcinoma (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Interferon alfa *(Roferon-A®, Viraferon®)* TAG recommendation: Mar 2013

for use in: Chronic myelogenous leukaemia (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2013: Commissioned as a Hospital Only treatment by NHS Norfolk & Waveney in line with Cancer Network regimens.

March 2013: The TAG revised the previous Amber classification to Red (Hopistal Only) in line with the current commissioning position.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Interferon alfa *(Roferon-A®, Viraferon®)* TAG recommendation: Nov 2007

for use in: In combination with ribavirin for Hepatitis C, and for Hepatitis B - as per NICE 75 and CG 165 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2010.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Interferon beta 1a *(Avonex®, Rebif®)* TAG recommendation: Jul 2018

for use in: Multiple Sclerosis - as per NICE TA 527 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: March 2002:
Funded by a DoH risk sharing scheme

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NICE TA 32 (January 2002) and NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

July 2018:
The TAG acknowledged NICE TA 527: Beta interferons (Avonex®, Betaferon®, Extavia®, Rebif®) and glatiramer acetate (Copaxone®) for treating multiple sclerosis, which stated:
1.1 Interferon beta 1a is recommended as an option for multiple sclerosis only if:
* the person has relapsing-remitting multiple sclerosis and
* the companies provide it according to commercial arrangements.
1.2 Interferon beta 1b (Extavia) is recommended as an option for treating multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or
* the person has secondary progressive multiple sclerosis with continuing relapses and
* the company provides it according to the commercial arrangement.
1.3 Glatiramer acetate is recommended as an option for multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and
* the company provides it according to the commercial arrangement.
1.4 Interferon beta 1b (Betaferon) is not recommended as an option for treating multiple sclerosis.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Interferon beta 1b (Extavia®) *(Extavia®)* TAG recommendation: Jul 2018

for use in: Multiple Sclerosis - as per NICE TA 527 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: March 2002:
Funded by a DoH risk sharing scheme

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NICE TA32 (January 2002) and NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

July 2018:
The TAG acknowledged NICE TA 527: Beta interferons (Avonex®, Betaferon®, Extavia®, Rebif®) and glatiramer acetate (Copaxone®) for treating multiple sclerosis, which stated:
1.1 Interferon beta 1a is recommended as an option for multiple sclerosis only if:
* the person has relapsing-remitting multiple sclerosis and
* the companies provide it according to commercial arrangements.
1.2 Interferon beta 1b (Extavia) is recommended as an option for treating multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or
* the person has secondary progressive multiple sclerosis with continuing relapses and
* the company provides it according to the commercial arrangement.
1.3 Glatiramer acetate is recommended as an option for multiple sclerosis, only if:
* the person has relapsing-remitting multiple sclerosis and
* the company provides it according to the commercial arrangement.
1.4 Interferon beta 1b (Betaferon) is not recommended as an option for treating multiple sclerosis.

Lenalidomide *(REVLIMID®)* TAG recommendation: Apr 2020

for use in: (with rituximab) for previously treated follicular lymphoma as per NICE TA627 April 2020 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2020.

Specific points: April 2020 - Discussed at D+TC meeting as TAG cancelled due to covid. Lenalidomide with rituximab is recommended, within its marketing authorisation, as an option for previously treated follicular lymphoma (grade 1 to 3A) in adults. It is only recommended if the company provides lenalidomide according to the commercial arrangement. The recommendation of Red (Hospital / Specialist use only) was supported by the D+TC

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Lenalidomide *(Revlimid®)* TAG recommendation: May 2018

for use in: POEMS syndrome - as per NHSE policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Lenalidomide *(Revlimid®)* TAG recommendation: May 2018

for use in: Cancer - as per NHSE policy / Cancer Drugs Fund (Various indications).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. SACT and CDF national audit.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Lenalidomide *(Revlimid®)* TAG recommendation: Apr 2021

for use in: maintenance treatment after an autologous stem cell transplant for newly diagnosed multiple myeloma as per TA680 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: April 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Lenalidomide ▼ *(Revlimid® ▼)* TAG recommendation: Nov 2014

for use in: Treatment of myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality - as per NICE TA 322 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2014.

Specific points: Lenalidomide is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the MHRA Yellow Card scheme.

November 2014:
The TAG acknowledged NICE TA 322 and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioned drug.
November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Lenalidomide ▼ *(Revlimid® ▼)* TAG recommendation: Jul 2009

for use in: Treatment of multiple myeloma in people who have received at least two prior therapies - as per NICE TA 171 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2009.

Specific points: July 2009 - the TAG acknowledged NICE Technology Appraisal Guidance No. 171.
Lenalidomide is a black triangle drug ▼ which requires monitoring for adverse effects and reporting via the MHRA Yellow Card scheme.
Prescriber's Rating 4 - Possibly helpful. The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

Funded by a DoH risk sharing scheme

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

Lenalidomide plus dexamethasone *(Revlimid®)* TAG recommendation: Sep 2019

for use in: Previously untreated multiple myeloma (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG & D&TC noted TA587 - June 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Lenalidomide plus dexamethasone *(Revlimid®)* TAG recommendation: Sep 2019

for use in: Multiple myeloma after 1 treatment with bortezomib (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2019.

Specific points: September 2019: The NHS Norfolk & Waveney CCGs' TAG and D&TC noted NICE TA586 - June 2019 and recommended a traffic light classification of Red (Hospital/Specialist only) for this NHS England commissioning responsibility treatment.

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Mifamurtide *(Mepact®)* TAG recommendation: Nov 2011

for use in: Treatment of osteosarcoma (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2011.

Specific points: The TAG noted NICE TA Guidance 235 (October 2011 http://guidance.nice.org.uk/TA235) which states that mifamurtide in combination with postoperative multi-agent chemotherapy is recommended within its licensed indication as an option for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection in children, adolescents and young adults and when mifamurtide is made available at a reduced cost to the NHS under the patient access scheme.

Commissioned by NHS Norfolk & Waveney Drugs & Therapeutics Commissioning in line with Cancer Network regimens. Non tariff treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Natalizumab ▼ *(Tysabri® ▼)* TAG recommendation: Sep 2007

for use in: Highly active relapsing-remitting multiple sclerosis in adults - as per NHS England policy and NICE TA 127 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2007.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

NHS England Policy: NHSCB/D04/P/a (April 2013) - http://www.england.nhs.uk/wp-content/uploads/2013/04/d04-p-a.pdf

Nivolumab *(Opdivo®)* TAG recommendation: Jun 2023

for use in: chemotherapy for neoadjuvant treatment of resectable non-small-cell lung cancer TA876 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Ozanimod *(Zeposia®)* TAG recommendation: Jul 2023

for use in: moderately to severely active ulcerative colitis as per TA828 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Specific points: July 2023 - formulary application accepted

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

In general this category covers:
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- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Peginterferon alfa *(Pegasys®, PegIntron®, ViraferonPeg®)* TAG recommendation: Nov 2009

for use in: Treatment of chronic hepatitis C (with ribavirin) (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: September 2010.

Specific points: November 2010: the TAG noted NICE TA 200 which states that:
1.1 Combination therapy with peginterferon alfa (2a or 2b) and ribavirin is recommended as a treatment option for adults with chronic hepatitis C:
who have been treated previously with peginterferon alfa (2a or 2b) and ribavirin in combination, or with peginterferon alfa monotherapy, and
whose condition either did not respond to treatment or responded initially to treatment but subsequently relapsed or
who are co-infected with HIV.

1.2 Shortened courses of combination therapy with peginterferon alfa (2a or 2b) and ribavirin are recommended for the treatment of adults with chronic hepatitis C who:
have a rapid virological response to treatment at week 4 that is identified by a highly sensitive test and
are considered suitable for a shortened course of treatment.

1.3 When deciding on the duration of combination therapy, clinicians should take into account the licensed indication of the chosen drug (peginterferon alfa-2a or peginterferon alfa-2b), the genotype of the hepatitis C virus, the viral load at the start of treatment and the response to treatment (as indicated by the viral load).

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Peginterferon alfa *(Pegasys® /ViraferonPeg®)* TAG recommendation: Jan 2014

for use in: Treating children and young people with chronic hepatitis C (with ribavirin) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2013.

Specific points: NICE TA 300 (Nov 2013) Recommended as an option by NICE for treating children and young people with chronic hepatitis C. N&W CCGs-D&TCG noted the TAG recommendation. Treatment is likely to be administered through specialist centres. SCG-commissioning responsibility.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Peginterferon alfa *(Pegasys®, PegIntron®, ViraferonPeg®)* TAG recommendation: Sep 2006

for use in: Treatment of mild chronic hepatitis C (with ribavirin) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2006.

Specific points: NICE TA 106 (August 2006) states:
1.1 Combination therapy, comprising peginterferon alfa-2a and ribavirin or peginterferon alfa-2b and ribavirin, is recommended, within the licensed indications of these drugs, for the treatment of mild chronic hepatitis C.
1.2 Monotherapy with peginterferon alfa-2a or peginterferon alfa-2b is recommended, within the licensed indications of these drugs, for the treatment of mild chronic hepatitis C for people who are unable to tolerate ribavirin, or for whom ribavirin is contraindicated.
1.3 The decision on whether a person with mild chronic hepatitis C should be treated immediately or should wait until the disease has reached a moderate stage ('watchful waiting') should be made by the person after fully informed consultation with the responsible clinician. The decision to treat need not depend on a liver biopsy to determine the stage of the disease if treatment is initiated immediately. However, a biopsy may be recommended by the clinician for other reasons or if a strategy of watchful waiting is chosen.
1.4 This recommendation has been updated and replaced by NICE technology appraisal guidance 200 ('Peginterferon alfa and ribavirin for the treatment of chronic hepatitis C').

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Peginterferon alfa-2a *(Pegasys, ViraferonPeg)* TAG recommendation: Jul 2013

for use in: Chronic Hepatitis B (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2013.

Specific points: NICE CG 165 (June 2013) updates and replaces 1.2 to 1.4 in NICE TA 96 regarding adefovir dipivoxil.
NICE TAs 153, 154, 173 and 1.1 of NICE TA 96 have been incorporated into CG165 and remain extant.

April 2013; NHS England Specialised Commissioning responsibility.

July 2013: NICE CG 165 (June 2013) noted by the TAG and the D&TCG.

Peginterferon beta-1a *(PLEGRIDY®))* TAG recommendation: Mar 2020

for use in: for treating relapsing–remitting multiple sclerosis as per TA624 - Feb 2020 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2020.

Specific points: March 2020 - The TAG recommended a traffic light classification of Red (Hospital / Specialist use only). This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Peginterferon Beta-1a *(Plegridy®)* TAG recommendation: May 2018

for use in: Multiple sclerosis - as per NHS England policy SSC1534 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2014.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Policy SSC1534. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pomalidomide ▼ *(Imnovid® ▼)* TAG recommendation: Mar 2017

for use in: In combination with dexamethasone - treatment of relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib as per NICE TA 427 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2017.

Specific points: May 2015: The TAG acknowledged the NICE TA 338 (March 2015) and recommended a classification of Double Red (Not recommended for routine use) for this SCG-commissioned drug.

March 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

March 2017: The TAG acknowledged NICE TA 427 (January 2017) and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Ponesimod *(Ponvory®)* TAG recommendation: Mar 2022

for use in: relapsing–remitting multiple sclerosis as per TA767 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: NHS England

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.2.4 - Other immunomodulating drugs

Simeprevir / Peginterferon + Ribavirin *(Olysio® / Various)* TAG recommendation: May 2018

for use in: Hepatitis C - as per NHSE policy (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Siponimod *(Mayzent®)* TAG recommendation: Dec 2020

for use in: secondary progressive multiple sclerosis as per TA656 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

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Thalidomide *(Thalidomide Celgene®)* TAG recommendation: Sep 2011

for use in: Multiple myeloma (first-line) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2011.

Specific points: NICE TA 228 (http://guidance.nice.org.uk/TA228) states:
Thalidomide in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma in people for whom high-dose chemotherapy with stem cell transplantation is considered inappropriate.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

March 2016: The TAG noted NG 35 (February 2016) - Myeloma: diagnosis and management

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Upadacitinib *(Rinvoq®)* TAG recommendation: Dec 2022

for use in: active ankylosing spondylitis as per TA829 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Dec 2022 - formulary application accepted. Classification amended to Red - Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4 - Hormone antagonists

Abiraterone *(Zytiga®)* TAG recommendation: May 2016

for use in: Metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (in combination with prednisone or prednisolone) - as per NICE TA 387 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2016.

Specific points: May 2016: The TAG noted NICE TA 387 for treatment:
* in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated
* only when the company rebates the drug cost of abiraterone from the 11th month until the end of treatment for people who remain on treatment for more than 10 months.

And recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Abiraterone acetate *(Zytiga®)* TAG recommendation: Jul 2012

for use in: Castration resistant metastatic prostate cancer previously treated with docetaxel - as per NICE TA 259 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2012.

Specific points: NICE TA 259 states that:
1.1 Abiraterone in combination with prednisone or prednisolone is recommended as an option for the treatment of castration-resistant metastatic prostate cancer in adults, only if:
* their disease has progressed on or after one docetaxel-containing chemotherapy regimen, and
* the manufacturer provides abiraterone with the discount agreed in the patient access scheme.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

8.3.4.2 - Prostate cancer and gonadorelin analogues

Apalutamide *(Erleada®)* TAG recommendation: Nov 2021

for use in: with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer as per TA740 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Apalutamide *(Erleada®)* TAG recommendation: Nov 2021

for use in: androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer as per TA741 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4.2 - Prostate cancer and gonadorelin analogues

Darolutamide *(Nubeqa®)* TAG recommendation: Jul 2023

for use in: with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer TA903 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Darolutamide *(Nubeqa®)* TAG recommendation: Dec 2020

for use in: with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer as per TA660 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2020.

Specific points: Dec 2020 - The TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4.2 - Prostate cancer and gonadorelin analogues

Degarelix *(Firmagon®)* TAG recommendation: Jan 2020

for use in: Advanced hormone-dependent prostate cancer - as per NICE TA 404 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2016.

Specific points: July 2014:
NICE FAD (April 2014):
Recommended as an option under specified criteria. The FAD is currently under appeal.

The TAG noted the NICE FAD and recommended a classification of Double Red (Not recommended for routine use) until final NICE guidance is clear.

July 2014: The Norfolk and Waveney CCGs' D&TCG noted that Degarelix is likely to be CCG-commissioning responsibility.
The D&TCG agreed that the treatment is not commissioned but will be revisited when final NICE guidance is published and commissioning responsibility is clarified.

September 2016: Degarelix, a selective LHRH antagonist, would likely be used as an alternative to LHRH agonists, goserelin, leuprorelin and triptorelin, in patients with spinal metastases, particularly those at risk of / with compressive disease. However it is a more expensive option.

The TAG acknowledged NICE TA 404 (August 2016) and recommended a classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending submission of business applications to support its use locally.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted that although NICE TA 404 (August 2016) specifies that the treatment should be provided at a discounted price, the company's current discount offer is time-limited which may result in a cohort of patients being given treatment whose needs will outlast the availability of the drug at the required discounted price.

The D&TCG noted and supported the TAG's recommendation that Degarelix (Firmagon®) for treating advanced hormone-dependent prostate cancer in people with spinal metastases is classified as Double Red (Not recommended for routine use) pending submission of business applications to support its use locally.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendation of January 2020. The NNUH formulary application submitted was accepted and the traffic light classification amended to Red (Hospital/Specialist only) for oncology patients only.

Enzalutamide *(Xtandi®)* TAG recommendation: Sep 2014

for use in: Metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen - as per NICE TA 316 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2014.

Specific points: September 2014: NICE TA 316 (July 2014)
Recommends enzalutamide as an option for this indication if discounted under PAS.The TAG acknowledged NICE TA 316 and recommended a traffic light classification of Red (Hospital/Specialist only.)

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4.2 - Prostate cancer and gonadorelin analogues

Enzalutamide *(Xtandi®)* TAG recommendation: Mar 2016

for use in: Metastatic hormone-relapsed prostate cancer before chemotherapy is indicated - as per NICE TA 377 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG noted NICE TA 377 (January 2016) which recommends use of enzalutamide as an option for people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated.
The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Noted by the CCGs' D&TCG in March 2016.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Enzalutamide *(Xtandi®)* TAG recommendation: Aug 2021

for use in: hormone-sensitive metastatic prostate cancer as per TA712 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: NHS England commissioned medication

8.3.4.3 - Somatostatin analogues

Lanreotide *(Somatuline LA®)* TAG recommendation: May 2013

for use in: Carcinoid and other neuroendocrine tumours - for new patients (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2013: Commissioning responsibility for cancer-related indications has been transferred to the NHS England SCG which does not support shared care prescribing for cancer-related treatments.
Existing patients could be repatriated gradually with only new patients coming under a Red classification.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decisions:

Red (Hospital/Specialist prescribing only) for new patients starting treatment for cancer-related indications from 1st April 2013 onwards.

CCGs will seek reimbursement for any related Primary Care prescribing.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4.3 - Somatostatin analogues

Lanreotide *(Somatuline® LA)* TAG recommendation: May 2013

for use in: Acromegaly (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment, superseding previous local agreement.

Http://www.england.nhs.uk/wp-content/uploads/2013/06/a03-spec-endo-adult.pdf

Lanreotide *(Somatuline®)* TAG recommendation: May 2018

for use in: Congenital hyperinsulinism (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only. Lowest cost product to be used.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pl%3d&tabid=2668&portalid=1

Octreotide *(Sandostatin®)* TAG recommendation: May 2013

for use in: Carcinoid and other neuroendocrine tumours (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2013: Commissioning responsibility for cancer-related indications has been transferred to the NHS England SCG which does not support shared care prescribing for cancer-related treatments.
Existing patients could be repatriated gradually with only new patients coming under a Red classification.

May 2013 N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decisions:

Red (Hospital/Specialist prescribing only) for new patients starting treatment for cancer-related indications from 1st April 2013 onwards.

CCGs will seek reimbursement for any related Primary Care prescribing.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

8.3.4.3 - Somatostatin analogues

Octreotide *(Sandostatin®)* TAG recommendation: May 2013

for use in: Acromegaly (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment, superseding previous local agreement.

Http://www.england.nhs.uk/wp-content/uploads/2013/06/a03-spec-endo-adult.pdf

Octreotide *(Sandostatin® - Generics are available)* TAG recommendation: May 2018

for use in: Congenital hyperinsulinism (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Pasireotide *(Signifor®)* TAG recommendation: May 2018

for use in: Cushing's Disease - as per NHS England Policy 16052/P (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16052/P. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.1.1.1 - Iron deficiency anaemia in IBD

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.1.1 - Iron deficiency anaemia in IBD

Ferric maltol (Feraccru®) *(Feraccru®)* TAG recommendation: Mar 2019

for use in: Treatment of iron-deficiency anaemia in adults with Inflammatory Bowel Disease that are intolerant of at least 2 other oral iron products (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG noted that Feraccru® capsules containing 231.5mg ferric maltol (equivalent to 30mg ferrous iron), which are licensed to treat iron deficiency anaemia in inflammatory bowel disease (IBD) are currently used in-Trust at the NNUH but requests have also been made to GPs.
28 days' supply (56) costs £47.60 compared with ferrous fumarate or sulphate preparations costing £1 to £3.
Recommended by the Prescribing Reference Group to be added to the Norfolk & Waveney DROP List.
The TAG also recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application for use of Feraccru® is submitted.

July 2017: Noted and supported by the D&TCG - Not commissioned

September 2017:
The TAG considered an NNUH application for use in iron deficiency anaemia (mild-moderate) in adult patients with inflammatory bowel disease that are intolerant or have failed 1st line oral iron agents.
The TAG was advised that where other iron preparations are not effective / not tolerated, the next treatment option is IV iron infusion. Feraccru® is significantly more expensive than standard oral iron preparations but is cheaper and less invasive than administering IV iron.
The TAG was concerned about the low quality of supporting evidence provided with this application (2 placebo-controlled RCTs), and also noted that the SMC had published their decision not to commission use of this treatment.
The TAG therefore agreed that a revised recommendation regarding this item is deferred until more evidence to support such use is provided particularly regarding the effectiveness and tolerability of Feraccru® compared to other iron salts

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG.

November 2017:
The TAG considered further information provided by the NNUH which aimed to clarify that ferric maltol is the next proposed treatment option in patients with clinically inactive disease after use of oral ferrous salt products have failed, either due to intolerance or inadequate response. The TAG agreed that use of ferric maltol was clinically acceptable, based on the available evidence, providing that all cost-effective oral ferrous salt products (i.e. sulphate, fumarate and gluconate) are tried before ferric maltol is used. The TAG also advised that if the local costs of running an IV iron service (which had been set up in primary care to treat patients found to be anaemic pre-operatively in order to ensure their fitness for surgery in a timely fashion) were greater than using ferric maltol in this specific patient group, then such use was reasonable.
The TAG agreed to recommend a revised traffic light classification from Double Red (Not recommended for routine use) to Red (Hospital / Specialist use only) until the treatment pathway is finalised via the D&TCG.

November 2017:
The D&TCG considered the additional information provided by the NNUH, and the TAG's revised recommendation. The D&TCG felt that it was unclear whether the patients who are currently taking ferric maltol had tried all other ferrous salt alternatives, which are considerably cheaper than the proposed treatment, before being moved to Feraccru®. There were also outstanding questions regarding the status of the IV iron service currently provided in primary care. The D&TCG therefore felt that the case for using ferric maltol (Feraccru®) was not sufficiently proven to be able to justify introducing a new product to the local health economy which costs more than standard oral care and which may not necessarily reduce the costs of delivering IV iron in the future. Whilst the D&TCG appreciated the NNUH's intentions in proposing use of Feraccru®, the committee was not convinced that adding Feraccru® to local treatment pathway would save enough to justify its additional costs. The D&TCG therefore decided to maintain the current commissioned position of Double Red (Not recommended for routine use / Not commissioned).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.1.1 - Iron deficiency anaemia in IBD

November 2018: The PRG recommendation that the TAG considers reviewing and updating the Double Red (Not recommended for routine use) classification to this treatment in line with its revised licensed indication for treatment of anaemia of any cause was supported by the TAG.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and D&TC recommendation.

March 2019: The TAG considered the NNUH's revised application, which proposed restricted use of this oral chelated iron product in a small number of patients with inflammatory bowel disease with iron deficiency anaemia who cannot tolerate standard oral iron salts and who then require IV iron infusions (~30 patients). Patients often require 2 day case appointments to complete the required IV treatment.
The TAG agreed to support the revised application and recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation) for a 12 week course only in patients with IBD who had been unable to tolerate 2 other oral iron preparations.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC supported the revised application for use in principle.
However due to concerns that use of Ferric maltol (Feraccru®) would become widespread in primary care as a general treatment for iron deficiency anaemia, the D&TC recommended a revised classification of Red (Hospital/Specialist use only), where the specialist provides the complete treatment course.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

9.1.3 - Drugs used in sickle cell disease

Crizanlizumab *(Adakveo®)* TAG recommendation: Dec 2021

for use in: preventing sickle cell crises in sickle cell disease as per TA743 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Darbepoetin alfa *(Aranesp®)* TAG recommendation: Jan 2015

for use in: Treatment of anaemia in people with cancer having chemotherapy - as per NICE TA 323 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2014.

Specific points: January 2015: The TAG noted NICE Technology Appraisal Guidance No.323 (including review of NICE TA 142) (November 2014) - Erythropoesis-stimulating agents (epoetin and darbepoetin) in treatment of anaemia in people with cancer having chemotherapy which recommends use of these treatments as options, within their marketing authorisations. If equally suitable, the product with the lowest acquisition cost should be used.

The TAG noted that the NICE Costing Report states that this is a CCG-commissioning responsibility.
The TAG therefore acknowledged NICE TA 323 and recommended a revised traffic classification of Red (Hospital only).

The Norfolk & Waveney CCGs' Drugs and Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation and agreed that the treatment was commissioned as an In-Tariff treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.3 - Drugs used in sickle cell disease

Deferasirox *(Exjade®)* TAG recommendation: May 2013

for use in: Treatment of chronic iron overload due to frequent blood transfusions (but not for use in MDS) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2013: Commissioning responsibility now with NHS England Specialised Commissioning (SCG). Deferasirox is one of a number of treatments which SCG has stated should be repatriated to Secondary care and in the future be provided via Homecare. Therefore GPs should no longer prescribe this treatment under the previous shared care agreement.

Recent supply/ procurement problems in Primary Care have resulted in the supply deferasirox returning to hospitals by default.

N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decision:
Red (Hospital /Specialist prescribing only) for all patients.

CCGs will seek reimbursement for any Primary Care prescribing related to these patients from 1st April 2013.

Deferiprone *(Ferriprox®)* TAG recommendation: Jan 2013

for use in: Chronic iron overload related to frequent blood transfusions (not for use in MDS) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Desferrioxamine mesilate *(Desferal®)* TAG recommendation: Jan 2013

for use in: Anaemia related to chronic iron overload (not for use in MDS) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2013: Commissioned by NHS Norfolk & Waveney. Non-tariff treatment. Notification required.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.3 - Drugs used in sickle cell disease

Dexrazoxane (Savene®) *(Savene®)* TAG recommendation: May 2018

for use in: Anthracycline extravasation (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Trust Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eculizumab *(Soliris®)* TAG recommendation: May 2018

for use in: C3 glomerulopathy (post transplant) - as per NHSE policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Policy 16054/P. Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eculizumab *(Soliris®)* TAG recommendation: May 2018

for use in: Paroxysmal noctural haemoglobinuria (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Service Specification - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Eculizumab *((Soliris®))* TAG recommendation: Mar 2023

for use in: Atypical haemolytic uremic syndrome (aHUS) HST1 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2015.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.3 - Drugs used in sickle cell disease

Erythropoietin (epoetin / darbepoetin) *(Various)* TAG recommendation: Jan 2015

for use in: Treatment of anaemia in people with cancer having chemotherapy - as per NICE TA 323 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2014.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No.142 (May 2008) - Anaemia (cancer-treatment induced): erythropoetin (alpha and beta) and darbepoetin.

Erythropoietin analogues with iron injections are recommended as a possible treatment for anaemia caused by cancer treatment only in:

* women receiving platinum-based chemotherapy for cancer of the ovaries who have a blood haemoglobin level of 8 g/100 ml or lower
* people who have very severe anaemia and cannot receive blood transfusions.

April 2013: NHS England SCG took over commissioning responsibility for this treatment. Not listed by SCG therefore not commissioned. Traffic light revised to Double Red.

January 2015: The TAG noted NICE Technology Appraisal Guidance No.323 (including review of NICE TA 142) (November 2014) - Erythropoesis-stimulating agents (epoetin and darbepoetin) in treatment of anaemia in people with cancer having chemotherapy which recommends use of these treatments as options, within their marketing authorisations. If equally suitable, the product with the lowest acquisition cost should be used.

The TAG noted that the NICE Costing Report states that this is a CCG-commissioning responsibility.
The TAG therefore acknowledged NICE TA 323 and recommended a revised traffic classification of Red (Hospital only).

The Norfolk & Waveney CCGs' Drugs and Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation and agreed that the treatment was commissioned as an In-Tariff treatment.

Erythropoietin / Epoetin *(Eprex®, NeoRecormon® and others)* TAG recommendation: May 2013

for use in: Dialysis-induced anaemia (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: April 2013:
NHS England Area Team is now the commissioner responsible for this treatment.

Commissioned use is for patients on Renal dialysis only including via outpatients and only as per NICE CG114 http://www.nice.org.uk/guidance/CG114 and Trust guidelines.

July 2015: The TAG and the D&TCG noted and acknowledged (NICE) NG 8 (June 2015) - Anaemia management in people with chronic kidney disease.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.3 - Drugs used in sickle cell disease

Hydroxycarbamide (hydroxyurea) - generic *(Generic)* TAG recommendation: Sep 2011

for use in: Sickle Cell disease (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2011:
The TAG noted the EoE SCG Commissioning Policy v.1 (November 2009) - Hydroxycarbamide (hydroxyurea) in Sickle Cell Disease and acknowledged the document as a reference upholding the PCTs' previous decision not to fund Siklos®.
The TAG recommended a Double Red (Not recommended for routine use) classification for Siklos® and a Red (Hospital Only) classification for generic hydroxycarbamide for use in sickle cell disease.

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided to maintain the previous decision to fund only GENERIC hydroxycarbamide for use in sickle cell disease.

Methoxy polyethylene glycol-epotein beta ▼ *(Mircera® ▼)* TAG recommendation: Nov 2011

for use in: Symptomatic anaemia associated with Chronic Kidney Disease (dialysis patients only) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2011.

Specific points: February 2011: NICE CG 114 - management of chronic kidney disease - http://www.nice.org.uk/nicemedia/live/13329/52851/52851.pdf

November 2011: The TAG agreed to support the NNUH's business case for use of Mircera® as a cost-effective treatment option.

NB This recommendation does not apply to use in the treatment of anaemia induced by cancer treatment.

April 2013:
NHS England Area Team is now the commissioner responsible for this treatment.

Commissioned use is for patients on Renal dialysis only, including via outpatients and only as per NICE CG114 http://www.nice.org.uk/guidance/CG114 and Trust guidelines.

Pegcetacoplan *(Aspaveli®)* TAG recommendation: Apr 2022

for use in: paroxysmal nocturnal haemoglobinuria as per TA778 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.3 - Drugs used in sickle cell disease

Roxadustat *(Evrenzo®)* TAG recommendation: Jun 2023

for use in: symptomatic anaemia in chronic kidney disease as per TA807 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

June 2023 - applicaton accepted by TAG

9.1.4 - Drugs used in platelet

Avatrombopag *(Doptelet®)* TAG recommendation: Apr 2022

for use in: Treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure as per TA626 (June 2020) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case. This recommendation was supported by the D+TC

April 2022 - Formulary application accepted

Caplacizumab *(Cablivi®)* TAG recommendation: Jan 2021

for use in: with plasma exchange and immunosuppression for treating acute acquired thrombotic thrombocytopenic purpura as per TA667 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: Jan 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only). Supported by D+TC and ratified by CCG Governing Body

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.4 - Drugs used in platelet

Eltrombopag *(Revolade®)* TAG recommendation: Sep 2013

for use in: Treatment of chronic immune (idiopathic) thrombocytopenic purpura - as per NICE TA 293 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2013.

Specific points: September 2013: The TAG considered NICE TA 293 Eltrombopag in the treatment of chronic immune (idiopathic) thrombocytopenic purpura, now recommended as an "option" within licensed indications under specified criteria.
NHS Norfolk & Waveney's Drugs and Therapeutics Commissioning Group (D&TCG) noted that although patient numbers are small, treatment costs are high and notification of use in individual patients will be required.

November 2013: Commissioned as per NNUH business application. The D&TCG also recommended that oral eltrombopag should be considered for use before subcutaneous romiplostim due to equivalent, or potentially lower, treatment costs and a less invasive route of administration.

Lusutrombopag *(MULPLEO®))* TAG recommendation: Apr 2022

for use in: thrombocytopenia in people with chronic liver disease needing a planned invasive procedure as per TA617 Jan 2020 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2020. There is a shared care protocol approved by TAG.

Specific points: March 2020 - The TAG recommended a traffic light classification of Double Red (Not recommended for routine use / Not commissioned) pending provision of a business case. This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

April 2022 - formulary application accepted

Romiplostim *(Nplate®)* TAG recommendation: Jul 2011

for use in: Chronic immune (idiopathic) thrombocytopenic purpura (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 221 which recommends romiplostim as an option for use under specified criteria (http://guidance.nice.org.uk/TA221):

Romiplostim is recommended for the treatment of adults with chronic immune (idiopathic) thrombocytopenia purpura:
* whose condition is refractory to standard
active treatments and rescue therapies or
* who have severe disease and a high risk of bleeding that needs frequent courses of rescue therapies and
* if the manufacturer makes romiplostim
available with the discount agreed as part of
the patient access scheme.
Only a haematologist should start and supervise treatment with romiplostim.

9.1.6 - Drugs used in neutropenia

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.6 - Drugs used in neutropenia

Filgrastim *(Various ▼)* TAG recommendation: Jul 2012

for use in: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2012: The TAG noted the East of England Priorities Advisory Committee (PAC) policy "Guidance on the use of pegfilgrastim & lenograstim in adult patients receiving cytotoxic chemotherapy - April 2012" which states that since there is no significant difference in clinical effectiveness between rhG-CSF products (filgrsatim, lenograstim and pegfilgrastim), daily filgrastim, self-administered by the patient, is the preferred option.

The policy also states that there are circumstances in which it is more practical and convenient to use the other products as follows:
Lenograstim should only be used in preference to filgrastim for the clinical indications that filgrastim lacks namely: Mobilisation of peripheral blood progenitor cells (PBPCs).
Weekly pegfilgrastim should only be used in place of a daily GCSF where the associated costs of ensuring daily GCSF administration outweigh the higher purchase price typically paid for Pegfilgrastim.

Situations where such may be considered are in those deemed psychosocial where patients would otherwise need high levels of support to receive one of the daily GCSFs.

April 2013: NHS England SCG / Local Area Team have taken over commissioning responsibility for this treatment. Product with lowest acquisition cost to be used.

Filgrastim *()* TAG recommendation: May 2018

for use in: Barth Syndrome - specialist centres only (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Lenograstim *(Granocyte®)* TAG recommendation: May 2018

for use in: Barth Syndrome - Highly specialised criteria by Specialist centres only (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria by Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.6 - Drugs used in neutropenia

Lenograstim *(Granocyte®)* TAG recommendation: Jul 2012

for use in: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2012: The TAG noted the East of England Priorities Advisory Committee (PAC) policy "Guidance on the use of pegfilgrastim & lenograstim in adult patients receiving cytotoxic chemotherapy - April 2012" which states that since there is no significant difference in clinical effectiveness between rhG-CSF products (filgrsatim, lenograstim and pegfilgrastim), daily filgrastim, self-administered by the patient, is the preferred option.

The policy also states that there are circumstances in which it is more practical and convenient to use the other products as follows:
Lenograstim should only be used in preference to filgrastim for the clinical indications that filgrastim lacks namely: Mobilisation of peripheral blood progenitor cells (PBPCs).
Weekly pegfilgrastim should only be used in place of a daily GCSF where the associated costs of ensuring daily GCSF administration outweigh the higher purchase price typically paid for Pegfilgrastim.

Situations where such may be considered are in those deemed psychosocial where patients would otherwise need high levels of support to receive one of the daily GCSFs.

April 2013: NHS England SCG / Local Area Team have taken over commissioning responsibility for this treatment. Product with lowest acquisition cost to be used.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.6 - Drugs used in neutropenia

Pegfilgrastim *(Neulasta®)* TAG recommendation: Jul 2012

for use in: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2012: The TAG noted the East of England Priorities Advisory Committee (PAC) policy "Guidance on the use of pegfilgrastim & lenograstim in adult patients receiving cytotoxic chemotherapy - April 2012" which states that since there is no significant difference in clinical effectiveness between rhG-CSF products (filgrsatim, lenograstim and pegfilgrastim), daily filgrastim, self-administered by the patient, is the preferred option.

The policy also states that there are circumstances in which it is more practical and convenient to use the other products as follows:
Lenograstim should only be used in preference to filgrastim for the clinical indications that filgrastim lacks namely: Mobilisation of peripheral blood progenitor cells (PBPCs).
Weekly pegfilgrastim should only be used in place of a daily GCSF where the associated costs of ensuring daily GCSF administration outweigh the higher purchase price typically paid for Pegfilgrastim.

Situations where such may be considered are in those deemed psychosocial where patients would otherwise need high levels of support to receive one of the daily GCSFs.

January 2013: Listed as "Not Commissioned" by NHS Norfolk & Waveney.

April 2013: NHS England SCG / Local Area Team have taken over commissioning responsibility for this treatment. Product with lowest acquisition cost to be used.
IFR approval required for this treatment.

9.1.7 - Drugs used to mobilise stem cells

Plerixafor *(Mozobil®)* TAG recommendation: Jul 2015

for use in: Stem cell mobilisation (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2015: The TAG and the D&TCG noted NHS England Clinical Commissioning Policy B04/P/b: (Update January 2015) for use of plerixafor for stem cell mobilisation.

NHS England SCG-commissioning responsibility

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.1.7 - Drugs used to mobilise stem cells

Plerixafor *(Mozobil®)* TAG recommendation: Mar 2011

for use in: Mobilisation of stem cells in Bone Marrow Transplant (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: Commissioning responsibility transferred to NHS England SCG.

September 2013: Interim Clinical Commissioning Policy Statement: Use of Plerixafor for Stem Cell Mobilisation Reference: NHS ENGLAND B04/PS/a
http://www.england.nhs.uk/wp-content/uploads/2013/09/b04-psa1.pdf

9.2.1.1 - Nutrition and Blood

Sodium zirconium cyclosilicate *(Lokelma®)* TAG recommendation: Jan 2020

for use in: Hyperkalaemia in adults - emergency care (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA599 - September 2019 was noted and afforded a traffic light classification of Red (Hospital/Specialist only) for this CCG commissioning responsibility treatment.

February 2020: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of January 2020. The Trust formulary application by QEH was accepted and the traffic light classification of Red (Hospital/Specialist only) for emergency care to remain.

9.3 - Intravenous nutrition

Intravenous nutrition *(SMOFlipid®)* TAG recommendation: Nov 2010

for use in: Total Parenteral Nutrition in premature infants with intestinal failure (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: SMOF Lipid is used in total parenteral nutrition (TPN) for pre-term neonates with intestinal failure, who require TPN for more than 4 weeks. The standard product, Intralipid®, can exacerbate LFTs, and cause liver damage.

December 2010: the business case for use of SMOF lipid was approved by the NHS Norfolk Drugs & Therapeutics Commissiioning Group.

April 2013: Commissioning responsibility for parenteral nuttrition trannsferred to NHS England SCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.3 - Intravenous nutrition

Total parenteral nutrition *(Various)*

for use in: Various (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts N/A.

NICE has not issued any guidance.

Specific points: Supplied and funded under a special contract.

9.4.1 - Foods for special diets

Sapropterin *(Kuvan®)* TAG recommendation: Oct 2021

for use in: hyperphenylalaninaemia in phenylketonuria as per TA729 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2021.

Specific points: NHS England commissioned treatment

Sapropterin (Tetrahydrobiopterin (BH4, THB)) *(Kuvan® ▼)* TAG recommendation: Jul 2011

for use in: Management of Phenylkentonuria (PKU) only during pregnancy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Phenylketonuria (PKU) is a rare genetic metabolic disease in which there is a deficiency phenylalanine hydroxylase which results in raised blood phenylalanine levels which can reach neurotoxic concentrations. The condition is characterised by poor neurocognitive and neuromotor development with subsequent impairment of intelligence and social functioning. Clinical management to date has been by dietary restriction of phenylalanine.

Sapropterin is a newer drug treatment available for PKU. Clinical studies in paediatric and adult patients have demonstrated that for some patients it can lead to important reductions in blood phenylalanine levels.

Sapropterin is designated an orphan drug. It is an expensive treatment, with typical annual costs in the range £20,000 to £50,000 depending on the actual dose. This is several times more expensive than usual management with special dietary foods and supplements. Sapropterin is unlikely to meet conventional criteria for cost-effectiveness in terms of cost per quality adjusted life year.

April 2013: Commissioning responsibility transferred to NHS England SCG, which issued Clinical Commissioning Policy: Sapropterin (Kuvan®) For Phenylketonuria: Use in Pregnancy
Reference: NHSCB/E12/p/a
http://www.england.nhs.uk/wp-content/uploads/2013/04/e12-p-a.pdf

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.4.1 - Foods for special diets

Tetrahydrobiopterin (BH4, THB) - aka Sapropterin *(Sapropterin (Kuvan®))* TAG recommendation: May 2018

for use in: Phenylketonuria (PKU) - Specialist centres only - Highly specialised criteria only (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Service Specification - Specialist centres only. Highly specialised criteria only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.5.1.2 - Hypercalcaemia & hypercalciuria

Cinacalcet *(Mimpara®)* TAG recommendation: Feb 2007

for use in: Refractory secondary hyperparathyroidism in patients with end-stage renal disease under specific criteria - as per NICE TA 117 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: January 2007.

Specific points: In January 2007 the following guidance was issued by NICE, which did not recommend routine use but did specify criteria for limited use of cinacalcet, as follows -
NICE Guidance (TAG 117): Cinacalcet in secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy: Cinacalcet is not recommended for the routine treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.
Cinacalcet is recommended for the treatment of refractory secondary hyperparathyroidism in patients with end-stage renal disease (including those with calciphylaxis) only in those:
who have 'very uncontrolled' plasma levels of intact parathyroid hormone (defined as greater than 85 pmol/litre [800 pg/ml]) that are refractory to standard therapy, and a normal or high adjusted serum calcium level, and
in whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits.

The TAG therefore agreed to maintain the Double Red classification for routine use in secondary hyperparathyroidism and parathyroid cancer (see separate entry) but agreed to support a Red (Hospital use only) classification for patients meeting the criteria specified by NICE.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.5.1.2 - Hypercalcaemia & hypercalciuria

Etelcalcetide (aka Velcalcetide) *(Parsabiv®)* TAG recommendation: May 2018

for use in: Secondary hyperparathyroidism in patients with chronic kidney disease on haemodialysis (A licensed indication).

Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per IFR approval - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.5.2.2 - Phosphate-binding agents

Sucroferric oxyhydroxide *(Velphoro®)* TAG recommendation: May 2018

for use in: Control serum phosphorus in dialysis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Used as per Trust Guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

9.5.3 - Fluoride

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.5.3 - Fluoride

Fluoride supplements -Toothpaste; dental products *(Duraphat 0.619% DPF; 1.1% DPF Toothpaste)* TAG recommendation: May 2015

for use in: Prevention of dental caries in at-risk patients (where the specialist is a dentist) - as per N&W DROP List (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Duraphat toothpaste is on the N&W DROP List.

It is acknowledged that there is a cohort of patients with head and neck cancers who are advised by oncologists to use it life-long to obviate the increased risk of dental caries. Although dentists do not have the provision to write repeat prescriptions GPs should not be expected to prescribe for a condition they do not manage or monitor. Patients should be encouraged to regularly attend a dentist to monitor their dental health and provide treatment if necessary.
Duraphat® toothpaste remains on the DROP List and should not prescribed by GPs on FP10.

The TAG therefore recommended a classification of Red (Specialist (i.e. dental) use only - Not to be prescribed by GPs) for this product.

January 2016:
The TAG noted NG 30 (December 2015) Oral health promotion: general dental practice
This guideline covers how general dental practice teams can convey advice about:
* oral hygiene and the use of fluoride
* diet, smoking, smokeless tobacco and alcohol intake.

9.6.2 - Vitamin B group

Vitamin B Co / Co Strong tablets *()* TAG recommendation: Sep 2018

for use in: Time-limited use (10 days) only in re-feeding syndrome (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2018: The TAG noted the PRG recommendation that the TAG supports restricted use only of Vitamin B Co / Co strong tablets, by specialists, for 10 days only in re-feeding syndrome and considers applying a Red (Hospital / Specialist use only) classification for restricted use only.
No longer supported for prescribing in primary care.
The TAG agreed to support the PRG's recommendation

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG &D&TC recommendations.

9.8.1 - Drugs used in metabolic disorders

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.8.1 - Drugs used in metabolic disorders

(L-) Carnitine *(Various - Carnitor®)* TAG recommendation: May 2018

for use in: Carnitine Deficiency (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised database and criteria.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Asfotase alfa *(Strensiq®)* TAG recommendation: Jun 2023

for use in: paediatric-onset hypophosphatasia HST23 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Avalglucosidase alfa *(AVAL®)* TAG recommendation: Sep 2022

for use in: Pompe disease as per TA821 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Carglumic acid *(Carbaglu®)* TAG recommendation: May 2018

for use in: Treatment hyperammonaemia in urea cycle disorder (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.8.1 - Drugs used in metabolic disorders

Cysteamine (Mercaptamine) *(Cystagon®; Procysbi®)* TAG recommendation: May 2018

for use in: Neuropathic cystinosis (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Service Specification. Specialist centre only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Galsufase *()* TAG recommendation: May 2018

for use in: Mucopolysaccharidosis VI - specialist centre only (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Imiglucerase *(Cerezyme®)* TAG recommendation: Mar 1998

for use in: Gaucher's disease (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: April 2013: Commissioning responsibility for this treatment transferred to NHS England SCG.

Highly specialised use only.

Sodium Phenylbutyrate *(Ammonaps®, Pheburane®)* TAG recommendation: May 2018

for use in: Acute hyperammonaemia due to urea cycle disorders (specialist use only) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

9.8.1 - Drugs used in metabolic disorders

Taliglucerase alfa *(Elelyso®)* TAG recommendation: May 2018

for use in: Gaucher's Disease (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - Specialist centres only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Velaglucerase alfa *(VPRIV®)* TAG recommendation: May 2018

for use in: Type I Gaucher's disease (specialist use only) - as per NHS England specification (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist Centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

10.1.3 - Drugs that suppress the rheumatic disease process

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Abatacept *(Orencia®)* TAG recommendation: Sep 2015

for use in: Treatment of Juvenile Idiopathic Arthritis (JIA) as per NICE TA 373 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: September 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

Regarding use of abatacept in JIA:
Abatacept and Tocilizumab both have good evidence to support their use in Poly-articular forms of JIA which have failed anti-TNF therapy but there is no head to head comparative trial to assess effectiveness. Tocilizumab appears to have a faster onset of action than Abatacept and therefore may be preferred in cases where arthritis is widespread and severe. However Tocilizumab has been associated with liver function abnormalities, and appears in clinical practice to have a greater risk of infections being under-recognised by medical staff due to its effect on suppressing both the symptoms of fever and measurement of acute phase reactants. The choice of which to use should therefore be at the discretion of the paediatric rheumatologist. A patient should fail 3 different classes of biologic before being referred for autologous stem cell rescue or bone-marrow transplantation.

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

January 2016:
The TAG noted NICE TA 373 which recommends use of Abatacept (Orencia®), adalimumab (Humira®), etanercept (Enbrel®) and tocilizumab (RoActemra®) as possible treatments for children and young people with polyarticular juvenile idiopathic arthritis.
Adalimumab and etanercept are recommended as options for enthesitis-related juvenile idiopathic arthritis.
Etanercept is recommended as a possible option for psoriatic juvenile idiopathic arthritis.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

The TAG noted that NICE TA 373 (December) differed from NHS England's interim policy (July 2015) regarding the clinical conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Abatacept *(Orencia®)* TAG recommendation: Sep 2010

for use in: Rheumatoid arthritis - after other DMARDs including a TNF inhibitor - as per NICE TA 195 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: NICE TA 195 (August 2010) states that adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are recommended as treatment options only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.

NICE TA 234 (August 2011) (http://guidance.nice.org.uk/TA234) states:
Abatacept in combination with methotrexate is NOT recommended for the treatment of moderate to severe active rheumatoid arthritis in adults whose disease has responded inadequately to one or more conventional non-biological disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate. (i.e. First-line use of abatacept after non-biologic DMARDs have proved ineffective)
Please see separate "Double Red" entry related to this guidance.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Abatacept *(Orencia®)* TAG recommendation: May 2013

for use in: Rheumatoid arthritis - 1st line biologic after failure of non-biologic DMARDs - as per NICE TA 280 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2013.

Specific points: NICE TA 280 (rapid review of NICE TA 234) (http://guidance.nice.org.uk/TA280) states:
Abatacept in combination with methotrexate is recommended as an option for the treatment of moderate to severe active rheumatoid arthritis in adults whose disease has responded inadequately to two conventional non-biological disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate, only if:
* it is used in accordance with the recommendations for other biological DMARDs in Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis (NICE technology appraisal guidance 130) and
* the manufacturer provides abatacept with the discount agreed in the patient access scheme.

1.2 People currently receiving abatacept whose disease does not meet the criteria in section 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) - Commissioned as Red (Hospital / Specialist only) in line with NICE TA 280 (April 2013)

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Abatacept (subcutaneous) *(Orencia® (subcutaneous))* TAG recommendation: Sep 2014

for use in: First line biologic option for moderate to severe active rheumatoid arthritis in adults who responded inadequately to one or more DMARDS (including MTX) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2013.

Specific points: September 2014:
The TAG noted the application to use s/c abatacept in an identified cohort of 25 patients as a first line option as per predicted outcome of review of current NICE pathway which places IV abatacept as a third-line option. NNUH wish to be able to revert to another biologic option (an anti-TNF) if treatment with s/c abatacept fails, before considering use of rituximab, as per the current NICE treatment pathway. The TAG was satisifed that there is no evidence of inferiority for the use of s/c abatacept compared with IV infusion. The TAG supported the application and recommended a classification of Red (Hospital only) with a Prescriber's Rating of 3 - Offers an advantage - The product has some value but does not fundamentally change therapeutic practice.

September 2014: The Norfolk & Waveney CCGs D&TCG noted the application for the use of s/c abatacept as per the described treatment pathway and supported and commissioned for the 25 patients stated in the business case. Further details required around all costs related to the delivery of this treatment.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Jul 2016

for use in: Treatment of (non-radiographic) axial spondyloarthritis - as per local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: November 2014: The TAG members were satisified with the evidence presented in the NNUH's application for the use of Certolizumab Pegol (Cimzia®) and Adalimumab (Humira®) in a specific patient group previously treated via clinical trials. Business application requested after two patients funded via the IFR process. A classification of Red (Hospital/Speicalist) only was recommended.

November 2014: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

July 2016: The TAG acknowledged that the business application contains stricter criteria for use of the recommended treatments than NICE TA 383.

The agreed algorithm is as follows:
1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)

6. The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the NNUH's business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Jul 2016

for use in: Moderate to severe hidradenitis suppurativa - as per NICE TA 392 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2016.

Specific points: July 2016: NICE TA 392 (June 2016) recommends use of adalimumab as an option in adults whose disease has not responded to conventional systemic therapy, and only if provided it at the price agreed in the patient access scheme.

The TAG noted NICE TA 392 and recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Sep 2013

for use in: 2nd line anti-TNF in patients with joint or skin autoimmune disease who develop IBD on etanercept - as per local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2013:
The TAG supported the NNUH's application for use of adalimumab in this niche group of patients.
Prescriber's Rating: "Possibly helpful"

Supported and commissioned by the CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Jan 2016

for use in: Treatment of children and young people with polyarticular juvenile idiopathic arthritis and for enthesitis-related juvenile idiopathic arthritis as per NICE TA 373 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: January 2016:
The TAG noted NICE TA 373 which recommends use of Abatacept (Orencia®), adalimumab (Humira®), etanercept (Enbrel®) and tocilizumab (RoActemra®) as possible treatments for children and young people with polyarticular juvenile idiopathic arthritis.
Adalimumab and etanercept are recommended as options for enthesitis-related juvenile idiopathic arthritis.
Etanercept is recommended as a possible option for psoriatic juvenile idiopathic arthritis.

The TAG noted that NICE TA 373 differed from NHS England's interim policy (July 2015) regarding the clinical conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally.

The TAG noted NICE TA 373 (December 2015) and recommended a classification of Red (Hospital/Specialist only) for these SCG-commissioning responsibility treatments.

January 2016:
The Norfolk & waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE TA 373 and the TAG's recommendation.

Adalimumab *(Humira®)* TAG recommendation: Jan 2016

for use in: Children with Severe Refractory Uveitis with onset in childhood (age 2 or more up to 18 or less) - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2016: The TAG noted the NHS England Interim Clinical Commissioning Policy D12X02 (November 2015). It was noted that NHS England has been provided with the trial data ahead of publishing and has found it so compelling that they have agreed to fund. The TAG therefore recommended a classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Adalimumab *(Humira® / Biosimilar)* TAG recommendation: May 2018

for use in: Behcet's syndrome (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Highly specialised criteria - specialist centre only

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Jul 2016

for use in: Ankylosing spondilitis - as per local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No.143 May 2008 - Adalimumab, etanercept and infliximab for ankylosing spondilitis.
Adalimumab and etanercept were recommended for use; infliximab was not recommended for use.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

July 2016: The TAG acknowledged that the NNUH's business application contained stricter criteria for use of the recommended treatments than NICE TA 383. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Nov 2014

for use in: Treatment of psoriatic arthritis (including switching between treatments) - as per local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA Guidance 199 which states that Etanercept, infliximab and adalimumab are all recommended for the treatment of active and progressive psoriatic arthritis, based on specific criteria. Treatment choice should be started with the least expensive drug
(taking into account drug administration costs, required dose and product price per dose).
Treatment should be discontinued if people's disease does not show an adequate response on the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. Healthcare professionals should also consider continuing treatment if people's skin disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks in the absence of an adequate PsARC response. This assessment should be done by a dermatologist to determine whether continued treatment is appropriate on the basis of the skin response alone.

November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported. A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Sep 2015

for use in: Juvenile idiopathic rheumatoid arthritis (JIA) - option in children with chronic anterior uveitis - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2011.

Specific points: Sept - Dec 2008: Referred to NICE as part of the 17th wave. Following an update on the anticipated licence for adalimumab in this therapeutic area, limiting the use of this drug to a small population with juvenile idiopathic arthritis, NICE had further discussions with the Department of Health to establish how best to progress the appraisal and removed it from the NICE work programme.
July 2011: Following on from the licence extension for adalimumab for juvenile idiopathic arthritis NICE conducted an additional draft scope consultation in November 2010. As a result of the consultation this topic will not be re referred onto the technology appraisals work programme.

Not commissioned in NHS Norfolk & Waveney.

September 2015:
The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

Regarding adalimumab for JIA:
Etanercept is the usual first choice for JIA. It is licensed and approved by NICE. However there is increasing anecdotal evidence that it should not be used in children with Chronic Anterior Uveitis as it has been associated with severe, and even sight-threatening worsening of uveitis. In those circumstances Adalimumab would be the usual first-choice as it has the best evidence for efficacy in uveitis as well as JIA and is currently the focus of a multi-centre trial (Refn NHSE suggested treatment pathway (July 2015)).

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

January 2016: The TAG noted that NICE TA 373 (December) differed from NHS England's interim policy (July 2015) regarding the clinical conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Adalimumab *(Humira®)* TAG recommendation: Sep 2017

for use in: Plaque psoriasis in children and young people - as per NICE TA 455 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 455 (July 2017) and recommended traffic light classification of Red (Hospital/Specialist only)) for this SCG-commissioning responsibility treatment.
NICE recommends adalimumab as an option for those aged 4 years or older, only if the disease:
* is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and
* has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.
Stop adalimumab at 16 weeks, if the psoriasis has not responded adequately i.e. if a 75% reduction in the baseline PASI score has not been achieved.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Adalimumab *(various, plus biosimilars)* TAG recommendation: Jul 2021

for use in: moderate rheumatoid arthritis after conventional DMARDs have failed as per TA715 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: Biosimilars should be used where available. Pathway under review

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab *(Humira®)* TAG recommendation: Sep 2010

for use in: Rheumatoid arthritis - after other DMARDs including a TNF inhibitor - as per local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA 195: which states that adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are recommended as treatment options only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.
Adalimumab monotherapy and etanercept
monotherapy are recommended as treatment options for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to methotrexate, or when methotrexate is withdrawn because of an adverse event.
Treatment with adalimumab, etanercept, infliximab and abatacept should be continued only if there is an adequate response (as defined in the guidance) 6 months after initiation of therapy. Treatment should be monitored, with assessment of DAS28,at least every 6 months and continued only if an adequate response is maintained.

The TAG noted NICE's algorithm (November 2010) on biologic drugs for rheumatoid arthritis.

March 2016: The TAG and the CCGs' Drugs & Therapeutics Ccommissioning Group noted NICE TA 375 (January 2016) which states that Adalimumab (Humira®), etanercept (Enbrel®), infliximab (Remicade®, Remsima®, Inflectra®), certolizumab pegol (Cimza®), golimumab (Simponi®), tocilizumab (RoActemra®) and abatacept (Orencia®) are recommended for treating rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed only if:
* disease is severe, i.e. a disease activity score (DAS28) greater than 5.1 and
* disease has not responded to intensive therapy with a combination of conventional disease modifying antirheumatic drugs (DMARDs) and
Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or is not tolerated, when the specified criteria are met.

The TAG and the D&TCG agreed that the treatments recommended in NICE TA 375 (January 2016) are commissioned as Red (Hospital/Specialist only) but only in line with the previously agreed treatment pathway for rheumatoid arthritis, pending a revised RA pathway which will be considered by the TAG in May 2016.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

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Adalimumab *(Humira®)* TAG recommendation: Sep 2017

for use in: Treatment of adults with psoriasis - as per NICE TA 146 and the local treatment pathway (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2008.

Specific points: July 2008: The TAG noted NICE Technology Appraisal Guidance No. 146 June 2008 which recommended use.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (Taltz®), Secukinumab (Cosentyx®) and Apremilast (Otezla®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used as a second line choice where anti-TNF contraindicated, depending on patient factors and co-morbidities, as stated in the local treatment pathway.
The pathway places use of Adalimumab as the first line choice for most patients with Psoriasis (and Psoriatic Arthritis) due to being more effective than etanercept and having fewer adverse effects.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Adalimumab (biosimilar) *(Imraldi® / Amjevita®)* TAG recommendation: Mar 2019

for use in: Peripheral spondyloarthritis - following use of 3 DMARDs, as per NNUH application (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2019: The TAG considered the NNUH's application and was advised that the proposed use of biosimilar adalimumab was outside of current NICE guidance, for a very small number of patients who are significantly disabled by spondyloarthropathy in the lower limbs.
Patients would have been treated with 3 DMARDs before being considered for a biologic agent.
The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).

March 2019: The NHS Norfolk & Waveney CCGs D&TC noted and supported the TAG recommendation.

Adalimumab (biosimilar) *(various)* TAG recommendation: Jun 2023

for use in: weekly use for dose escalations in NICE-approved rheumatology indications (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Restricted use - Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Anakinra *(Kineret®)* TAG recommendation: Jan 2022

for use in: Still's disease as per TA685 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case.

Jan 2022 - commissioning responsibility noted as NHSE so traffic light amended to Red

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Anakinra *(Kineret®)* TAG recommendation: Sep 2015

for use in: Treatment of Juvenile Idiopathic Arthritis (JIA) - as per NHS England policy (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

Anakinra *(Kineret®)*

for use in: Cryopyrin-associated periodic syndrome (CAPS) - as per NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only. Highly specialised database.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Apremilast ▼ *(Otezla® ▼)* TAG recommendation: Sep 2017

for use in: Treatment of moderate to severe plaque psoriasis that has not responded to systemic therapy, or where systemic therapy is contraindicated or not tolerated - as per NICE TA 419 and the local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2016.

Specific points: January 2016: The TAG noted NICE TA 368 (November 2015) for the treatment of moderate to severe plaque psoriasis that has not responded to systemic therapy, or where systemic therapy is contraindicated or not tolerated and recommended a classification of Double Red (Not recommended for routine use/not commissioned) for this CCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

January 2017: The TAG acknowledged NICE TA 419 (November 2016) which updated and replaced TA 368, for treating moderate to severe chronic plaque psoriasis in adults only if:
* the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
* treatment is stopped if the psoriasis has not responded adequately at 16 weeks; an adequate response is defined as:
a 75% reduction in the PASI score (PASI 75) from when treatment started or
a 50% reduction in the PASI score (PASI 50) and a 5 point reduction in DLQI from start of treatment
and recommended a traffic light classification of Double Red (Not recommended for use/not commissioned) for this CCG-commissioning responsibility treatment, pending the provision of a business case and treatment pathway.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

July 2017: The TAG supported an NNUH application and proposed Biological Treatment Pathway for psoriasis (the NNUH has been confirmed as a specialist centre for the treatment of psoriasis), with recommended amendments, and recommended revised traffic light classifications from Double Red (not recommended for routine use) to Red (Hospital/Specialist only) for apremilast, secukinumab and ixekizumab if used in line with NICE TA 419, NICE TA 350 and NICE TA 442 respectively (*although a business application for ixekizumab has yet to be submitted).

July 2017: The D&TCG noted the TAG's recommendations and decided to maintain the classifications as Double Red (Not recommended for routine use) in the interim, until the draft treatment pathway has been clarified and resubmitted.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Apremilast (Otezla®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used only where comorbidities preclude use of biologics, as an alternative to biologic therapy in less severe disease in line with NICE criteria, as stated in the local treatment pathway.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Apremilast ▼ *(Otezla® ▼)* TAG recommendation: Jul 2017

for use in: Active psoriatic arthritis in adults - as per NICE TA 433 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2017.

Specific points: January 2016: The TAG noted NICE TA 372 (December 2015) for apremilast (alone or in combination with disease modifying anti-rheumatic drug (DMARD) therapy) for the treatment of active psoriatic arthritis in adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or such therapy is not tolerated and recommended a classification of Double Red (Not recommended for routine use/not commissioned) for this CCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

March 2017: The TAG noted that NICE TA 433 (February 2017) updates and replaces NICE TA 372 and recommends Apremilast (Otezla®) as an option for treating active psoriatic arthritis in adults only if:
* they have peripheral arthritis with 3 or more tender joints and 3 or more swollen joints and
* their disease has not responded to adequate trials of at least 2 standard DMARDs, given either alone or in combination and
* apremilast is provided with discount agreed under PAS.

The TAG reaffirmed the traffic light classification of Double Red (Not recommended for routine use / Not Commissioned) pending a local treatment pathway being finalised for this CCG-commissioning responsibility treatment.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG agreed to revise the current Double Red (Not recommended for routine use) classification for apremilast (Otezla®) for active psoriatic arthritis in adults to Red (Hospital/Specialist only) as per NICE TA 433 and in line with the treatment pathway for the use of biologics in psoriatic arthritis from the NNUH (also on behalf of the JPUH and QEH).

Avacopan *(Tavneos®)* TAG recommendation: Oct 2022

for use in: severe active granulomatosis with polyangiitis or microscopic polyangiitis as per TA825 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2022.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Baricitinib *(Olumiant®)* TAG recommendation: May 2022

for use in: moderate to severe atopic dermatitis as per TA681 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2021.

Specific points: April 2021 - awaiting submission of business case

May 2022 - application accepted. Classification amended to red/hospital only

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Baricitinib ▼ *(Olumiant® ▼)* TAG recommendation: Jan 2018

for use in: (with or without methotrexate) for active moderate to severe rheumatoid arthritis in adults - as per NICE TA 466 and locally commissioned treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 466 (August 2017) for active moderate to severe rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs), only if:
1.1
* disease is severe (a disease activity score [DAS28] of more than 5.1) and
* the company provides baricitinib with the discount agreed in the patient access scheme.
1.2 Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if:
* disease is severe (a DAS28 of more than 5.1) and
* they cannot have rituximab and
* the company provides baricitinib with the discount agreed in the patient access scheme.
1.3 Baricitinib can be used as monotherapy for people who cannot take methotrexate because it is contraindicated, or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.
and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use, and its place in the local treatment pathway clarified.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

January 2018: The TAG noted the business case and treatment pathway submittted by the NNUH, and that the cheapest appropriate treatment option within the treatment pathway for rheumatoid arthritis would be used for each patient.
The TAG agreed to recommend that use of Baricitinib (Olumiant®) for moderate to severe rheumatoid arthritis in adults as per NICE TA 466 (August 2017) is classified as Red Hospital only).

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Belimumab ▼ *(Benlysta® ▼)* TAG recommendation: Jan 2022

for use in: treating active autoantibody-positive systemic lupus erythematosus (replaces TA397) as per TA752 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Specific points: July 2016: The TAG noted NICE TA 397 (June 2016) which recommends belimumab as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults under specified criteria. The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for this SCG-commissioning responsibility treatment.

Dec 2021 - TA752 replaced TA397

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted TA 397 and the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Certolizumab Pegol *(Cimzia®)* TAG recommendation: Nov 2014

for use in: Treatment of severe (non-radiographic) axial spondyloarthritis - as per NICE TA 383 and locally agreed pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2014: The TAG members were satisified with the evidence presented in the NNUH's application for the use of Certolizumab Pegol (Cimzia®) and Adalimumab (Humira®) in a specific patient group previously treated via clinical trials. Business application requested after two patients funded via the IFR process. A classification of Red (Hospital/Specialist) only was recommended.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

July 2016: The TAG acknowledged that the NNUH's business application contains stricter criteria for use of the recommended treatments than NICE TA 383.

The agreed algorithm is as follows:
1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)

6. The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the NNUH's application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

under the section 1.1.

Certolizumab pegol *(Cimizia®)* TAG recommendation: Jul 2016

for use in: Ankylosing spondylitis - as per NICE TA 383 and locally agreed pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: July 2016: The TAG acknowledged that the NNUH's business application submitted following the publication of NICE TA 383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, contains stricter criteria for use of the recommended treatments than NICE TA 383.

The algorithm agreed as follows:

1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)1

6.The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and agreed to commission the treatments in NICE TA 383 in line with the business application submitted.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Certolizumab pegol *(Cimzia®)* TAG recommendation: May 2019

for use in: For treating moderate to severe plaque psoriasis in adults - as per NICE TA 574 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2019.

Specific points: May 2019: The TAG acknowledged NICE TA 574 April 2019) which states:
1.1 Recommended by NICE as an option for plaque psoriasis in adults, only if:
* the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
* the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
* the lowest maintenance dosage of certolizumab pegol is used (200mg every 2 weeks) after the loading dosage and
* the company provides the drug according to the commercial arrangement.

1.2 Stop certolizumab pegol at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:
* a 75% reduction in the PASI score (PASI75) from when treatment started or
* a 50% reduction in the PASI score (PASI 50) and a 5 point reduction in DLQI from when treatment started.

The TAG recommended a traffic light classification of Red (Hospital / Specialist use only) in line with the Joint CSU / Trusts Business Application which was also considered by the TAG; the revised specialist treatment pathway for psoriasis to be brought to the July 2019 TAG meeting.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation in line with the joint CSU/Acute Trusts business application.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation in line with the joint CSU/Acute Trusts business application.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Certolizumab pegol *(Cimzia®)* TAG recommendation: Mar 2010

for use in: Treatment of rheumatoid arthritis - as per NICE TA 186 and locally agreed pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2010.

Specific points: NICE Technology Appraisal Guidance 186:
Certolizumab pegol is recommended as an option for the treatment of people with rheumatoid arthritis only if:
Certolizumab pegol is used as described for tumour necrosis factor (TNF) inhibitor treatments in "Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis" (NICE TAG 130) and
The manufacturer provides the first 12 weeks of Certolizumab pegol (10 pre-loaded 200mg syringes) free of charge to all patients starting treatment.

July 2010: The TAG considered and supported a business case from the NNUH for use in severe rheumatoid arthritis. This recommendation was approved by the NHS Norfolk Drug & Therapeutics Commissioning Programme Board on 25th August 2010.

January 2011: The TAG noted NICE's algorithm (November 2010) on biologic drugs for rheumatoid arthritis for which the NNUH plans to make a application for the addition of certolizumab.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Certolizumab pegol (with or without MTX) *(Cimzia ®)* TAG recommendation: Jul 2017

for use in: Psoriatic arthritis (including switching between treatments) after inadequate response to DMARDs - as per NICE TA 445 and locally agreed pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2017.

Specific points: November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported. A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

July 2017: The TAG acknowledged NICE TA 445 (May 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending approval of a treatment pathway (and thereafter Red (Hospital/Specialist only)) for these CCG-commissioning responsibility treatments.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG considered and supported a proposed treatment pathway, subject to re-wording in line with NICE guidance, for use of biologics in psoriatic arthritis from the NNUH (also on behalf of the JPUH and the QEH).
The D&TCG otherwise agreed to commission Certolizumab pegol (Cimzia®) and Secukinumab (Consentyx®) for treating active psoriatic arthritis after inadequate response to DMARDs as Red (Hospital/Specialist only).

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Sep 2015

for use in: Idiopathic juvenile arthritis - polyarticular, psoriatic and enthesitis-related JIA as per NICE TA 373 and NHS England policy (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: March 2002 NICE:
Etanercept is recommended for children aged 4 to 17 years with active polyarticular-course juvenile idiopathic arthritis whose condition has not responded adequately to, or who have proved intolerant of, methotrexate. Etanercept should be prescribed in accordance with relevant sections of the British Paediatric Rheumatology Group (BPRG) protocol.

September 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

January 2016: The TAG noted NICE TA 373 which replaces NICE TA 35 (2002) which recommends use of Abatacept (Orencia®), adalimumab (Humira®), etanercept (Enbrel®) and tocilizumab (RoActemra®) as possible treatments for children and young people with polyarticular juvenile idiopathic arthritis.
Adalimumab and etanercept are recommended as options for enthesitis-related juvenile idiopathic arthritis.
Etanercept is recommended as a possible option for psoriatic juvenile idiopathic arthritis.

The TAG noted that NICE TA 373 (December) differed from NHS England's interim policy (July 2015) regarding the clinical conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted NICE TA 3737 and the TAG's recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Jul 2016

for use in: Axial spondyloarthritis (severe, non-radiographic) where NSAIDs not effective or not tolerated - as per NICE TA 383 and local policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: July 2016: The TAG acknowledged that the business application submitted following the publication of NICE TA 383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, contains stricter criteria for use of the recommended treatments than NICE TA 383.

The agreed algorithm is as follows:
1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)

6. The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the NNUH's application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application submitted.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Sep 2010

for use in: Rheumatoid arthritis - after other DMARDs including a TNF inhibitor - as per NICE TA 195 and local policy (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA 195: which states that adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are recommended as treatment options only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.
Adalimumab monotherapy and etanercept
monotherapy are recommended as treatment options for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to methotrexate, or when methotrexate is withdrawn because of an adverse event.
Treatment with adalimumab, etanercept, infliximab and abatacept should be continued only if there is an adequate response (as defined in the guidance) 6 months after initiation of therapy. Treatment should be monitored, with assessment of DAS28,at least every 6 months and continued only if an adequate response is maintained.

January 2011: The TAG noted NICE's algorithm (November 2010) on biologic drugs for rheumatoid arthritis.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Etanercept *(various, plus biosimilars)* TAG recommendation: Jul 2021

for use in: moderate rheumatoid arthritis after conventional DMARDs have failed as per TA715 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: Biosimilars should be used where available. Pathway under review

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Jul 2016

for use in: Ankylosing spondilitis - as per NICE TA 383 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: November 2004: Based on the information available it was agreed to support use of the anti-TNF drugs infliximab and etanercept for treatment of patients with ankylosing spondilitis with inadequate response to or who are unable to tolerate conventional therapy.

July 2008: The TAG noted NICE Technology Appraisal Guidance No.143 May 2008 - Adalimumab, etanercept and infliximab for ankylosing spondilitis.
Adalimumab and etanercept were recommended for use; infliximab was not recommended for use.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

uly 2016: The TAG acknowledged that the business application contains stricter criteria for use of the recommended treatments than NICE TA 383. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

Filgotinib *(Jyseleca®)* TAG recommendation: Jun 2021

for use in: moderate to severe rheumatoid arthritis as per TA676 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - Awaiting submission of business case

June 2021 - Business case accepted. Filgotinib available as an option further down pathway. Blueteq will be available. Pathway to be updated

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Mar 2016

for use in: For rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed - as per NICE TA 375 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG and the CCGs' Drugs & Therapeutics Ccommissioning Group noted NICE TA 375 (January 2016) which states that Adalimumab (Humira®), etanercept (Enbrel®), infliximab (Remicade®, Remsima®, Inflectra®), certolizumab pegol (Cimza®), golimumab (Simponi®), tocilizumab (RoActemra®) and abatacept (Orencia®) are recommended for treating rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed only if:
* disease is severe, i.e. a disease activity score (DAS28) greater than 5.1 and
* disease has not responded to intensive therapy with a combination of conventional disease modifying antirheumatic drugs (DMARDs) and Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or is not tolerated, when the specified criteria are met.

The TAG and the D&TCG agreed that the treatments recommended in NICE TA 375 (January 2016) are commissioned as Red (Hospital/Specialist only) but only in line with the previously agreed treatment pathway for rheumatoid arthritis, pending a revised RA pathway which will be considered by the TAG in due course: available via https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=x0Dz1utBzAY%3d&tabid=1401&portalid=1&mid=2120

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Jul 2016

for use in: Ankylosing spondilitis - as per NICE TA 233 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: NICE TA 233 states: Golimumab is recommended as an option for the treatment of severe, active ankylosing spondylitis in adults only if:
* it is used as described for adalimumab and etanercept in 'Adalimumab, etanercept and infliximab for ankylosing spondylitis' (NICE technology appraisal guidance 143) and
* the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose in accordance with the patient access scheme.

September 2011: The NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided NOT to commission or fund golimumab for ankylosing spondilitis as per NICE TA 233 (August 2011) until there is agreement on a local treatment pathway and a business case for use is approved.

June 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided to commission this treatment in line with NICE TA 233.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

July 2016: The TAG acknowledged that the business application contains stricter criteria for use of the recommended treatments than NICE TA 383.

The agreed algorithm is as follows:

1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)

6. The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the NNUH's application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Jul 2011

for use in: Treatment of rheumatoid arthritis after the failure of previous disease-modifying anti-rheumatic drugs - as per NICE TA 225 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 225 which stated the following:
1.1 Golimumab in combination with methotrexate is recommended as an option for the treatment of rheumatoid arthritis in adults whose rheumatoid arthritis has responded inadequately to conventional disease-modifying anti-rheumatic drugs (DMARDs) only, including methotrexate, if:
* it is used as described for other tumour necrosis factor (TNF) inhibitor treatments in 'Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis' (NICE technology appraisal guidance 130), and
* the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, agreed as part of the patient access scheme.
1.2 Golimumab in combination with methotrexate is recommended as an option for the treatment of rheumatoid arthritis in adults whose rheumatoid arthritis has responded inadequately to other DMARDs, including a TNF inhibitor, if:
* it is used as described for other TNF inhibitor treatments in 'Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor' (NICE technology appraisal guidance 195), and
* the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, agreed as part of the patient access scheme.
1.3 When using the disease activity score (DAS28), healthcare professionals should take into account any physical, sensory or learning disabilities, communication difficulties, or disease characteristics that could adversely affect patient assessment and make any adjustments they consider appropriate.

June 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided to commission this treatment in line with NICE TA 225.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Golimumab *(Simponi®)* TAG recommendation: Nov 2014

for use in: Treatment of psoriatic arthritis (including switching between treatments) - as per NICE TA 220 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 220 as follows:

Golimumab is recommended as an option for the treatment of active and progressive psoriatic arthritis in adults only if:
* it is used as described for other tumour necrosis factor (TNF) inhibitor treatments in Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis' (NICE technology appraisal guidance 199)**, and
* the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose.
(http://guidance.nice.org.uk/TA199)

June 2012: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group decided to commission this treatment in line with NICE TA 220.

November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported. A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

Guselkumab *(Tremfya®)* TAG recommendation: Dec 2021

for use in: active psoriatic arthritis after inadequate response to DMARDs as oer TA711 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2021.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Dec 2021 - formulary application accepted by TAG, D+TC and GB

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Guselkumab *(Tremfya®)* TAG recommendation: Sep 2018

for use in: Moderate to severe plaque psoriasis in adults - as per NICE TA 521 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2018.

Specific points: July 2018: The TAG acknowledged NICE TA 521 (June 2018) for treating moderate to severe plaque psoriasis in adults, only if:
* the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
* the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated and
* the company provides the drug according to the commercial arrangement.

The TAG discussed the process for commissioning a NICE Fast track drug.

The TAG would usually recommend a classification of Double Red (Not recommended for routine use), pending submission of a business application and agreement on the place in the treatment pathway is reached, when a CCG-commissioning responsibility treatment is recommended as an option for use by NICE.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC confirmed that the interim position for this treatment is Double Red (Not recommended for routine use) / Not commissioned pending the submission of a business application from local provider Trusts and agreement on its place in the treatment pathway for psoriasis.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

September 2018: The TAG considered the NNUH's application in conjunction with an update of the local specialist treatment pathway for psoriasis which specifies that Guselkumab, along with Ustekinumab, Secukinumab, Brodalumab, or Ixekizumab, are possible second line choices where an anti-TNF is contraindicated or not tolerated, depending on patient factors, co-morbidities and cost. The lowest cost option should be chosen, taking into account route of administration, dose and cost per dose. Prior approval through BluTeq is required for each of these agents before initiation.
The TAG therefore recommended a revised traffic light of Red (Specialist only), and to support the NNUH's application.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Rheumatoid arthritis - use in children, aligning with NICE TA 130 (NHSE responsibility) (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Ankylosing spondylitis - use in children, aligning with NICE TA 143 (NHSE responsibility) (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Treatment of psoriatic arthritis - use in children, aligning with NICE TA 199 (NHSE responsibility) (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

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The advice is specific to the indication.

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- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab *(Remicade®; Biosimilars also available)* TAG recommendation: May 2018

for use in: Behcet's Disease (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2004:
Due to the current lack of supporting evidence it was agreed that use of the anti-TNF drugs infliximab and etanercept for treatment of patients with Behcet's disease is not recommended for routine use (Double Red).

May 2018:
This treatment is now NHS England commissioning responsibility. Specialist centre only - Highly specialised criteria

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(various, plus biosimilars)* TAG recommendation: Jul 2021

for use in: moderate rheumatoid arthritis after conventional DMARDs have failed as per TA715 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: Biosimilars should be used where available. Pathway under review

Red - 'Hospital / Specialist only'

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Sep 2015

for use in: Treatment of Juvenile Idiopathic Arthritis (JIA) - in patients with uveitis only if etanercept or adalimumab not appropriate or are ineffective (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

Regarding use of Infliximab in JIA:
Infliximab has some evidence of effectiveness against uveitis, but has a higher risk of infusion-related reactions and is more expensive. It would normally be considered as an alternative to either Etanercept or Adalimumab only when adherence to Etanercept or Adalimumab is suspected to be poor or when treatment with Adalimumab has not proven efficacious in a child with Uveitis and Arthritis.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

against its price rather than for Inflectra® as previously agreed.

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Graft versus host disease (Not a licensed indication).
Prescribing responsibility: Not recommended for routine use.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Specialist centre only - as per IFR approval.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Infliximab *(Various brands available)* TAG recommendation: May 2018

for use in: Psoriasis - use in children, aligning with NICE TA 134 (NHSE responsibility) (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

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Drugs for which the Trust is responsible for prescribing.

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The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab (Biosimilar to be used 1st line) *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Sep 2010

for use in: Rheumatoid arthritis - after other DMARDs including a TNF inhibitor - as per NICE TA 195 (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA 195: which states that adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are recommended as treatment options only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.
Adalimumab monotherapy and etanercept
monotherapy are recommended as treatment options for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to methotrexate, or when methotrexate is withdrawn because of an adverse event.
Treatment with adalimumab, etanercept, infliximab and abatacept should be continued only if there is an adequate response (as defined in the guidance) 6 months after initiation of therapy. Treatment should be monitored, with assessment of DAS28,at least every 6 months and continued only if an adequate response is maintained.

January 2011: The TAG noted NICE's algorithm (November 2010) on biologic drugs for rheumatoid arthritis.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Infliximab (biosimilar) *(Cost effective biosimilars available))* TAG recommendation: Jul 2016

for use in: Axial spondyloarthritis (non- radiographic) - as per NICE TA 383 and NNUH application (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016.

July 2016: The TAG acknowledged that the NNUH's business application contained stricter criteria for use of the recommended treatments than NICE TA 383. The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

May 2017:
The TAG acknowledged NG 65 (February 2017) and noted the importance of timely recognition and referral for suspected spondyloarthritis under the section 1.1.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab (biosimilar) *(Cost effective biosimilar to be used)* TAG recommendation: Mar 2016

for use in: Rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed - as per NICE TA 375 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: January 2016.

Specific points: March 2016: The TAG and the CCGs' Drugs & Therapeutics Ccommissioning Group noted NICE TA 375 (January 2016) which states that Adalimumab (Humira®), etanercept (Enbrel®), infliximab (Remicade®, Remsima®, Inflectra®), certolizumab pegol (Cimza®), golimumab (Simponi®), tocilizumab (RoActemra®) and abatacept (Orencia®) are recommended for treating rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed only if:
* disease is severe, i.e. a disease activity score (DAS28) greater than 5.1 and
* disease has not responded to intensive therapy with a combination of conventional disease modifying antirheumatic drugs (DMARDs) and Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or is not tolerated, when the specified criteria are met.

The TAG and the D&TCG agreed that the treatments recommended in NICE TA 375 (January 2016) are commissioned as Red (Hospital/Specialist only) but only in line with the previously agreed treatment pathway for rheumatoid arthritis, pending a revised RA pathway which will be considered by the TAG in May 2016.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab (biosimilar) *(Lowest acquisition cost product to be used)* TAG recommendation: Jul 2016

for use in: Ankylosing spondilitis - severe active, where NSAIDs are not effective or not tolerated - as per NICE TA 383 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2016.

Specific points: July 2008: The TAG noted NICE Tehnology Appraisal Guidance No.143 May 2008 which recommended that inflximab is not used for ankylosing spondilitis. The guidance stated that people currently being treated for this indication should have the option to continue until they and their clinicians consider it appropriate to stop.

March 2016:
The TAG and the CCGs' D&TCG noted NICE TA 383 (February 2016) - TNF-alpha inhibitors (Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) for ankylosing spondylitis and non-radiographic axial spondyloarthritis, and agreed that the treatments recommended in NICE TA 383 (February 2016) which are currently commissioned as Red (Hospital/Specialist only), should be maintained in line with the previously agreed treatment pathway for ankylosing spondylitis and axial spondyloarthritis, pending consideration of a revised application and pathway by the TAG in May 2016. This will include review of the use of infliximab in ankylosing spondilitis.

July 2016: The TAG acknowledged that the business application contains stricter criteria for use of the recommended treatments than NICE TA 383.

The agreed algorithm is as follows:
1. Consultant-verified diagnosis of axial SpA (AS or non-radiographic)

2. Imaging will be discussed at radiology MDT and findings verified and recorded in minutes

3. Non-radiographic patients with severe disease who have negative imaging and a raised CRP to be discussed at rheumatology MDT in order to ensure that the raised CRP can be attributed to non-radiographic axial SpA rather than other potential causes

4. Consideration is to be given to the presence of extra-articular manifestations when selecting the most appropriate TNF inhibitor (e.g avoiding etanercept in patients with recurrent acute anterior uveitis (AAU), considering adalimumab in patients with colitis etc). Extra-articular manifestations are common in axSpA; AAU (20-30%), colitis (10-12%), psoriasis (8-10%).

5. In women of child-bearing age consideration should be given to future pregnancies when selecting the agent of choice certolizumab pegol is compatible with all three trimesters of pregnancy and has reduced placental transfer compared with other TNF inhibitors (TNFis) (LOE 2−, GOR D, SOA 97.9%)

6. The final decision to initiate TNF therapy and the choice of agent should be decided by the treating consultant in conjunction with the patient. Unless contra-indicated, the cheapest TNF inhibitor will be selected.

The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital /Specialist only) for the treatments in line with the business application.

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation, and agreed to commission the treatments in NICE TA 383 in line with the NNUH's business application.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Infliximab (biosimilar) *(Cost effective product to be used)* TAG recommendation: Nov 2014

for use in: Psoriatic arthritis (switching between treatments) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported.

A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

Penicillamine *(Distamine®)* TAG recommendation: Sep 2018

for use in: Wilson's disease (as recommended by a specialist centre - Cambs Universty Hospitals /Addenbrooke's Hospital) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2018: The TAG recommend a traffic light classification of Red (Hospital use only) with specific reference to possible recommended use by the CUH Trust (Addenbrooke's Hospital) - to support GPs who may be approached to prescribe this treatment.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Risankizumab *(Skyrizi®)* TAG recommendation: Nov 2019

for use in: Psoriasis as per NICE TA596 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: July 2019: The TAG noted the application from QEH for use pre-NICE using Free of Charge stock and recommended a traffic light classification of Double Red (Not recommended for routine use).

July 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation

December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA596 - August 2019 and the updated treatment pathway for 2-3 biologic options was noted and afforded a traffic light classification of Red (Hospital/Specialist use only)

Risankizumab *(Skyrizi®)* TAG recommendation: Dec 2022

for use in: active psoriatic arthritis after inadequate response to DMARDs as per TA803 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Dec 2022 - formulary application accepted. Ameded to Red - Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Sarilumab *(Kevzara)* TAG recommendation: Mar 2021

for use in: adult patients (aged 18 years and older) hospitalised with COVID-19 in accordance with the criteria set out in the NHS England document.as per ES34 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Secukinumab *(Cosentyx®)* TAG recommendation: Nov 2021

for use in: moderate to severe plaque psoriasis in children and young people as per TA734 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Secukinumab *(Cosentyx®)* TAG recommendation: Dec 2021

for use in: non-radiographic axial spondyloarthritis as per TA719 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: pending formulary application

Dec 2021 - formulary application accepted by TAG, D+TC and GB

Secukinumab ▼ *(Cosentyx® ▼)* TAG recommendation: Nov 2016

for use in: Active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors - as per NICE TA 407 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 407 (September 2016) recommended by NICE as an option, only if the company provides it with the discount agreed in the patient access scheme, and also an application for use as a 2nd or 3rd line traetment option from the NNUH, and recommended a traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted that secukinumab is already in use and a treatment pathway will be confirmed for local use. The D&TCG otherwise supported the TAG recommendation. Commissioned as Red (Hospital/Specialist only) as per NICE TA 407 and the NNUH's application and a revised local treatment pathway.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Secukinumab ▼ *(Cosentyx® ▼)* TAG recommendation: Sep 2017

for use in: Treatment of moderate to severe plaque psoriasis - as per NICE TA 350 and the local treatment pathway (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2015.

Specific points: July 2015:
The TAG noted the NICE FAD (May 2015) for secukinumab (Cosentyx®) for treating moderate to severe plaque psoriasis and recommended a likely future classification of Red (Hospital only) pending the publication of the NICE TA.

The NICE FAD states:
Secukinumab for treatment of moderate to severe plaque psoriasis is recommended only when:
* the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology LifeQuality Index (DLQI) > 10
* the disease has failed to respond to standard systemic therapies, - ciclosporin, methotrexate and PUVA, or these treatments are contraindicated or are not tolerated
* Secukinumab is provided at discount agreed under PAS.

July 2015:
The D&TCG noted the TAG's likely future traffic light recommendation and confirmed that the treatment is not commissioned pending publication of the final NICE TA and agreement on the treatment's place in a locally approved treatment pathway.

September 2015: The TAG noted NICE TA 350 (July 2015) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending the production and agreement of a Trust business case and treatment pathway.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

July 2017: The TAG supported an NNUH application and proposed Biological Treatment Pathway for psoriasis (the NNUH has been confirmed as a specialist centre for the treatment of psoriasis), with recommended amendments, and recommended revised traffic light classifications from Double Red (not recommended for routine use) to Red (Hospital/Specialist only) for apremilast, secukinumab and ixekizumab if used in line with NICE TA 419, NICE TA 350 and NICE TA 442 respectively (*although a business application for ixekizumab has yet to be submitted).

July 2017: The D&TCG noted the TAG's recommendations and decided to maintain the classifications as Double Red (Not recommended for routine use) in the interim, until the draft treatment pathway has been clarified and resubmitted.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Secukinumab (Cosentyx®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used as a second line choice where anti-TNF contraindicated, depending on patient factors and co-morbidities, as stated in the local treatment pathway.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Secukinumab ▼ (with or without MTX) *(Consentyx® ▼)* TAG recommendation: Jul 2017

for use in: Active psoriatic arthritis after inadequate response to DMARDs - as per NICE TA 445 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2017.

Specific points: July 2017: The TAG acknowledged NICE TA 445 (May 2017) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending approval of a treatment pathway (and thereafter Red (Hospital/Specialist only)) for these CCG-commissioning responsibility treatments.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG considered and supported, subject to being reworded in line with NICE guidance, a proposed treatment pathway for use of biologics in psoriatic arthritis from the NNUH (also on behalf of the JPUH and the QEH).
The D&TCG otherwise agreed to commission Certolizumab pegol (Cimzia®) and Secukinumab (Consentyx®) for treating active psoriatic arthritis after inadequate response to DMARDs as Red (Hospital/Specialist only).

Tocilizumab *(RoActemra)* TAG recommendation: Mar 2021

for use in: adult patients (aged 18 years and older) hospitalised with COVID-19 in accordance with the criteria set out in the NHS England document.as per ES33 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tocilizumab *(RocActemra®)* TAG recommendation: Jan 2012

for use in: Systemic juvenile idiopathic arthritis - as per NICE TA 238 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2011.

Specific points: NICE TA Guidance 238 (December 2011 http://guidance.nice.org.uk/TA238) states that tocilizumab is recommended for systemic juvenile idiopathic arthritis under a Patient Access Scheme.

July 2013: Confirmed as commissioning responsibility of NHS England Specialist Commissioning for this clinical indication.

Sepetmber 2015: The TAG noted E03/P/d (E03X04) (July 2015) (NHS England commissioning policy) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

Treatment of Juvenile Idiopathic Arthritis (JIA):
Anti-TNFs may be used 1st line only in:
* Patients with Axial disease or sacroiliitis (see Appendix A). This is accepted and NICE-approved practice in adults with Spondyloarthropathy.
* Patients with Systemic-Onset JIA who show signs of Macrophage Activation Syndrome (MAS).

Biologic therapies:
(Biologics should not be used unless a patient is intolerant to, or has failed optimised treatment with MTX (defined as 15mg/m2 given subcutaneously once-weekly for at least 3 months; higher doses have no evidence to suggest increased efficacy)).

Regarding use of tocilizumab in JIA:
Abatacept and Tocilizumab both have good evidence to support their use in Poly-articular forms of JIA which have failed anti-TNF therapy but there is no head to head comparative trial to assess effectiveness. Tocilizumab appears to have a faster onset of action than Abatacept and therefore may be preferred in cases where arthritis is widespread and severe. However Tocilizumab has been associated with liver function abnormalities, and appears in clinical practice to have a greater risk of infections being under-recognised by medical staff due to its effect on suppressing both the symptoms of fever and measurement of acute phase reactants. The choice of which to use should therefore be at the discretion of the paediatric rheumatologist. A patient should fail 3 different classes of biologic before being referred for autologous stem cell rescue or bone-marrow transplantation.

The TAG also recommended that the pathway for treatment of children with JIA Appendix A be applied to the treatment of rising young adults with JIA (CCG-commissioning responsibility).

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also considered what treatment pathway is followed for patients >18 years and agreed that the suggested pathway for children should be considered locally for young adults with JIA.

November 2015: The TAG recommended that CCGs should adopt the NHS England treatment pathway for JIA in children as a whole to cover the commissioning responsibility for care of young adults >18 years with JIA. The treatments in the pathway are recommended as Red (Hospital / Specialist use only) for this indication.

November 2015: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

January 2016: The TAG noted that NICE TA 373 (December) differed from NHS England's interim policy (July 2015) regarding the clinical

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

conditions covered and the recommended treatments and recommended waiting until NHS England published its final policy document post NICE TA 373 before making any changes to what is commissioned locally.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tocilizumab (monotherapy) *(RoActemra®)* TAG recommendation: Sep 2013

for use in: 5th line monotherapy in moderate to severe rheumatoid arthritis (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2013: The TAG considered the NNUH's application for use of tocilizumab as monotherapy in patients with moderate to severe rheumatoid arthritis who have responded inadequately to, or are intolerant to, two or more DMARDs and one TNF antagonist (given as monotherapy) and are intolerant to MTX, or where continued MTX treatment is inappropriate.

A traffic light classification was recommended of Red (Hospital only) for use of tocilizumab as monotherapy following intolerance or inadequate response to at least TWO other anti-TNF agents, i.e. with the proviso that the application be amended to show Etanercept as 2nd line anti-TNF and then Tocilizumab 3rd line after adalimumab.

November 2013: Amended application forwarded to the N&W CCGs Drugs &Therapeutics Commissioning Group (D&TCG).

The D&TCG noted that IV administration has additional service costs.

The D&TCG supported the NNUH's business application in principle, subject to local agreement regarding possible use of subcutaneous (SC) abatacept.

The NNUH Rheumatology department has since advised that as tocilizumab is for monotherapy, and there is no data for use of abatacept without methotrexate, they would not anticipate using SC abatacept for this indication until supporting evidence becomes available.

NNUH business application will therefore be submitted to the Acute Commissioning Board regarding additional service costs related to IV tocilizumab for completion of commissioning arrangements.

June 2014: CCG Combined Commissioned Drug Therapies list updated to state: "Commissioned. Non Tariff. Notification required."
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/combined_commissioned_drug_therapies_list.pdf

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tocilizumab (with methotrexate) *(RoActemra®)* TAG recommendation: Mar 2012

for use in: Rheumatoid arthritis in adults - as per NICE TA 247 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2012.

Specific points: March 2012:
The TAG noted NICE TA 247 (review of TA 198) which states that:
Tocilizumab in combination with methotrexate is recommended as an option for the treatment of rheumatoid arthritis in adults if:
* the disease has responded inadequately to disease-modifying anti-rheumatic drugs (DMARDs) and it is used as described for tumour necrosis factor (TNF) inhibitor treatments in 'Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis' (NICE technology appraisal guidance 130), specifically the recommendations on disease activity and choice of treatment or
* the disease has responded inadequately to DMARDs and a TNF inhibitor and the person cannot receive rituximab because of a contraindication to rituximab, or because rituximab is withdrawn because of an adverse event, and tocilizumab is used as described for TNF inhibitor treatments in 'Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor' (NICE technology appraisal guidance 195), specifically the recommendations on disease activity or
* the disease has responded inadequately to one or more TNF inhibitor treatments and to rituximab
* and the manufacturer provides tocilizumab with the discount agreed as part of the Patient Access Scheme.
* People currently receiving tocilizumab for the treatment of rheumatoid arthritis who do not meet the criteria above should have the option to continue treatment until they and their clinicians consider it appropriate to stop.
The TAG noted that the NICE treatment algorithm does not include golimumab which received a positive NICE TA (225) in June 2011. The TAG also awaits proposals on a treatment pathway from local rheumatology specialists. Noted by the D&TCG. Commissioned in line with NICE TA247.

September 2012: The TAG noted the East of England Priorities Advisory Committee (PAC) policy on tocilizumab which states that the most cost effective first line treatment should be used and that tocilizumab should not be used without methotrexate.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tocilizumab IV *(RoActemra® for infusion)* TAG recommendation: May 2018

for use in: Juvenile arthritis paediatric (where adult TA available - as per TA 247 & 375)) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Tocilizumab IV *(RoActemra® for infusion)* TAG recommendation: May 2018

for use in: Juvenile arthritis paediatric - as per NHS England Policy E03/P/d & NICE TA 373 (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per NHS England Clinical Commissioning Policy: E03/P/d and NICE TA 373.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tofacitinib *(Xeljanz®)* TAG recommendation: Mar 2019

for use in: Active psoriatic arthritis in adults after inadequate response to DMARDs under certain conditions - as per NICE TA 543 and local business application (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2018.

Specific points: November 2018: The TAG noted NICE TA 543 (October 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending the submission of a business application and confirmation of place in the local treatment pathway for this CCG-commissioning responsibility treatment.

November 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG and the D&TC recommendation.

March 2019:
The TAG was advised that the application aimed to clarify proposed criteria for use of tofacitinib, which is a mid-priced treatment option between biosimilar anti-TNFs and the non-biosimilar options.
The application proposes that tofacitinib would only be used before anti TNFs as follows:
Tofacitinib may be useful first line over Adalimumab in specific clinical circumstances where biosimilar Adalimumab cannot be used:
* True needle phobia
* Severe bacterial infection
* MS/demyelination
* Severe heart failure
* Active malignancy

The TAG agreed to support the Trust application and recommended a traffic light classification of Red (Hospital/Specialist use only).

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted that around 40 patients across the CCGs would be likely to be treated in line with the application. The recommendation of the TAG was noted and supported.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendation.

Tofacitinib *(Xeljanz®)* TAG recommendation: Nov 2021

for use in: juvenile idiopathic arthritis as per TA735 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2021.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tofacitinib *(Xeljanz®)* TAG recommendation: Mar 2019

for use in: Moderately to severely active ulcerative colitis in adults - as per NICE TA 547 (option after biosimilar adalimumab) (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE issued Guidance in: November 2018.

Specific points: January 2019: The TAG noted NICE TA 547 (November 2018) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending the submission of a business application and confirmation of place in the local treatment pathway for this CCG-commissioning responsibility treatment.

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

March 2019: The TAG was advised that although NICE TA 547 implied that tofacitinib could be used first-line ahead of adalimumab, the cost-modelling was based on the price of Humira® rather than biosimilars. Biosimilar adalimumab remains as the recommended first-line biologic treatment option for this indication.
Tofacitinib would however be cheaper than 2nd line options infliximab and to a greater extent, vedolizumab.
The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Tofacitinib ▼ *(Xeljanz® ▼)* TAG recommendation: Jan 2018

for use in: Treatment of moderate to severe active rheumatoid arthritis in adults (with and without methotrexate) - as per NICE TA 480 and local pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 480 (Oct 17) which recommends the following:
1.1 Tofacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs), only if:
* disease is severe (a disease activity score [DAS28] of more than 5.1) and
* the company provides tofacitinib with the discount agreed in the patient access scheme.
1.2 Tofacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot have, other DMARDs, including at least 1 biological DMARD, only if:
* disease is severe (a DAS28 of more than 5.1) and
* they cannot have rituximab and
* the company provides tofacitinib with the discount agreed in the patient access scheme.
1.3 Tofacitinib can be used as monotherapy for adults who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.
1.4 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.

January 2018: The TAG noted the business application and treatment pathway and that the cheapest appropriate treatment option within the treatment pathway for rheumatoid arthritis would be used for each patient.
The TAG agreed to recommend that use of Tofacitinib (Xeljanz®) for moderate to severe rheumatoid arthritis in adults as per NICE TA 480 (October 2017) is classified as Red Hospital only).

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported and TAG recommendation.

Local commissioned specialist treatment pathway for rheumatoid arthritis available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=7nGZ_Vdf-Co%3d&tabid=1401&portalid=1&mid=2120

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Upadacitinib *(Rinvoq®)* TAG recommendation: Jul 2023

for use in: previously treated moderately to severely active Crohn's disease TA905 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2023.

Upadacitinib *(Rinvoq®)* TAG recommendation: Jan 2022

for use in: moderate rheumatoid arthritis as per TA744 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2021.

Specific points: Jan 2022 - formulary application accepted by TAG, D+TC and GB

Upadacitinib *(Rinvoq®)* TAG recommendation: Apr 2022

for use in: active psoriatic arthritis after inadequate response to DMARDs as per TA768 - Feb 2022 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2022.

Specific points: April 2022 - formulary application accepted

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.3 - Drugs that suppress the rheumatic disease process

Upadacitinib *(Rinvoq®)* TAG recommendation: Mar 2021

for use in: severe rheumatoid arthritis as per TA665 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2020.

Specific points: Jan 2021 - TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case. Supported by D+TC and ratified by CCG Governing Body

March 2021 - TAG accepted the business case and recommended a traffic light classification of Red (Hospital / Specialist use only)

Upadacitinib *(Rinvoq®)* TAG recommendation: Jun 2023

for use in: active non-radiographic axial spondyloarthritis TA861 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Specific points: formulary application required

June 2023 - applicaton accepted

Upadacitinib *(Rinvoq®)* TAG recommendation: Jul 2023

for use in: moderately to severely active ulcerative colitis TA856 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Specific points: July 2023 - formulary application accepted

10.1.4 - Gout and cytotoxic-induced hyperuricaemia

Rasburicase *(Fasturtec®)* TAG recommendation: Nov 2009

for use in: Prophylaxis & treatment of acute hyperuricaemia to prevent renal failure in patients with high tumour burden who are at risk of tumour lysis syndrome (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Rasburicase is a recombinant enzyme, urate oxidase, which converts uric acid into a more soluble product, allantoin, which does not further damage the kidneys. Rasburicase is proposed for patients who are at high risk of TLS and renal failure in whom allopurinol is contraindicated or deemed inadequate. If dialysis is required this results in chemotherapeutic treatment of the haematological malignancy being stopped.
Prescriber's Rating 2. A real advance - the product is an important therapeutic innovation but has certain limitations.

April 2013: Commissioning responsibility for this treatment transferred to NHS England SCG.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.1.13 - Drugs that suppress the rheumatic disease process

Certolizumab pegol (with and without MTX) *(Cimzia®)* TAG recommendation: Nov 2016

for use in: Active rheumatoid arthritis in adults after inadequate response or intolerance to other disease-modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor-alpha (TNF-alpha) inhibitor (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2016.

Specific points: November 2016:
The TAG noted NICE TA 415 (October 2016) Certolizumab pegol (Cimzia®)(with MTX and as monotherapy) for treating active rheumatoid arthritis in adults after inadequate response or intolerance to other disease-modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor-alpha (TNF-alpha) inhibitor, in combination with methotrexate only if:
* disease activity is severe and
* rituximab is contraindicated or not tolerated
and as monotherapy only if:
* disease activity is severe and
* rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated
and recommended a traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted that the locally agreed Treatment Pathway for Rheumatoid Arthritis will be amended to acknowledge NICE TA 415 (October 2016).
The D&TCG otherwise noted and supported the TAG's recommendation.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

10.2 - Drugs used in neuromuscular disorders

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.2 - Drugs used in neuromuscular disorders

Ataluren *((Translarna®))* TAG recommendation: Mar 2023

for use in: Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene in people aged ≥5 years who can walk - as per NHS England policy HST22 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2023.

Diroximel fumarate *(Vumerity®)* TAG recommendation: Jul 2022

for use in: relapsing–remitting multiple sclerosis as per TA794 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Risdiplam *(Evrysdi®)* TAG recommendation: Jan 2022

for use in: spinal muscular atrophy as per TA755 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

10.2.2 - Skeletal muscle relaxants

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.2.2 - Skeletal muscle relaxants

Cannabis Extract Spray ▼ *(Sativex® ▼)* TAG recommendation: Sep 2022

for use in: ymptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2011: Despite the long-standing TAG Red classification (Hospital (JPUH) Only), the PCTs are not funding use of Sativex. The JPUH funds have covered on-going use of Sativex for patients who had participated in the clinical trials conducted via the JPUH.

The TAG noted that NICE has stopped the Technology Appraisal process pending the development of a Clinical Guideline for MS. The TAG also considered a clinical review and recommendations from MTRAC and the SMC, neither of which support use of Sativex®.

On the basis of there being recent evidence reviews which did not support use of Sativex, the TAG agreed to revise its previous Red recommendation for use in spasticity and muscle pain in MS to Double Red (Not recommended for routine use).

January 2015: The TAG noted and supported NICE CG 186 regarding the following drug treatment recommendations under Section 1.5 - MS symptom management and rehabilitation:
For spasticity:
First- line: Use baclofen or gabapentin. If not tolerated consider switching to the other drug. Consider combining baclofen and gabapentin if individual drugs do not provide adequate relief, or side effects from individual drugs prevent the dose being increased.
Second-line: Consider tizanidine or dantrolene.
Third-line: Consider benzodiazepines; be aware of their potential benefit in treating nocturnal spasms. DO NOT offer Sativex® for spasticity in MS.
For oscillopsia:
First-line: Gabapentin.
Second-line: Consider memantine. Refer for specialist advice if there is no improvement after treatment with gabapentin and memantine, or side effects prevent continued use.
Lack of mobility in MS:
DO NOT use fampridine as it is not cost-effective. Fatigue in MS:
Offer amantadine. DO NOT use vitamin B12 injections for fatigue.
Relapse and exacerbation: Offer oral methylprednisolone 0.5 g daily for 5 days. Do not use lower doses, nor provide a rescue course to treat next relapse.
The TAG noted that the full NICE Clinical Guideline 186 also states that "modafanil should not be used to treat fatigue in MS."
Other treatments:
Consider amitriptyline to treat emotional lability.
DO NOT offer vitamin D solely for MS.
DO NOT offer omega-3 or -6 fatty acids.
Although the TAG decided not to assign new "Traffic lLght" recommendations to any of the above-listed treatments, it was agreed that previous Double Red (Not recommended for routine use) recommendations for Sativex® for spasticity and for fampridine for reduced mobility were in line with NICE CG 186 and should be maintained.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations regarding NICE CG 186 with particular reference to the treatments which are not recommended which will be drawn to the attention of local prescribers.

September 2022 - Sativex formulary application accepted by TAG and D+TC

10.3.1 - Drugs that suppress the rheumatic disease process

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

10.3.1 - Drugs that suppress the rheumatic disease process

Tocilizumab IV *(RoActemra® for infusion)* TAG recommendation: May 2018

for use in: Takayasu arteritis - as per NHS England policy 16056/P (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. NHS England Policy 16056/P - Specialist centres only.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

10.3.2 - Plant alkaloids - rubefacient

Capsaicin transdermal patches (Qutenza®) *(Qutenza®)* TAG recommendation: Sep 2018

for use in: Peripheral neuropathic pain in non-diabetic patients (specialist use only) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2018:
The TAG noted the PRG recommendation of a Double Red (Not recommended for routine use) classification for this product as an interim measure, in the absence of a formal application for use from local pain services, to ensure that GPs are not approached to prescribe it.
The TAG noted that there are a small number of patients who benefit from this treatment and recommended a traffic light classification of Red (Hospital / Specialist use only) to meet this need.

September 2018:
The N&W CCGs' D&TC noted and supported the TAG's recommendation.

October 2018:
The N&W CCG's JSCC noted and supported the D&TC's recommendation

11.4.1 - Corticosteroids (used to treat the eye)

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.4.1 - Corticosteroids (used to treat the eye)

Dexamethasone intravitreal implant *(Ozurdex®)* TAG recommendation: May 2018

for use in: Non-infectious uveitis in the posterior segment of the eye in adults - as per NICE TA 460 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG noted the difference in responsible commissioner for adalimumab (SCG-commissioning responsibility) and dexamethasone intravitreal implant (CCG-commissioning responsibility) for treating non-infectious uveitis in the posterior segment of the eye in adults and acknowledged that local use would be determined by designation of a specialist centre status in any of the local provider trusts.
The TAG acknowledged NICE TA 460 (July 2017) and recommended traffic light classifications of Double Red (Not recommended for routine use) for these SCG-commissioning responsibility and CCG-commissioning responsibility treatments pending the submission and approval of a business application for their use.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

May 2018: The TAG considered the NNUH's application as per NICE TA 460 which also proposed use in both eyes (administered separately to mitigate the risk of endophthalmitis occurring after insertion) in patients presenting with bilateral uveitis with contraindications to anti-TNF and/or if there has been a positive response to unilateral application on previous occasions. The NNUH had sought information from the manufacturer and had provided evidence to support such use if required.
The application also proposed replacement implantation sooner than 6 monthly where the treatment has not remained effective for that time period. Around a third of patients may need replacement at 4 months (3 implants per year) rather 6-monthly.
These uses would be outside of NICE criteria.
The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital use only).

May 2018: The D&TC noted that the application included proposals for use of intravitreal dexamethasone implants outside of NICE TA 460. A review of the pathway and proforma would be required to accommodate such extended use which would need to be audited.
The D&TC agreed that more information is required from the Trust regarding the proposed use outside of NICE TA 460 but agreed to support commissioning as Red (Hospital only) for use strictly in line with NICE TA 460.

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations - commissioned as per above recommmendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.4.1 - Corticosteroids (used to treat the eye)

Dexamethasone intravitreal implant *(Ozurdex®)* TAG recommendation: Nov 2015

for use in: Treatment of diabetic macular oedema (DMO) in line with NICE TA 349 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2015.

Specific points: July 2015: The TAG noted the NICE FAD (May 2015) for dexamethasone intravitreal implant (Ozurdex®) for treating diabetic macular oedema (DMO) which recommends use only if:
* the implant is to be used in an eye with an intraocular (pseudophakic) lens and
* the diabetic macular oedema does not respond to non-corticosteroid treatment, or such treatment is unsuitable.
The TAG therefore recommended a likely future classification of Red (Hospital only) pending the publication of the NICE TA.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's likely future traffic light recommendation and confirmed that the treatment is not commissioned pending publication of the final NICE TA and agreement on the treatment's place in a locally approved pathway.

September 2015: The TAG noted NICE TA 349 (July 2015) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending the agreement on a revised local treatment pathway.

October 2015:
The D&TCG noted and supported the TAG's recommendations.
The committee was advised that the QEH has submitted, and the NNUH is working on, a proposed treatment pathway for this condition. The D&TCG recommended that the Trusts should liaise on the development of the pathway to ensure continuity of approach across the county.
It was also noted that, although not yet commissioned, there is switching between treatments for DMO occurring in local clinical practice.
The D&TCG agreed that the TAG should not consider one Trust's proposed treatment pathway in isolation.

November 2015: The TAG supported the NNUH's application in line with NICE TA 349. the TAG also noted that work is on-going regarding agreeing the treatment pathway for DMO with respect to proposals from the Trusts, including switching between treatments which is outside of NICE guidance.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG agreed that Dexamethasone intravitreal implants (Ozurdex®) for DMO are commissioned strictly in line with NICE TA 349 (July 2015) and classified as Red (Hospital/Specialist only). Use of Dexamethasone intravitreal implants (Ozurdex®) for DMO outside of NICE guidance is not commissioned.
Provider Trusts are invited to submit evidence-based and costed applications for any other use of Dexamethasone intravitreal implant (Ozurdex®) for DMO.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.4.1 - Corticosteroids (used to treat the eye)

Dexamethasone intravitreal implant ▼ *(Ozurdex®)* TAG recommendation: Sep 2011

for use in: Macular oedema secondary to retinal vein occlusion - as per NICE TA 229 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2011.

Specific points: NICE TA 229 (http://guidance.nice.org.uk/TA229) states:
1.1 Dexamethasone intravitreal implant is recommended as an option for the treatment of macular oedema following central retinal vein occlusion.

1.2 Dexamethasone intravitreal implant is recommended as an option for the treatment of macular oedema following branch retinal vein occlusion when:

* treatment with laser photocoagulation has not been beneficial, or
* treatment with laser photocoagulation is not considered suitable because of the extent of macular haemorrhage.

On 26th January 2012 the NHS Norfolk Drugs & Therapeutics Commissioning Group reconsidered the TAG's recommendation following a business application from the JPUH and decided to fund use of dexamethasone intravitreal implants in macular oedema secondary to retinal vein occlusion as per NICE TA 229 (July 2011) across NHS Norfolk and Waveney .

Fluocinolone acetonide intravitreal implant *(Iluvien®)* TAG recommendation: Nov 2020

for use in: Recurrent non-infectious uveitis as per TA590 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2019.

Specific points: October 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of September 2019. TA590 - July 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for routine use/not commissioned) pending the provision of a business case.

Nov 2020 - Business case supported by TAG and a traffic light classification of Red (Hospital / Specialist use only) was recommended. Fluocinolone would be used as an option in the treatment pathway as a second-line specialist choice after dexamethasone has failed or been contraindicated. Supported by D+TC and ratified by CCG Governing Body

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.4.1 - Corticosteroids (used to treat the eye)

Fluocinolone acetonide intravitreal implant *(Iluvien®)* TAG recommendation: Jul 2014

for use in: Treatment of chronic diabetic macular oedema after inadequate response to prior therapy - as per NICE TA 301 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2013.

Specific points: NICE TA 271 (January 2013 http://guidance.nice.org.uk/TA271) -
Not recommended by NICE
D&TCG decision March 2013: Not commissioned

January 2014: NICE TA 301 (Nov 2013) (rapid review of TA 271) for treatment of chronic diabetic macular oedema (DMO after an inadequate response to prior therapy. Recommended by NICE as an option under PAS.

June 2014: Commissioned by N&W CCGs-as per NICE TA 301, Non Tariff treatment; notification required.

July 2014: The TAG noted a summary of ophthalmological non-Tariff treatments, including fluocinolone, which had been accepted by Central CCGs Commissioning Board.

11.8 - Miscellaneous ophthalmic preparations

Voretigene Neparvovec *(Luxturna)* TAG recommendation: Mar 2023

for use in: Inherited Retinal Dystrophies HST11 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2019.

11.8.2 - Ocular diagnostic and peri-operative preparations

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)* TAG recommendation: Jan 2014

for use in: Treatment of Wet Age-related Macular Degeneration in patients unresponsive to or intolerant of ranibizumab - as per locally commissioned pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2013.

Specific points: September 2013: The TAG noted that NICE TA 294 recommended aflibercept as an option for treatment of wet AMD as per NICE guidance for ranibizumab under specified criteria.

The TAG agreed to review the evidence for the use of aflibercept outside NICE guidance for three identified patient groups:
those who are non-responders to ranibizumab; those who are intolerant of ranibizumab; those who require frequent doses of ranibizumab.

January 2014: New Medicines Evidence Review considered by the TAG for patients previously treated who have intolerance to ranibizumab. Very rare effect with only one local patient reported to date. Use in this group supported on the basis of the evidence available and providing that a clear definition of how tolerance would be measured is provided. Classification of Red (Hospital only) recommended.

N&W CCGs D&TCG supported the application in theory but not commissioned until a treatment pathway is agreed.

New Medicine Evidence Review considered for patients previously treated who have not responded adequately to ranibizumab. Use in this group supported by the TAG on the basis of biological plausibility. Treatment failures or non-responders to be defined in line with NICE criteria. Patients to be assessed three times before a decision would be made to stop treatment. Re-classification of Red (Hospital only recommended).

N&W CCGs D&TCG supported the recommendation in theory but not commissioned until treatment pathway agreed.

May 2014: The TAG supported a document laying out criteria for switching between aflibercept and ranibizumab for treatment of wet AMD which stated:

NICE criteria are met:
1. Use either Aflibercept or Ranibizumab as appropriate.

2. Patients requiring more than 8 injections of ranibizumab, or aflibercept, in the last 12 months can change to the other treatment if considered appropriate, as per TAG recommendation (January 2014).

3. Intolerance to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of intolerance:
Persistent sub-retinal or intra-retinal fluid on a number of consecutive occasions despite repeated intravitreal injections of ranibizumab, or aflibercept, OR
where continued use of ranibizumab or aflibercept is unsuitable because of an allergic response, AND
where there is still potential for improvement in vision with further treatment.

4. Inadequate response to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of inadequate response:
Where ranibizumab or aflibercept has not shown clinical benefit after optimum treatment AND
where there is still potential for improvement in vision with further treatment.

5. NICE stopping and starting criteria apply as before.

6. All treatments to be in line with approved activity charges.

7. All initiations and changes to be notified and be subject to audit.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

June 2014: CCG Combined Commissioned Drug Therapies list updated to state: "Commissioned. Non Tariff. Notification required."
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/combined_commissioned_drug_therapies_list.pdf

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Aflibercept *(Eylea®)* TAG recommendation: Jul 2018

for use in: Treatment of visual impairment due to myopic choroidal neovascularisation in adults - as per NICE TA 486 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2017.

Specific points: November 2017:
The TAG acknowledged NICE TA 486 (Nov 17) which states:
Recommended as an option by NICE. Ranibizumab is already recommended by NICE for this indication. An indirect comparison of aflibercept and ranibizumab shows that both drugs provide similar overall health benefits. The total costs of aflibercept are the same as or less than ranibizumab.
If both aflibercept and ranibizumab are considered to be suitable treatments, the least costly should be used, taking into account anticipated administration costs, dosage and price per dose.

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use and confirmation of its place in the local treatment pathway.

July 2018:
The TAG agreed to support the QEH's application and proposed treatment algorithm, and recommended a traffic light classification of Red (Hospital/Specialist only)

July 2018: The NHS Norfolk & Waveney CCGs' D&TC agreed to support the application as Red (Hospital / Specialist only) and acknowledged that this is another extension in the treatment of eye disease. Monitoring of aflibercept in line with NICE TA 486 will be undertaken via a proforma

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)*

for use in: Treatment of Diabetic Macular Oedema (DMO) as part of a treat and extend regimen in line with the locally commissioned treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented would be for the commissioners to determine.
The TAG also recommended that a review should be carried out to see if the protocol was cost effective.

The D&TCG agreed to commission use of Aflibercept (Eylea®) and Ranibizumab (Lucentis®) for treatment of Diabetic Macular Oedema (DMO) under a treat and extend regimen as Red (Hospital use only) and would require a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)* TAG recommendation: Nov 2015

for use in: Treatment of visual impairment caused by diabetic macular oedema (DMO) as per NICE TA 346 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2015.

Specific points: July 2015: The TAG noted the NICE FAD (May 2015) for aflibercept (Eylea®) for treating diabetic macular oedema (DMO) which recommends use only if:
* the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and
* aflibercept is provided at discount agreed under PAS.
The TAG recommended a likely future classification of Red (Hospital only) pending the publication of the NICE TA.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's likely future traffic light recommendation and confirmed that the treatment is not commissioned pending publication of the final NICE TA and agreement on the treatment's place in a locally approved pathway.

September 2015: The TAG noted NICE TA 346 (July 2015) and recommended a traffic light classification of Double Red (Not recommended for routine use) pending the provision of a business application and patient pathway.

October 2015:
The D&TCG noted and supported the TAG's recommendations.
The committee was advised that the QEH has submitted, and the NNUH is working on, a proposed treatment pathway for this condition. The D&TCG recommended that the Trusts should liaise on the development of the pathway to ensure continuity of approach across the county.
It was also noted that, although not yet commissioned, there is switching between treatments for DMO occurring in local clinical practice.
The D&TCG agreed that the TAG should not consider either Trust's proposed treatment pathway in isolation.

November 2015: The TAG noted and supported the NNUH application in line with NICE TA 346 (July 2015).
The TAG also noted that work is on-going regarding agreeing the treatment pathway for DMO with respect to proposals from the Trusts, including switching between treatments which is outside of NICE guidance.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG agreed that aflibercept for DMO be commissioned strictly in line with NICE TA 346 (July 2015) and is classified as Red (Hospital/Specialist only).
Use of aflibercept for DMO outside of NICE guidance is not commissioned.
Provider Trusts are invited to submit evidence-based and costed applications for any other use of aflibercept for DMO.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)* TAG recommendation: Jan 2014

for use in: Wet Age-related Macular Degeneration (AMD) in patients requiring frequent doses with ranibizumab (around eight or more injections per eye per year required to maintain the condition) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2013.

Specific points: September 2013: The TAG noted that NICE TA 294 recommended aflibercept as an option for treatment of wet AMD as per NICE guidance for ranibizumab under specified criteria.

The TAG agreed to review the evidence for the use of aflibercept outside NICE guidance for three identified patient groups:
those who are non-responders to ranibizumab; those who are intolerant of ranibizumab; those who require frequent doses of ranibizumab.

January 2014: New Medicine Evidence Review considered by the TAG - use in patients requiring frequent doses of ranibizumab was recommended on the basis of the evidence available. Classification to be amended to Red (Hospital only).

N&W CCGs D&TCG supported the recommendation. Commissioned.

May 2014: The TAG supported a document laying out criteria for switching between aflibercept and ranibizumab for treatment of wet AMD which stated:

NICE criteria are met:
1. Use either Aflibercept or Ranibizumab as appropriate.

2. Patients requiring more than 8 injections of ranibizumab, or aflibercept, in the last 12 months can change to the other treatment if considered appropriate, as per TAG recommendation (January 2014).

3. Intolerance to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of intolerance:
Persistent sub-retinal or intra-retinal fluid on a number of consecutive occasions despite repeated intravitreal injections of ranibizumab, or aflibercept, OR
where continued use of ranibizumab or aflibercept is unsuitable because of an allergic response, AND
where there is still potential for improvement in vision with further treatment.

4. Inadequate response to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of inadequate response:
Where ranibizumab or aflibercept has not shown clinical benefit after optimum treatment AND
where there is still potential for improvement in vision with further treatment.

5. NICE stopping and starting criteria apply as before.

6. All treatments to be in line with approved activity charges.

7. All initiations and changes to be notified and be subject to audit.

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Aflibercept *(Eylea®)* TAG recommendation: Mar 2014

for use in: Visual impairment caused by macular oedema secondary to central retinal vein occlusion - as per NICE TA 305 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2014.

Specific points: March 2014:
The TAG noted NICE TA 305 (Feb 2014) which recommends aflibercept solution for injection as an option for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion only if the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme.

March 2014 D&TCG meeting:
CCG-commissioning responsibility.
TAG recommendation noted and supported.
Service implications regarding commissioning this treatment require referral to the Acute Commissioning Board for central Norfolk CCGs.

March 2017: The TAG considered the local Trust's application in line with the proposed treatment pathway for CRVO and agreed that such use would be finalised along with the appropriate treatment pathway as described above.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation and commissioned the treatment in line with the locally agreed treatment pathway for CRVO.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)* TAG recommendation: Sep 2013

for use in: Wet Age-related Macular Degeneration (AMD) in new patients (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2013.

Specific points: May 2013: The TAG noted that Great Yarmouth & Waveney CCG may wish to use aflibercept in order to reduce activity costs in a group of patients who are currently being treated with ranibizumab. The ophthalmologists at JPUH are in agreement with the proposed use. On the basis of evidence presented, the TAG agreed that aflibercept is non-inferior to ranibizumab for wet AMD and should therefore be considered as an option for new patients, in line with the SMC guidance - Red (Hospital Only).

September 2013: The TAG noted NICE TA 294 and recommended that the treatment be classified as Red (Hospital/Specialist only) for newly diagnosed patients.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) supported the commissioning of the treatment for newly diagnosed patients. It was noted that NICE recommended out-patient service provision. Negotiations are ongoing regarding the appropriate tariff to be charged by specialist services.

See separate entries for Aflibercept in the treatment of patients requiring frequent doses of ranibizumab, who have not responded adequately to ranibizumab or who are intolerant of ranibizumab.

May 2014: The TAG supported a document laying out criteria for switching between aflibercept and ranibizumab for treatment of wet AMD which stated:

NICE criteria are met:
1. Use either Aflibercept or Ranibizumab as appropriate.

2. Patients requiring more than 8 injections of ranibizumab, or aflibercept, in the last 12 months can change to the other treatment if considered appropriate, as per TAG recommendation (January 2014).

3. Intolerance to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of intolerance:
Persistent sub-retinal or intra-retinal fluid on a number of consecutive occasions despite repeated intravitreal injections of ranibizumab, or aflibercept, OR
where continued use of ranibizumab or aflibercept is unsuitable because of an allergic response, AND
where there is still potential for improvement in vision with further treatment.

4. Inadequate response to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of inadequate response:
Where ranibizumab or aflibercept has not shown clinical benefit after optimum treatment AND
where there is still potential for improvement in vision with further treatment.

5. NICE stopping and starting criteria apply as before.

6. All treatments to be in line with approved activity charges.

7. All initiations and changes to be notified and be subject to audit.

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Aflibercept *(Eylea®)* TAG recommendation: Jul 2017

for use in: Treatment of Wet Age-related Macular Degeneration (AMD) as part of a treat and extend regimen in line with the locally commissioned treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented would be for the commissioners to determine.
The TAG also recommended that a review should be carried out to see if the protocol was cost effective.

The D&TCG agreed to commission use of Aflibercept (Eylea®) and Ranibizumab (Lucentis®) for treatment of Wet Age-related Macular Degeneration (AMD) under a treat and extend regimen as Red (Hospital use only) and would require a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept *(Eylea®)* TAG recommendation: Mar 2017

for use in: Visual impairment caused by macular oedema after branch retinal vein occlusion - as per NICE TA 409 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2016.

Specific points: November 2016:
The TAG acknowledged NICE TA 409 (September 2016) and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility pending the provision and submission of a business application.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation of Double Red (Not recommended for routine use), pending the approval of a business application.

March 2017: The TAG considered the local Trust's application in line with the proposed treatment pathway for BRVO and agreed that such use would be finalised along with the appropriate treatment pathway as described above.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation and commissioned the treatment in line with the locally agreed treatment pathway for BRVO.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Aflibercept (switched to Ranibizumab (Lucentis®) *(Eylea®)* TAG recommendation: Jan 2014

for use in: Switching between products in the treatment of Wet Age-related Macular Degeneration (AMD) in previously treated patients who have not responded adequately to, or who have intolerance to aflibercept (Eylea®) - as per locally commissioned pathway (A

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2013.

Specific points: January 2014: New Medicine Evidence Review considered by the TAG for switching from initial treatment with aflibercept to ranibizumab. The TAG acknowledged this need could potentially occur in patients having received treatment with aflibercept first line. Recommended providing that starting and stopping criteria clearly laid down.

N&W CCGs-D&TCG supported the recommendation in theory but treatment not commissioned until a treatment pathway is agreed.

May 2014: The TAG supported a document laying out criteria for switching between aflibercept and ranibizumab for treatment of wet AMD which stated:

NICE criteria are met:
1. Use either Aflibercept or Ranibizumab as appropriate.

2. Patients requiring more than 8 injections of ranibizumab, or aflibercept, in the last 12 months can change to the other treatment if considered appropriate, as per TAG recommendation (January 2014).

3. Intolerance to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of intolerance:
Persistent sub-retinal or intra-retinal fluid on a number of consecutive occasions despite repeated intravitreal injections of ranibizumab, or aflibercept, OR
where continued use of ranibizumab or aflibercept is unsuitable because of an allergic response, AND
where there is still potential for improvement in vision with further treatment.

4. Inadequate response to ranibizumab or aflibercept:
It is appropriate to change to the other treatment using the following definition of inadequate response:
Where ranibizumab or aflibercept has not shown clinical benefit after optimum treatment AND
where there is still potential for improvement in vision with further treatment.

5. NICE stopping and starting criteria apply as before.

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

6. All treatments to be in line with approved activity charges.

7. All initiations and changes to be notified and be subject to audit.

June 2014: CCG Combined Commissioned Drug Therapies list updated to state: "Commissioned. Non Tariff. Notification required."
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/combined_commissioned_drug_therapies_list.pdf

Brolucizumab *(Beovu®)* TAG recommendation: Apr 2021

for use in: wet age-related macular degeneration as per TA672 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: April 2021 - The TAG recommended a Red (Hospital / Specialist Only) classification.
Pathway accepted. .

Faricimab *(Vabysmo®)* TAG recommendation: Oct 2022

for use in: wet age-related macular degeneration as per TA800 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Oct 2022 - Further discussion on pathway and costings continuing to be undertaken. Trusts are keen to use these treatments so recommend to use most cost-effective options

Faricimab *(Vabysmo®)* TAG recommendation: Oct 2022

for use in: diabetic macular oedema as per TA799 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Oct 2022 - Further discussion on pathway and costings continuing to be undertaken. Trusts are keen to use these treatments so recommend to use most cost-effective options

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Ocriplasmin intravitreal injection ▼ *(Jetrea® ▼)* TAG recommendation: Jan 2014

for use in: Treatment of vitreomacular traction in adults - as per NICE TA 297 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2013.

Specific points: November 2013: The TAG noted that NICE TA 297 recommended the treatment as an option only if an epiretinal membrane is not present and the patient has a stage II full-thickness macular hole with a diameter of 400 micrometres or less and/or have severe symptoms.

The TAG recommended the Double Red classification pending the submission of a business case from local providers and clarification regarding the treatment's place in therapy.

November 2013: The D&TCG noted that Norfolk CCGs will await patient numbers from interested providers subject to agreement regarding tariff costs.
Not commissioned in Norwich, North, South and West Norfolk in the interim period.

However Great Yarmouth & Waveney CCG has already commissioned use of ocriplasmin through a block contract with the JPUH.

January 2014: Classification revised by the TAG to Red (Hospital only) following receipt of an application from NNUH. Norfolk CCGs noted and supported the NNUH business application providing that use is in line with NICE TA 297, that related audits are conducted with results reported to commissioners as appropriate, and that notification of such use is reported to Norfolk commissioners.

Ranibizumab *(Lucentis®)* TAG recommendation: Jan 2014

for use in: Choroidal neovascularisation associated with pathological myopia (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: November 2013.

Specific points: NICE TA 298 (Nov 2013) Recommended as an option by NICE under PAS.
N&W CCGs D&TCG noted the TAG recommendation of Red (Hospital/Specialist only). The NNUH business application to be passed directly to the D&TCG when available.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Ranibizumab *(Lucentis®)* TAG recommendation: Jul 2017

for use in: Treatment of Wet Age-related Macular Degeneration (AMD) as part of a treat and extend regimen in line with the locally commissioned treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented would be for the commissioners to determine.
The TAG also recommended that a review should be carried out to see if the protocol was cost effective.

The D&TCG agreed to commission use of Aflibercept (Eylea®) and Ranibizumab (Lucentis®) for treatment of Wet Age-related Macular Degeneration (AMD) under a treat and extend regimen as Red (Hospital use only) and would require a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.

March 2018: The TAG acknowledged NICE NG 82 (January 2018) - Age-related macular degeneration and noted that it included recommendations regarding treatment thresholds which deviated from the previously commissioned NICE TAs.
The TAG also noted the recommendations that suspected cases should be referred to the local service within 1 working day, and that appropriate treatment should started within 2 weeks of confirmed diagnosis of wet AMD, which will have service implications for addressing by CCGs.
References to use of bevacizumab as a treatment option were noted and would be further considered as appropriate following to the outcome of the judicial review.

March 2018: The D&TC noted the TAG's comments regarding NG 82 (January 2018) and confirmed that the previously agreed commissioning position and treatment pathway for wet AMD are maintained for the time being.

April 2018: The JSCC supported the D&TC's recommendations.

Ranibizumab *(Lucentis®)* TAG recommendation: Jul 2017

for use in: Treatment of Diabetic Macular Oedema (DMO) as part of a treat and extend regimen in line with the locally commissioned treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG agreed to recommend the clinical appropriateness of the potential of following a Treat and Extend protocol. The arrangements of how this would be implemented would be for the commissioners to determine.
The TAG also recommended that a review should be carried out to see if the protocol was cost effective.

The D&TCG agreed to commission use of Aflibercept (Eylea®) and Ranibizumab (Lucentis®) for treatment of Diabetic Macular Oedema (DMO) under a treat and extend regimen as Red (Hospital use only) and would require a report on the savings made through use of the Treat & Extend regimen after one year's data has been captured.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Ranibizumab *(Lucentis®)* TAG recommendation: Mar 2013

for use in: Visual impairment due to diabetic macular oedema (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2013.

Specific points: NICE TA 274 (February 2013 http://guidance.nice.org.uk/TA274) (rapid review of TA237) states that:
Ranibizumab is recommended as an option for treating visual impairment due to diabetic macular oedema only if:
the eye has a central retinal thickness of 400 micrometres or more at the start of treatment
and
the manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).

D&TCG decision (March 2013:) The price of ranibizumab has been reduced recently. The prevalence of diabetes in Norfolk is much higher than national average. The numbers given in NICE's costing template were 28 patients; in Norfolk there are around 225 patients.
Contract details to be finalised. Commissioned as per NICE TA 274 subject to local agreement regarding service implications.

Ranibizumab *(Lucentis®)* TAG recommendation: Sep 2008

for use in: Neovascular (wet) age-related macular degeneration (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2008.

Specific points: NICE Technology Appraisal Guidance No. 155 August 2008 recommends ranibizumab as an option for the treatment of wet age-related macular degeneration under specified circumstances. The cost of ranibizumab beyond 14 injections in the treated eye is to be met by the manufacturer.

Ranibizumab *(Lucentis®)* TAG recommendation: Jul 2013

for use in: Treatment of visual impairment caused by macular oedema secondary to retinal vein occlusion (RVO) (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2013.

Specific points: NICE Technology Appraisal 283 (May 2013) states that ranibizumab is recommended as an option for treating visual impairment caused by macular oedema:
* following central retinal vein occlusion or

* following branch retinal vein occlusion only if treatment with laser photocoagulation has not been beneficial, or when laser photocoagulation is not suitable because of the extent of macular haemorrhage and

* only if the manufacturer provides ranibizumab with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 274.

July 2013: The NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) approved the TAG's recommendation - a business case for use has been sent to Contracting to complete commissioning process.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

11.8.2 - Ocular diagnostic and peri-operative preparations

Verteporfin *(Visudyne®)* TAG recommendation: Sep 2010

for use in: With photodynamic therapy (PDT) - Chronic Central Serous Chorio-Retinopathy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG considered an application from the NNUH for In-tariff but off-label use of verteporfin with PDT (photodynamic therapy) in Chronic Central Serous Chorio-retinopathy (CCSCR).
The TAG noted the lack of robust high grade evidence and agreed that the long term effect on patients who respond is not clear.
Assessment of the available evidence using the decision-making framework criterion suggested tendency to the good. The TAG therefore recommended that the application was classified as Red (Hospital Only) but as a majority view only.
This recommendation has been referred to the NHS Norfolk Planned Care Commissioning Programme Board for a final decision.
The PCT has since taken the view that this is an In-Tariff treatment which hospital trusts may elect to use within their own costs.

2012:
Following the establishment of NHS England, verteporfin with PDT became a non-tariff treatment.

13.5.1 - Preparations for eczema

Alitretinoin *(Toctino®)* TAG recommendation: Sep 2009

for use in: Treatment of severe chronic hand eczema - as per NICE TA 177 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2009.

Specific points: NICE Technology Appraisal Guidance 177 August 2009 details the criteria for use of alitretinoin and states that only dermatologists, or physicians with experience in both managing and severe chronic hand eczema and the use of systemic retinoids, should start and monitor treatment with alitretinoin.

13.5.2 - Oral retinoids for psoriasis

Acitretin *(Neotigason®)* TAG recommendation: Nov 2012

for use in: All indications (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2012.

Specific points: Not for prescribing in primary care on recommendation of local dermatology specialists.

Recommendation supported by the Drugs & Therapeutics Commissioning Group (D&TCG).

13.5.3 - Drugs affecting the immune response

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Bimekizumab *(Bimzelx®)* TAG recommendation: Oct 2021

for use in: moderate to severe plaque psoriasis as per TA723 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: September 2021.

Specific points: CCG commissioned treatment

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Brodalumab *(Kyntheum®)* TAG recommendation: Mar 2019

for use in: Moderate to severe plaque psoriasis - as per NICE TA 511 (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE issued Guidance in: March 2018.

Specific points: May 2018: The TAG acknowledged NICE TA 511 (March 2018) which states:
Recommended by NICE as an option for treating plaque psoriasis in adults, only if:
* the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
* the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated and
* the company provides the drug with the discount agreed in the patient access scheme.

and recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment, pending submission of an application for its use and agreement on its place in the treatment pathway.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2018: The NHS Norfolk & Waveney JSCC noted and supported the TAG & D&TC recommendation.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

March 2019: The TAG considered the NNUH's application and was advised that brodalumab is proposed as biologic option for consideration alongside ixekizumab, guselkumab and secukinumab in the local treatment pathway as 3rd line treatment options after cost-effective anti-TNFs and ustekinumab.
The TAG agreed to support the application and recommended a traffic light classification of Red (Hospital/Specialist use only).

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Dupilumab *(Dupixent®)* TAG recommendation: Jan 2022

for use in: severe asthma with type 2 inflammation as per TA751 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2021.

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Sep 2017

for use in: Plaque psoriasis in children and young people - as per NICE TA 455 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 455 (July 2017) and recommended traffic light classification of Red (Hospital/Specialist only)) for this SCG-commissioning responsibility treatment.
NICE recommends etanercept as an option for those aged 6 years or older, only if the disease:
* is severe, as defined by a total PASI of 10 or more and
* has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.
Stop etanercept at 12 weeks if the psoriasis has not responded adequately i.e. if a 75% reduction in the baseline PASI score has not been achieved.

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Nov 2014

for use in: Active and progressive psoriatic arthritis - as per NICE 199 and local policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA Guidance 199 which states that Etanercept, infliximab and adalimumab are all recommended for the treatment of active and progressive psoriatic arthritis, based on specific criteria. Treatment choice should be started with the least expensive drug
(taking into account drug administration costs, required dose and product price per dose).
Treatment should be discontinued if people's disease does not show an adequate response on the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. Healthcare professionals should also consider continuing treatment if people's skin disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks in the absence of an adequate PsARC response. This assessment should be done by a dermatologist to determine whether continued treatment is appropriate on the basis of the skin response alone.

November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported. A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Etanercept *(Enbrel® / Benepali® ▼)* TAG recommendation: Sep 2017

for use in: Psoriasis - as per NICE TA 103 and the local treatment pathway (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2006.

Specific points: NICE TA 103 (July 2006) states that:
1.1 Etanercept, within its licensed indications, administered at a dose not exceeding 25 mg twice weekly is recommended for the treatment of adults with plaque psoriasis only when the following criteria are met:

The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10.

The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments.

1.2 Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these patients.
An adequate response is defined as either:
a 75% reduction in the PASI score from when treatment started (PASI 75)
or
a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from when treatment started.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (Taltz®), Secukinumab (Cosentyx®) and Apremilast (Otezla®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used as a second line choice where anti-TNF contraindicated, depending on patient factors and co-morbidities, as stated in the local treatment pathway.
The pathway places use of etanercept as a possible first-line option but after consideration of adalimumab which has been shown to be more effective , with fewer adverse effects.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Guselkumab *(Tremfya®)* TAG recommendation: Jan 2023

for use in: treating active psoriatic arthritis after inadequate response to DMARDs as per TA815 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

Jan 2023 - application accepted and amended to red

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Infliximab (biosimilar) *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Mar 2008

for use in: Treatment of psoriasis in adults - as per NICE TA 134 and local treatment pathway (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: January 2008.

Specific points: NICE TAG 134 January 2008:
1. Infliximab, within its licensed indications, is recommended as a treatment option for adults with plaque psoriasis only when the following criteria are met.
1.1 The disease is very severe as defined by a total Psoriasis Area Severity Index (PASI) of 20 or more and a Dermatology Life Quality Index (DLQI) of more than 18.
1.2 The psoriasis has failed to respond to standard systemic therapies such as ciclosporin, methotrexate or PUVA (psoralen and long-wave ultraviolet radiation), or the person is intolerant to or has a contraindication to these treatments.
2. Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks. An adequate response is defined as either:
2.1 a 75% reduction in the PASI score from when treatment started (PASI 75) or
2.2 a 50% reduction in the PASI score (PASI 50) and a five-point reduction in the DLQI from when treatment started.
3. When using the DLQI healthcare professionals should take care to ensure that they take account of a patient's disabilities (such as physical impairments) or linguistic or other communication difficulties, in reaching conclusions on the severity of plaque psoriasis. In such cases healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a decision about whether to continue the use of the
drug in accordance with section 2.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (Taltz®), Secukinumab (Cosentyx®) and Apremilast (Otezla®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used as a second line choice where anti-TNF contraindicated, depending on patient factors and co-morbidities, as stated in the local treatment pathway.
The pathway places use of infliximab only for unstable disease or where rapid control is required.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Infliximab (biosimilar) *(Remicade® (until end Mar16 only); Remsima® ▼)* TAG recommendation: Sep 2010

for use in: Active and progressive psoriatic arthritis - as per NICE TA 199 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2010.

Specific points: September 2010: The TAG noted NICE TA Guidance 199 which states that Etanercept, infliximab and adalimumab are all recommended for the treatment of active and progressive psoriatic arthritis, based on specific criteria. Treatment choice should be started with the least expensive drug
(taking into account drug administration costs, required dose and product price per dose).
Treatment should be discontinued if people's disease does not show an adequate response on the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. Healthcare professionals should also consider continuing treatment if people's skin disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks in the absence of an adequate PsARC response. This assessment should be done by a dermatologist to determine whether continued treatment is appropriate on the basis of the skin response alone.

November 2014: The TAG supported the NNUH application for switching to a second, and if necessary a third biologic option for the treatment of psoriatic arthritis. Switching between infliximab, etanercept, adalimumab, golimumab and certolizumab supported. A classification of Red (Hospital only) recommended providing that the relative costs of the different treatment options are taken into consideration by the Trust specialists.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that the most cost-effective treatment option (regarding both acquisition and service costs), that is appropriate for the patient is used.

September 2015: The TAG noted NICE HTTA 329 - a resource developed to provide practical information and advice on the use of biosimilar versions of infliximab. This underpins the commissioning decision regarding the transition to biosimilar treatments.

October 2015:
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted NICE HTTA 329 and stated that Remsima® has not been commissioned for use locally for any indication.
Inflectra® is the locally commissioned biosimilar infliximab for agreed indications.
Inflectra® is to be used for any new patients requiring treatment with infliximab from October 2015 and will be used for all existing patients requiring treatment with infliximab from April 2016 - i.e. Trust invoices for infliximab will be paid at the Inflectra® price only from that time.

March 2016:
The D&TCG was advised that Remsima® is now the most cost-effective biosimilar infliximab product and that the Trusts will now be reimbursed against its price rather than for Inflectra® as previously agreed.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ixekizumab *(Taltz®)* TAG recommendation: Jan 2019

for use in: Active psoriatic arthritis after inadequate response to DMARDs, used alone or with methotrexate - as per NICE TA 537 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2018.

Specific points: September 2018: The TAG noted NICE TA 537 (August 2018) which states:
Ixekizumab (Taltz®) is recommended by NICE as an option for treating active psoriatic arthritis after inadequate response to DMARDs, used alone or with methotrexate, only if:
* it is used as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or
* the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after the first 12 weeks or
* TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis).
* the company provides it according to the commercial arrangement

The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission of a business application and confirmation of its place in the locally commissioned psoriatic arthritis treatment pathway.

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

January 2019: The TAG was advised that ixekizumab is an alternative to secukinumab within the current treatment pathway, is of similar cost and offers benefits in slightly better adverse effects profile and marginally faster onset of action.
Secukinumab has not been used widely within the NNUH to date since most patients are currently managed on biosimilar anti-TNFs.
The proposed treatment algorithm had been updated in line with NICE TA 537, and was supported by the TAG.
The TAG supported the business application and recommended a revised traffic light classification of Red (Hospital/Specialist only).

January 2019: The NHS Norfolk & Waveney CCGs' D&TC noted that the NNUH's application estimates use of ixekizumab in up to 10 patients per year; use would be long term. The treatment is cost-neutral compared to current therapy - only patients eligible for secukinumab or ustekinumab would be treated, and the presumption remains that the cheapest drug will be selected.
Noted and supported by the D&TC with acknowledgement that the commissioned treatment pathway requires revision.

Ixekizumab *(Taltz®)* TAG recommendation: Dec 2021

for use in: axial spondyloarthritis as per TA718 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2021.

Specific points: Pending submission of formulary application

Dec 2021 - formulary application accepted by TAG, D+TC and GB

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ixekizumab ▼ *(Taltz® ▼)* TAG recommendation: Sep 2017

for use in: 3rd line biologic option in moderate to severe plaque psoriasis under certain conditions - as per NICE TA 442 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2017.

Specific points: May 2017: The TAG acknowledged NICE TA 442 (April 2017) for treating moderate to severe plaque psoriasis only if:
* the disease is severe, as defined by a total PASI of 10 or more and a DLQI > 10
* the disease has not responded to standard systemic therapies, e.g. ciclosporin, methotrexate and PUVA
* or these treatments are contraindicated or the person cannot tolerate them

and recommended a traffic light classification of Double Red (Not recommended for routine use) until a treatment pathway has been agreed locally for this CCG-commissioning responsibility treatment, and a related business application supported.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations and decided that Ixekizumab (Taltz®) for treating moderate to severe plaque psoriasis as per NICE TA 442 (April 2017) is Not Commissioned until a treatment pathway for psoriasis has been agreed locally, and a related business application supported.

July 2017: The TAG supported an NNUH application and proposed Biological Treatment Pathway for psoriasis (the NNUH has been confirmed as a specialist centre for the treatment of psoriasis), with recommended amendments, and recommended revised traffic light classifications from Double Red (not recommended for routine use) to Red (Hospital/Specialist only) for apremilast, secukinumab and ixekizumab if used in line with NICE TA 419, NICE TA 350 and NICE TA 442 respectively (*although a business application for ixekizumab has yet to be submitted).

July 2017: The D&TCG noted the TAG's recommendations and decided to maintain the classifications as Double Red (Not recommended for routine use) in the interim, until the draft treatment pathway has been clarified and resubmitted.

September 2017: The TAG considered a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (Taltz®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only) as a third line option for treating moderate to severe plaque psoriasis in line with NICE TA 442 (April 2017) and the local treatment pathway.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation that Ixekizumab (Taltz®) is commissioned as a third line option for treating moderate to severe plaque psoriasis in line with NICE TA 442 , as specified in the local treatment pathway as Red (Hospital/Specialist only).

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Risankizumab *(Skyrizi®)* TAG recommendation: Nov 2019

for use in: Moderte to severe plaque psoriasis as per NICE TA596 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: August 2019.

Specific points: October 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation of September 2019. TA596 - August 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for routine use/not commissioned) until the psoriasis pathway has been approved for use. Pathway to return to TAG in November 2019.

December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA596 - August 2019 and the updated treatment pathway for 2-3 biologic options was noted and afforded a traffic light classification of Red (Hospital/Specialist use only)

Tildrakizumab *(Ilumetri®)* TAG recommendation: May 2019

for use in: Moderate to severe plaque psoriasis in adults - as per NICE TA 575 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2019.

Specific points: May 2019: The TAG acknowledged NICE TA 575 April 2019) which states:
1.1 Recommended by NICE as an option for plaque psoriasis in adults, only if:
* the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
* the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
* the company provides the drug according to the commercial arrangement.
1.2 Consider stopping tildrakizumab between 12 weeks and 28 weeks if there has not been at least a 50% reduction in the PASI score from when treatment started.
1.3 Stop tildrakizumab at 28 weeks if the psoriasis has not responded adequately. An adequate response is defined as:
* a 75% reduction in the PASI score (PASI 75) from when treatment started or
* a 50% reduction in the PASI score (PASI 50) and a 5 point reduction in DLQI from when treatment started.

The TAG recommended a traffic light classification of Red (Hospital / Specialist use only) in line with the Joint CSU / Trusts Business Application which was also considered by the TAG; the revised specialist treatment pathway for psoriasis to be brought to the July 2019 TAG meeting.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation in line with the joint CSU/Acute Trusts business application.

June 1029: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Tralokinumab *(Adtralza®)* TAG recommendation: Jun 2023

for use in: moderate to severe atopic dermatitis TA814 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

June 2023 - application accepted

Upadacitinib *(Rinvoq®)* TAG recommendation: Jun 2023

for use in: moderate to severe atopic dermatitis TA814 (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

June 2023 - application accepted

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ustekinumab *(Stelara®)* TAG recommendation: Nov 2012

for use in: Treatment of adults with moderate to severe psoriasis - as per NICE TA 180 and CG153 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: October 2012.

Specific points: NICE TA 180 (Sept 2009) recommends ustekinumab as a treatment option for adults with plaque psoriasis when
- the disease is severe with a PASI score of 10 or more and a Dermatology Life Quality Index score of more than 10
- and when the psoriasis has not responded to standard systematic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or the person is intolerant of or has a contraindication to these treatments
- and the manufacturer provides the 90 mg dose (two 45 mg vials) for people who weigh more than 100 kg at the same total cost as for a single 45 mg vial.

November 2012: The TAG acknowledged NICE CG 153 (October 2012 http://guidance.nice.org.uk/CG153)
Section 1.5.3.12 in the guidance now suggests that a clinician may consider changing to an alternative biological in adults if psoriasis has not responded adequately to the first biological drug treatment as defined at 10 weeks for infliximab, 12 weeks for etanercept and 16 weeks for adalimumab and ustekinumab. Where there has been an inadequate response to treatment with a second biologic the guidance states that "supra-specialist advice should be sought from a clinician with expertise in biological therapy".
The TAG recommended that Trusts revisit their business cases for this treatment and propose revised treatment pathway, to be forwarded to the Drugs & Therapeutics Commissioning Group (D&TCG).

December 2012: The D&TCG supported the NNUH's business case for treatment of severe psoriasis, including switching between biological drugs as per NICE CG 153, providing that there is no crossing between the arms of the treatment pathway described therein.

September 2017:
The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in plaque psoriasis.
The TAG agreed to support the pathway and to recommend revising the classification for use of Ixekizumab (Taltz®), Secukinumab (Cosentyx®) and Apremilast (Otezla®) from Double Red (Not recommended for routine use to Red (Hospital/Specialist only), to be used as a second line choice where anti-TNF contraindicated, depending on patient factors and co-morbidities, as stated in the local treatment pathway.

September 2017:
The local treatment pathway and the TAG's recommendations were noted and supported by the N&W D&TCG.

November 2017:
The TAG noted the update of NICE CG 153.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ustekinumab *(Stelara®)* TAG recommendation: Sep 2017

for use in: 2nd line (biologic) option for moderately to severely active Crohn's disease after previous treatment - as per NICE 456 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: July 2017: The TAG acknowledged NICE FAD (April 2017) and also an NNUH application and treatment pathway for treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. The TAG agreed that the treatment pathway would be amended to place ustekinumab ahead of vedolizumab in line with the NICE FAD on ustekinumab. The TAG was advised that local clinicians have previously indicated a preference for ustekinumab over vedolizumab.

Once the pathway was amended it would be shared with QEH and JPUH.

The TAG therefore recommended a traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation but decided to classify this treatment as Double Red (Not recommended for routine use) in the interim, until the NICE TA has been published and the draft treatment pathway clarified.

September 2017: The TAG considered a tabled paper outlining a proposed treatment pathway and recommendations for use of biologics in Crohn's disease.
The TAG agreed to support the pathway which recommended use of ustekinumab as a second line option for treating moderately to severely active Crohn's disease in adults.
The TAG therefore affirmed the previously recommended traffic light classification of Red (Hospital/Specialist only) for this CCG-commissioning responsibility treatment in line with NICE TA 456 (July 2017) and the local treatment pathway.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.
Use of ustekinumab as a second line option for treating moderately to severely active Crohn's disease in adults is commissioned as Red (Hospital/Specialist only) in line with NICE TA 456 (July 2017) and as specified in the local treatment pathway.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ustekinumab *(Stelara®)* TAG recommendation: Nov 2015

for use in: Treatment of active psoriatic arthritis, as monotherapy or in combination with methotrexate, following inadequate response to previous non-biological DMARDs - as per NICE TA 340 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2015.

Specific points: NICE TA 313 (May 2014)
Not recommended by NICE.

July 2014: NICE TA 313, which did not recommend use, noted by the TAG. Traffic light recommendation of Double Red (Not recommended for routine use).

July 2014: TAG recommendation noted by the Norfolk and Waveney CCGs D&TCG - not commissioned.

May 2015: The TAG noted the NICE FAD (March 2015) and agreed to recommend that a future classification for Ustekinumab (Stelara®) for treating active psoriatic arthritis in adults (rapid review of TA 313 May 2014) would be Red (Hospital use only) pending publication of the NICE TA guidance and the development of a treatment pathway.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and decided that the treatment is Not Commissioned - i.e. Double Red (Not recommended for routine use), pending publication of the related NICE Technology Appraisal Guidance.

July 2015: July 2015: The TAG noted the NICE TA 340 (June 2015) and recommended a revised classification of Red (Hospital only). (It was noted that this superseded the previous classification of Double Red (Not recommended for routine use/not commissioned) relating to NICE TA 313.)

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG acknowledged NICE TA 340 (June 2015) and noted the TAG's recommendation. The group decided it was necessary to determine the treatment's place in a clinical pathway before finalising a commissioning decision.

November 2015: The TAG noted and supported the NNUH's application in line with NICE TA 340 and recommended that Ustekinumab (Stelara®) for treatment of active psoriatic arthritis, as monotherapy or in combination with methotrexate, following inadequate response to previous non-biological DMARDs (as per NICE TA 340) 1. Treatment with TNF-alpha inhibitors would be considered but otherwise contraindicated.
2. The person received treatment with TNF-alpha inhibitors and either did not achieve good response or had to stop due to side-effects is classified as Red (Hospital / Specialist use only).

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ustekinumab *(Stelara)* TAG recommendation: Aug 2020

for use in: for treating moderately to severely active ulcerative colitis as per TA633 (June 2020) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: June 2020.

Specific points: July 2020 - The TAG acknowledged the guidance and recommended a classification of Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case and updated pathway. This recommendation was supported by the D+TC

August 2020 - The business case and pathway were supported by TAG and a classification of Red (Hospital / Specialist use only) was recommended. This was supported by the D+TC and ratified by the Norfolk and Waveney CCG Governing Body

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Ustekinumab *(Stelara®)* TAG recommendation: May 2018

for use in: Treatment of psoriasis and psoriatic arthritis in Paediatrics (where an adult NICE guidance is available - TAs 180, 340) - NHSE policy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Approved for use as per adult NICE TAs (TA180, TA340)

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Ustekinumab *(Stelara®)* TAG recommendation: Sep 2017

for use in: Plaque psoriasis in children and young people - as per NICE TA 455 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 455 (July 2017) and recommended traffic light classification of Red (Hospital/Specialist only)) for this SCG-commissioning responsibility treatment.
NICE recommends ustekinumab as an option for those aged 12 years or older, only if the disease:
* is severe, as defined by a total PASI of 10 or more
* has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated
Stop ustekinumab at 16 weeks, if the psoriasis has not responded adequately i.e. if a 75% reduction in the baseline PASI score has not been achieved.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.5.3 - Drugs affecting the immune response

Ustekinumab *(Stelara®)* TAG recommendation: Nov 2017

for use in: Dose escalation in the treatment of severe psoriasis which has responded inadequately to the initial ustekinumab dosage regimen (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: March 2017.

Specific points: November 2017:
The TAG considered the NNUH's application for this treatment regimen for increased doses and/or frequency of administration of ustekinumab (in line with licensed doses in the manufacturer's SPC and as recommended in the British Association of Dermatologists (BAD) guidelines for biologic therapy for psoriasis 2017), in a small number of patients who have only partially responded to standard treatment with ustekinumab. The aim is to optimise treatment without having to change the agent used.

The TAG agreed to support the application and recommended a classification of Red (Hospital/Specialist only) for consideration by the CCGs.

November 2017:
The Norfolk and Waveney Drugs & Therapeutics Commissionig Group (D&TCG) noted and supported the TAG's recommendations.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

13.6.2 - Oral preparations for acne

Isotretinoin *(Roaccutane®)* TAG recommendation: Apr 2005

for use in: Acne (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

13.6.2 - Oral preparations for acne

Isotretinoin *(Roaccutane®)* TAG recommendation: Nov 2012

for use in: All indications (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Not for prescribing in primary care on recommendation of local dermatology specialists.

Recommendation supported by the Drugs & Therapeutics Commissioning Group (D&TCG).

13.12 - Antiperspirants

Botulinum Toxin Type A *(Botox®)* TAG recommendation: Jan 2015

for use in: (severe) Focal hyperhidrosis - as per locally agreed policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: January 2015: Commissioning arrangements not yet finalised - awaiting the results of an audit of use of current treatments being prescribed in Primary Care and cost comparison with botulinum toxin.

June 2015:
The Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) agreed that they would be happy to commission the treatment in line with the priorities advisory committee (PAC) pathway for a period of 6 months - i.e. until the end of 2015. The service to then be audited to check clinical indication and determine numbers of patients being treated.

14.5 - Immunoglobulins

Anti-D immunoglobulin *(Various)* TAG recommendation: Apr 2000

for use in: Routine anti-D prophylaxis (RAADP) - as per NICE TA 156 (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE issued Guidance in: August 2008.

Specific points: August 2008: NICE Technology Appraisal Guidance No. 156 states that routine antenatal anti-D prophylaxis (RAADP) is recommended as a treatment option for all pregnant women who are rhesus D (RhD) negative and who are not known to be sensitised to the RhD antigen.
Preparations with the lowest associated acquisition cost available should be used.

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Human Normal Immunoglobulin (Aragam®) *(Aragam®)*

for use in: As per National Demand Management Plan - NHSE policy (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human Normal Immunoglobulin (Flebogamma®) *(Flebogamma®)*

TAG recommendation: May 2018

for use in: As per National Demand Management Plan (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011).

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human normal immunoglobulin (Gammagard®) *(Gammagard®)*

TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Human normal immunoglobulin (Gammanorm®) *(Gammanorm®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human normal immunoglobulin (Gammaplex®) *(Gammaplex®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human normal immunoglobulin (Gamunex®) *(Gamunex®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Human Normal Immunoglobulin (Hizentra) *(Hizentra®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy
Plan - NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human normal immunoglobulin (Intratect®) *(Intratect®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human normal immunoglobulin (IVIg) *(Privigen®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Immunoglobulin clinical guidelines (July 2011)

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Human Normal Immunoglobulin (Kiovig) *(Kiovig®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human Normal Immunoglobulin (Octagam) *(Octagam®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. Immunoglobulin clinical guidelines (July 2011)

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human Normal Immunoglobulin (Subcuvia®) *(Subcuvia®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE Policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Human Normal Immunoglobulin (Subgam®) *(Subgam®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human Normal Immunoglobulin (Vigam®) *(Vigam®)* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Human Normal Immunoglobulin (Vivaglobin®)) *(Vivaglobin® (for s-c infusion) (discontinued 2011))* TAG recommendation: May 2018

for use in: As per National Demand Management Plan - NHSE policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
HNI treatment is NHS England commissioning responsibility. As per Immunoglobulin clinical guidelines (July 2011) - use monitored on Quality Dashboard.
NHSE policy NHSCB/B09/PS/a (April 2013) - https://www.england.nhs.uk/wp-content/uploads/2013/04/b09-ps-a.pdf

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

14.5 - Immunoglobulins

Immunoglobulin ▼ *(Various; Octagam ▼)* TAG recommendation: Jul 2008

for use in: Various (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts N/A.

NICE has not issued any guidance.

Specific points: July 2008:
Demand Management Plan for Immunoglobulin Use - 2nd edition May 2008
The Department of Health has published this document in response to global supply shortages and supply problems specific to the UK.
The plan states that "GPs should not prescribe immunoglobulin; prescribing should be restricted to the specialist responsible for the patient's treatment."
The TAG therefore recommends that use of immunoglobulin is restricted to prescribing in Hospital only i.e. Red.

April 2013: Commissioning responsibility transferred to NHS England SCG.

15.2 - Local anaesthesia

Lidocaine Hydrocortisone mouthwash *()* TAG recommendation: Mar 2023

for use in: restricted specialist prescribing only for mouth pain and inflammation in autoimmune diseases and oncology (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

16.1 - Other items

Autologous anti-CD19-transduced CD3+ cells *(Tecartus®)* TAG recommendation: Mar 2021

for use in: relapsed or refractory mantle cell lymphoma as per TA677 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - TAG acknowledged the guidance and recommended a classification of Red (Hospital / Specialist use only)

17 - Non-BNF

Difelikefalin *(Kapruvia®)* TAG recommendation: Jun 2023

for use in: pruritus in people having haemodialysis TA890 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: May 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Red - 'Hospital / Specialist only'

Drugs for which the Trust is responsible for prescribing.

GPs should not be expected or approached to prescribe these drugs.

This list is not exhaustive, but indicates drugs for which a specific recommendation has been made by the Therapeutics Advisory Group.

The advice is specific to the indication.

In general this category covers:
- Drugs initiated by the Trust prior to transfer to GP prescribing as part of a shared-care protocol.
- Drugs prescribed as part of the preparation for a secondary care procedure:

17 - Non-BNF

Eladocagene exuparvovec *(Upstaza®)* TAG recommendation: Jun 2023

for use in: aromatic L-amino acid decarboxylase deficiency HST26 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Lumasiran *(Oxlumo®)* TAG recommendation: Jun 2023

for use in: hyperoxaluria type 1 HST25 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Onasemnogene abeparvovec *(Zolgensma®)* TAG recommendation: Jun 2023

for use in: spinal muscular atrophy HST15 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Onasemnogene abeparvovec *(Zolgensma®)* TAG recommendation: Jun 2023

for use in: presymptomatic spinal muscular atrophy HST24 (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: April 2023.

Specific points: Restricted use – Prescribing to remain with the hospital or specialist service. No prescribing in primary care

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.3.2 - Drugs for arrhythmias

Amiodarone *(Cordarone X®)* TAG recommendation: Jan 2023

for use in: Supraventricular and ventricular arrhythmias (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of.

NICE issued Guidance in: June 2014.

Specific points: NICE Clinical Guideline on Atrial Fibrillation published June 2006.

Prescribers should familiarise themselves with prescribing and monitoring advice contained in the manufacturer's Statement of Product Characteristics which is available via http://www.medicines.org.uk/emc/

Recommended Monitoring:
Thyroid function, LFT, U&E - every 6 months
Ophthalmological examination - annually
ECG - periodically
If pulmonary toxicity suspected, chest x-ray & lung function tests required.

July 2014: The TAG noted NICE CG 180 (June 2014) - Management of Atrial Fibrillation

May 2018:
The TAG recommended that GP prescribing and monitoring guidance for amiodarone be developed to support local use in primary care under the new CCGs' primary care drug monitoring LES.

July 2018:
The TAG supported a GP Prescribing and monitoring Guidance document to support its safe use in primary care.

July 2018:
The D&TC recommended that amiodarone should be classified as Level 3 under the CCGs' Local Enhanced Service agreement with GP practices for monitoring drug treatments in primary care.

Available via: https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=EHgd88MJpbk%3d&tabid=916&portalid=1&mid=2074

Jan 2023 - Existing guidance merged with RMOC SCA to create new shared care agreement. Classification amended to amber

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.3.2 - Drugs for arrhythmias

Dronedarone *(Multaq®)* TAG recommendation: Jan 2023

for use in: Non-permanent Atrial Fibrillation - for use only where amiodarone is contraindicated or has previously not been tolerated (except lung toxicity due to amiodarone) (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of one month.

NICE issued Guidance in: August 2010. There is a shared care protocol approved by TAG.

Specific points: September 2010:
The TAG considered a local proposal for use, an independent evidence review and noted NICE guidance as follows:
NICE TA 197: Dronedarone is recommended as an option for treatment of non-permanent AF only in people
* Whose AF is not controlled by 1st-line therapy, usually including beta-blockers and
* Who at least one of several specified cardiovascular risk factors and
* Who do not have unstable heart failure (NYHA Class III or IV)

The TAG agreed that:
*It would consider a revised proposal if dronedarone was placed after amiodarone, where amiodarone has not been tolerated.
* Definition of unacceptable effects related to amiodarone must be agreed and communicated clearly in any correspondence between specialists and GPs.
* The GP perspective is that the monitoring and side-effect profile of amiodarone is not a particular clinical issue.
* Dronedarone should NOT be offered where amiodarone has failed due to it having a similar mode of action and the DIONYSUS study showing it to be significantly inferior to amiodarone.

January 2011: The TAG considered a revised proposal for restricting use of dronedarone only where amiodarone is contraindicated e.g. in interstitial lung disease and thyroid disorders, has been proven to be not tolerated by patients previously treated with amiodarone.
The reasons for recommending use of dronedarone must be clearly stated in communications to GPs.

March 2011: The TAG noted recent MHRA safety reports regarding liver toxicity resulting in new requirements to monitor LFTs monthly for the first 6 months then 3-monthly, and increased risk of worsening or new onset heart failure associated with use of dronedarone.
The TAG recommended that a Shared Care Agreement is drawn up and is in place for at least a year to specify responsibilities for monitoring patients treated with dronedarone. The TAG accepted that safe systems are in place whilst an agreement is developed.

The TAG also welcomed clarification from the NNUH regarding which patients would be given dronedarone as follows:
Those patients with:
1) Demonstrated contraindication to amiodarone
a. Amiodarone-induced or pre-existing history of thyrotoxicosis
b. Amiodarone-induced or pre-existing history of pulmonary fibrosis (NB From Sept 2011 use of dronedarone is also contraindicated where there is history of lung toxicity due to amiodarone)
2) Intolerance of amiodarone
a. Specific allergic response
b. Intolerable GI disturbance
c. Unacceptable photo-sensitisation or additional risk (skin malignancy) - excluding patients with solar keratosis who are usually managed total sunblock and advice on avoiding sun exposure
3) Specific issues or concerns surrounding anti-coagulation
4) Specific pro-arrhythmic risk (unacceptable QT prolongation on amiodarone).

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.3.2 - Drugs for arrhythmias

November 2011: Following latest safety reports from the MHRA (http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131928) the TAG recommended that GPs should not be approached to take up any new prescribing for patients commenced on dronedarone until agreement has been reached on a shared care protocol.

The TAG agreed that:
* dronedarone should be re-classified as Red (Hospital Only) until a shared care protocol has been agreed.
* GPs are advised to identify any patients who are currently on dronedarone and ensure that adequate monitoring is carried out i.e. that their patients are still in sinus rhythm, are having appropriate blood monitoring and are not in heart failure.
* Patients failing to meet these criteria should be referred back to Secondary Care.

December 2011: The TAG Support Group approved a Shared Care Agreement devised in consultation with the NNUH Cardiologists. The traffic light status was therefore revised to Amber (option for GP prescribing under an approved shared care agreement).

January 2014: Revised Shared Care Agreement supported subject to amendments recommended by the TAG.
N&W CCGs D&TCG noted that the Shared Care Agreement had been revised.

July 2014: The TAG noted NICE CG 180 (June 2014) - Management of Atrial Fibrillation

May 2017: The TAG supported minor changes recommended by the authors of the shared care agreement and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an approved shared care agreement).

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

Jan 2023 - Existing SCA merged woth RMOC SCA and approved Jan 2023

2.5 - Heart failure treatments

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.5 - Heart failure treatments

Sacubitril / Valsartan ▼ *(Entresto® ▼)* TAG recommendation: Jul 2016

for use in: Symptomatic chronic heart failure with reduced ejection fraction in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 1 to 3 months until stable.

NICE issued Guidance in: April 2016.

Specific points: January 2016: The TAG noted that through the Early Access to Medicines scheme (EAMS), the drug is initially made available free of charge to the NHS. Novartis will manage all requests from specialist heart failure services and provide NHS England and CCGs with a regular update detailing the participating centres and the number of patients entered.

The TAG noted and supported the EoE PAC's recommendation to wait on the publication of NICE guidance before this treatment is used within the NHS.
The TAG had concerns that provision via EAMS would produce a cohort of patients already receiving treatment who may not fit any criteria later specified by NICE.
The TAG recommended a classification of Double Red (Not routinely commissioned) for this CCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations and confirmed Sacubitril / Valsartan (Entresto®) for treatment of symptomatic chronic heart failure with reduced ejection fraction in adults is not supported or commissioned ahead of NICE guidance - i.e. Double Red (Not recommended for rouitneroutinely commissioned).
Usual processes for commissioning the treatment would be followed if NICE publishes a positive technology appraisal for its use.

May 2016: The TAG noted NICE TA 388 (April 2016) for treatment in patients:
* with New York Heart Association (NYHA) class II to IV symptoms and
* with a left ventricular ejection fraction of 35% or less and
* who are already taking a stable dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs).
* Treatment should be started by a heart failure specialist with access to a multidisciplinary heart failure team.
* Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE CG 108 Chronic heart failure in adults: management.
And recommended a traffic light classification of Double Red (Not recommended for routine use/Not commissioned) pending the submission of a business case for this CCG-commissioning responsibility treatment.

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations and agreed that the treatment recommended in NICE TA 388 (April 2016) is maintained as Double Red (Not recommended for routine use/Not commissioned) pending the submission of a business case for this CCG-commissioning responsibility treatment.

July 2016: The TAG members agreed that the Sacubitril / Valsartan (Entresto®) should be re-classified as Red (Hospital/Specialist only) pending the submission and agreement on a shared care prescribing agreement,

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and agreed to commission the treatment as Red (Hospital/Specialist only). The D&TCG will review this commissioning position when a TAG-approved Shared Care Agreement is submitted for consideration.

The D&TCG recommended that such a Shared Care Proposal should state that the hospital specialists will manage patients on Sacubitril / Valsartan (Entresto®) for at least the first 3 months to ensure the patients are stabilised and are benefitting from treatment.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.5 - Heart failure treatments

The D&TCG also stated that the first 6 to 12 months' use of Sacubitril / Valsartan (Entresto®) in primary care under a TAG- approved Shared Care Agreement would be audited.

September 2016:
The TAG considered and supported the shared care proposal, subject to minor amendments to the text. The D&TCG noted and supported the shared care proposal, subject to minor changes to the text regarding GPs' participation in shared care agreements.

The shared care agreement can be accessed via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=ha4zGYckiNQ%3d&tabid=913&portalid=1&mid=2043f

November 2018: The TAG acknowledged NG 106 - Chronic heart failure in adults: diagnosis and management which includes recommendations on treating heart failure and the place of sacubitril / valsartan.

2.8.1 - Parenteral anticoagulant

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.1 - Parenteral anticoagulant

Heparin - Low Molecular Weight (LMWH) *(Various)*

TAG recommendation: Mar 2008

for use in: For patients requiring long term anticoagulation in whom warfarin is contraindicated or inappropriate (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: (Dalteparin, Enoxaparin, Tinzaparin)

March 2008:
Indication for Shared Care:
If an individual requires more than a few days anticoagulation treatment they are generally switched to oral therapy with warfarin. However there are certain situations where the prolonged use of heparin may be indicated:
* medium to long-term thromboprophylaxis for patients in whom oral anticoagulation is contraindi-cated (e.g. pregnancy).
* treatment of venous thromboembolism for patients in whom oral anticoagulation is contraindi-cated/ineffective (e.g. in pregnancy, certain patients with cancer, poor compliance.)
In these circumstances therapy with LMWH, which does not cross the placenta and is not interfered with by alcohol or other drugs, can be given subcutaneously.

A shared care agreement has been endorsed by haematology departments at the JPUH, NNUH and QEH.

Criteria for Patient Selection:
Patients requiring therapeutic or prophylactic anticoagulation who:
1. are pregnant (risk of teratogenicity with warfarin; other OACs not licensed)
2. have poor compliance/life style e.g. alcoholism and drug addiction
3. have high risk of bleeding e.g. existing thrombocytopenia / certain patients with cancer e.g. receiving myelosuppressive treatment
4. have thrombosis which is not controlled by an oral anticoagulant e.g. certain patients with cancer

September 2014: The TAG considered and supported a revised version of the local Shared Care Agreement which had been updated in line with current manufacturers' SPCs. The TAG agreed that it should be published as an interim agreement until wider commissioning arrangements are finalised.

September 2017: The revised draft of the shared care agreement had been reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes had been received from the authors / local specialists.
The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Accessible via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/lmwh.pdf

4.1.1 - Hypnotics

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.1.1 - Hypnotics

Melatonin prolonged-release tablets (Circadin) ▼ *(Circadin® ▼)* TAG recommendation: Mar 2011

for use in: Management of sleep disorders in children (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of up to 3 months.

NICE issued Guidance in: March 2009. There is a shared care protocol approved by TAG.

Specific points: MHRA guidance (August 2008: www.mhra.gov.uk/NewsCentre/CON023251): The licensed product available in the UK should be used wherever possible. This includes off-label use of the licensed product, if deemed suitable by the clinician.

March 2011: The Shared Care Agreement for Circadin for sleep disorders in children is available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2013: The TAG noted baseline audit results from NCH&C. Current version of shared care agreement to be extended until March 2014 pending publication of audit results from local specialist services (NCH&C). Request to add Bio-melatonin to current the Shared Care Agreement not supported in the interim.

N&W CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) supported the TAG recommendation. Melatonin prolonged- release (Circadin®) still commissioned as Amber (Option for GP prescribing under an approved shared care agreement).

July 2014: The TAG welcomed the final audit report on use of melatonin for sleep disorders in children presented by NCH&C and as a result agreed to support continued use of the Shared Care Agreement.

March 2017: The TAG and the NHS Norfolk & Waveney CCGs' D&TCG supported the additional criteria for use as outlined in the shared care agreement and recommended its continued use for the time being. This decision would be communicated to local providers.

The revised Shared Care Agreement is available for access via:
http://nww.knowledgeanglia.nhs.uk/tag/shared_care/circadin_sleep_disorders_children.pdf

Melatonin standard release *(Syncrodin, Adaflex)* TAG recommendation: Dec 2022

for use in: Management of sleep disorders in children (x).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of.

NICE has not issued any guidance.

Specific points: Shared Care Agreement updated Dec 2022

Standard release - Adaflex®
Film coated - Syncrodin®

Both preparations added to existing shared care agreement

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Atomoxetine *(Strattera®)* TAG recommendation: Jul 2015

for use in: Attention Deficit Hyperactivity Disorder in Adults for new treatment of symptoms that can be confirmed from childhood (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4 weeks.

NICE issued Guidance in: September 2008.

Specific points: In January 2015 the TAG agreed to support use of a Shared Care prescribing Agreement to support the newly commissioned specialist service (in Central and West Norfolk) for management and treatment of adults with ADHD, either diagnosed in childhood with continued need for treatment beyond adolescence, or newly diagnosed in adulthood.

The shared care agreement for Treatments for Adults with ADHD is available via the TAG's webpage at http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

July 2015: The TAG was advised that the Central and West Norfolk CCGs have not yet commissioned the NSFT service to support these patients and also use of the TAG's Shared Care prescribing Agreement. This was contrary to previous advice that services were available from April 2015. The Shared Care Agreement must therefore be withdrawn. TAG classification for these treatments to be revised from Amber to Black (In progress).
Conversely the TAG was also advised that GY&W CCG has now commissioned the NSFT service and that the Shared Care Agreement may now apply to their locality. The SCA to be published on the GY&W section of Knowledge Anglia. Re-classify as Amber (option for shared care prescribing) for this locality.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2015:
The TAG agreed to support further changes to the wording within the shared care document recommended by specialists at the NSFT to clarify use of the agreement.

October 2015:
Use of the revised shared care agreement supported by the Noroflk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (subject to commissioning arrangements being finalised in central and west Norfolk).

October 2015:
West Norfolk CCG confirmed that the specialist service for adults with ADHD has been commissioned in their area.

April 2016: Confirmation received that the central Norfolk CCGs have commissioned a specialist service for adults with ADHD from the NSFT - a unified N&W version of the Shared Care Agreement is published on Knowledge Anglia.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

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A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Atomoxetine *(Strattera® ▼)* TAG recommendation: May 2014

for use in: Attention Deficit Hyperactivity Disorder in Children & Adolescents (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of 8-12 wks/stable for 2 reviews.

NICE issued Guidance in: March 2006. There is a shared care protocol approved by TAG.

Specific points: January 2006 - Change in duration of specialist prescribing to "two outpatient appointments" to ensure stabilisation.
Shared Care Agreement revised to take account of recent MHRA guidance.
Available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

March 2006 NICE No.98: ADHD - methylphenidate, atomoxetine and dexamfetamine (review):
If a child or adolescent needs treatment with medication for ADHD, methylphenidate, atomoxetine and dexamfetamine are all recommended as possible choices. When deciding which to use, doctors should consider the following:

Whether the child or adolescent has other conditions such as epilepsy.
The side effects of each medicine.
Factors that might make it difficult for the person to take the medicine at the right time (for example, if it is difficult to take a dose during school hours).
The possibility that the medicine might be misused, or passed on to another person for misuse.
The individual preference of the child or adolescent and/or their family or carer. Where more than one of the medicines is considered to be appropriate for a child or adolescent, their doctor should choose the cheapest one.

Treatment with methylphenidate, atomoxetine or dexamfetamine should only be started after a specialist who is an expert in ADHD has thoroughly assessed the child or adolescent and confirmed the diagnosis. Once treatment has been started it can be continued and monitored by a GP.

September 2009 NICE CG for ADHD published.
May 2009: Shared Care agreement revised in line with NICE CG.

March 2012: Shared Care Agreement revised in line with MHRA-recommended monitoring requirements. The handover period has been increased to "Initiation and dose titration likely to be 8-12 weeks with at least 2 consecutive consultations with no change in dose."

Available via http://nww.knowledgenorfolk.nhs.uk/tag/shared_care/atomoxetine_for_adhd.pdf

March 2014: Review of Shared Care Agreement in progress.

May 2014: Responsibility for 6 -monthly montioring of height, weight, BP and pulse to be shared between speciaiists and GPs and results to be communicated between sectors to ensure that any trends in results indicating adverse effects of treatment are identified and acted upon, and treatment is reviewed as appropiate.

March - May 2017:
An updated version of the shared care agreement was noted and supported by the TAG.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

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The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

May 2019: The SCAs for use of Stimulants and for Atomoxetine for Children and adolescents with ADHD were reviewed and updated with reference to NG 87.
The TAG agreed that in view of local children's ADHD services being commissioned such that GPs could only refer children from age ≥ 6 years, that the age range as stated within the current SCAs should remain.
The TAG also agreed that the updated documents could be published.

May 2019: Noted and supported by the D&TC

TAG shared care agreement for atomoxetime in children and adolescents available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=g53Hm_iXLO4%3d&tabid=913&portalid=1&mid=2043

Amber - 'Option for Shared Care Prescribing'

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In the absence of a specific decision, general principles apply (see above).

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These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

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This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Dexamfetamine sulfate ▼ *(Use generic)* TAG recommendation: Jul 2015

for use in: Attention Deficit Hyperactivity Disorder in Adults for new treatment of symptoms that can be confirmed from childhood (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4 weeks.

NICE issued Guidance in: September 2008. There is a shared care protocol approved by TAG.

Specific points: In January 2015 the TAG agreed to support use of a Shared Care prescribing Agreement to support the newly commissioned specialist service (in Central and West Norfolk) for management and treatment of adults with ADHD, either diagnosed in childhood with continued need for treatment beyond adolescence, or newly diagnosed in adulthood.

The shared care agreement for Treatments for Adults with ADHD is available via the TAG's webpage at http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

July 2015: The TAG was advised that the Central and West Norfolk CCGs have not yet commissioned the NSFT service to support these patients and also use of the TAG's Shared Care prescribing Agreement. This was contrary to previous advice that services were available from April 2015. The Shared Care Agreement must therefore be withdrawn. TAG classification for these treatments to be revised from Amber to Black (In progress).
Conversely the TAG was also advised that GY&W CCG has now commissioned the NSFT service and that the Shared Care Agreement may now apply to their locality. The SCA to be published on the GY&W section of Knowledge Anglia. Re-classify as Amber (option for shared care prescribing) for this locality.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2015:
The TAG agreed to support further changes to the wording within the shared care document recommended by specialists at the NSFT to clarify use of the agreement.

October 2015:
Use of the revised shared care agreement supported by the Noroflk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (subject to commissioning arrangements being finalised in central and west Norfolk).

October 2015:
West Norfolk CCG confirmed that the specialist service for adults with ADHD has been commissioned in their area.

April 2016: Confirmation received that the central Norfolk CCGs have commissioned a specialist service for adults with ADHD from the NSFT - a unified N&W version of the Shared Care Agreement is published on Knowledge Anglia.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Amber - 'Option for Shared Care Prescribing'

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In the absence of a specific decision, general principles apply (see above).

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A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Dexamfetamine sulfate ▼ *(Generic)* TAG recommendation: Mar 1998

for use in: Attention Deficit Hyperactivity Disorder in children and adolescents (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of 4-8 wks / stable for 2 reviews.

NICE issued Guidance in: March 2006. There is a shared care protocol approved by TAG.

Specific points: NICE Guidance No. 98 (March 2006):
If a child or adolescent needs treatment with medication for ADHD, methylphenidate, atomoxetine and dexamfetamine are all recommended as possible choices. When deciding which to use, doctors should consider the following:

Whether the child or adolescent has other conditions such as epilepsy.
The side effects of each medicine.
Factors that might make it difficult for the person to take the medicine at the right time (for example, if it is difficult to take a dose during school hours).
The possibility that the medicine might be misused, or passed on to another person for misuse.
The individual preference of the child or adolescent and/or their family or carer.
Where more than one of the medicines is considered to be appropriate for a child or adolescent, their doctor should choose the cheapest one.

Treatment with methylphenidate, atomoxetine or dexamfetamine should only be started after a specialist who is an expert in ADHD has thoroughly assessed the child or adolescent and confirmed the diagnosis. Once treatment has been started it can be continued and monitored by a GP.

September 2008 NICE CG for ADHD published.

May 2009: Shared Care agreement revised in line with NICE CG.

March 2012: Shared Care Agreement revised in line with current clinical practice. Handover period reduced and now states - "Initiation and dose titration and stabilisation for at least two consecutive consultations with no change in dose. Usually 4-8 weeks with patient contact to clarify dosage and side effects."

March 2017:
An updated version of the shared care agreement was noted and supported by the TAG. The issue of whether GPs should have responsibility for annual review of height, weight, BP and pulse results would be revisited at the May 2017 TAG meeting.

Revised Shared Care Agreement available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

May 2019: The SCAs for use of Stimulants and for Atomoxetine for Children and adolescents with ADHD were reviewed and updated with

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

reference to NG 87.
The TAG agreed that in view of local children's ADHD services being commissioned such that GPs could only refer children from age ≥ 6 years, that the age range as stated within the current SCAs should remain.
The TAG also agreed that the updated documents could be published.

May 2019: Noted and supported by the D&TC

TAG shared care agreement for stimulants for ADHD in children and adolescents available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=j12y-zAhUQY%3d&tabid=913&portalid=1&mid=2043

Guanfacine Prolonged-Release ▼ *(Intuniv® ▼)* TAG recommendation: Dec 2022

for use in: Treatment of ADHD in children and adolescents where stimulants are not suitable, not tolerated or ineffective. (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for use of Guanfacine Prolonged-Release (Intuniv®) for children aged 6-17yr with ADHD for whom stimulants are not suitable, not tolerated or have been shown to be ineffective, in line with the NCH&C / NSFT joint application.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation. Commissioned as Red (Hospital/Specialist only) as a last line treatment option.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

Dec 2022 - Shared Care Agreement, based on RMOC national guidance, accepted for use.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Lisdexamfetamine Mesilate ▼ *(Elvanse® ▼)* TAG recommendation: Nov 2013

for use in: ADHD in children aged 6 years and over, up to 17 years when response to previous methylphenidate treatment is considered clinically inadequate (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4-8 wks / stable for 2 reviews.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: Recommended as Amber (Option for shared care and an approved Shared Care Agreement). Prescriber's rating: Possibly helpful. However the interim classification is Red - Hospital Only, until a written Shared Care Agreement is approved.

D&TCG Decision: Commissioned as Red (Hospital / Specialist Only) pending the development of an approved Shared Care Agreement, to be accompanied by a business case and treatment pathway.

November 2013: The TAG considered the revised shared care agreement for CNS stimulants for ADHD related disorders in children aged at least 6 years old and adolescents and supported the agreement subject to the recommended amendments.

November 2013: Revised Shared Care Agreement supported by the D&TCG.

March 2017:
An updated version of the shared care agreement was noted and supported by the TAG. The issue of whether GPs should have responsibility for annual review of height, weight, BP and pulse results would be revisited at the May 2017 TAG meeting.

Revised Shared Care Agreement available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

May 2019: The SCAs for use of Stimulants and for Atomoxetine for Children and adolescents with ADHD were reviewed and updated with reference to NG 87.
The TAG agreed that in view of local children's ADHD services being commissioned such that GPs could only refer children from age ≥ 6 years, that the age range as stated within the current SCAs should remain.
The TAG also agreed that the updated documents could be published.

May 2019: Noted and supported by the D&TC

TAG shared care agreement for stimulants for ADHD in children and adolescents available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=j12y-zAhUQY%3d&tabid=913&portalid=1&mid=2043

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Lisdexamfetamine Mesilate ▼ *(Elvanse®)* TAG recommendation: Jul 2015

for use in: Attention Deficit Hyperactivity Disorder in adults (if continued from childhhood) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4 weeks.

NICE issued Guidance in: September 2008. There is a shared care protocol approved by TAG.

Specific points: In January 2015 the TAG agreed to support use of a Shared Care prescribing Agreement to support the newly commissioned specialist service (in Central and West Norfolk) for management and treatment of adults with ADHD, either diagnosed in childhood with continued need for treatment beyond adolescence, or newly diagnosed in adulthood.

The shared care agreement for Treatments for Adults with ADHD is available via the TAG's webpage at http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

July 2015: The TAG was advised that the Central and West Norfolk CCGs have not yet commissioned the NSFT service to support these patients and also use of the TAG's Shared Care prescribing Agreement. This was contrary to previous advice that services were available from April 2015. The Shared Care Agreement must therefore be withdrawn. TAG classification for these treatments to be revised from Amber to Black (In progress).
Conversely the TAG was also advised that GY&W CCG has now commissioned the NSFT service and that the Shared Care Agreement may now apply to their locality. The SCA to be published on the GY&W section of Knowledge Anglia. Re-classify as Amber (option for shared care prescribing) for this locality.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2015:
The TAG agreed to support further changes to the wording within the shared care document recommended by specialists at the NSFT to clarify use of the agreement.

October 2015:
Use of the revised shared care agreement supported by the Noroflk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (subject to commissioning arrangements being finalised in central and west Norfolk).

October 2015:
West Norfolk CCG confirmed that the specialist service for adults with ADHD has been commissioned in their area.

April 2016: Confirmation received that the central Norfolk CCGs have commissioned a specialist service for adults with ADHD from the NSFT - a unified N&W version of the Shared Care Agreement is published on Knowledge Anglia.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

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This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Methylphenidate HCl *(Various - see Shared Care Agreement)* TAG recommendation: Jul 2015

for use in: ADHD in adults who had previously been treated, or who had symptoms identified, in childhood or adolescence (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4 weeks.

NICE issued Guidance in: September 2008. There is a shared care protocol approved by TAG.

Specific points: In January 2015 the TAG agreed to support use of a Shared Care prescribing Agreement to support the newly commissioned specialist service (in Central and West Norfolk) for management and treatment of adults with ADHD, either diagnosed in childhood with continued need for treatment beyond adolescence, or newly diagnosed in adulthood.

The shared care agreement for Treatments for Adults with ADHD is available via the TAG's webpage at http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

July 2015: The TAG was advised that the Central and West Norfolk CCGs have not yet commissioned the NSFT service to support these patients and also use of the TAG's Shared Care prescribing Agreement. This was contrary to previous advice that services were available from April 2015. The Shared Care Agreement must therefore be withdrawn. TAG classification for these treatments to be revised from Amber to Black (In progress).
Conversely the TAG was also advised that GY&W CCG has now commissioned the NSFT service and that the Shared Care Agreement may now apply to their locality. The SCA to be published on the GY&W section of Knowledge Anglia. Re-classify as Amber (option for shared care prescribing) for this locality.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2015:
The TAG agreed to support further changes to the wording within the shared care document recommended by specialists at the NSFT to clarify use of the agreement.

October 2015:
Use of the revised shared care agreement supported by the Noroflk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (subject to commissioning arrangements being finalised in central and west Norfolk).

October 2015:
West Norfolk CCG confirmed that the specialist service for adults with ADHD has been commissioned in their area.

April 2016: Confirmation received that the central Norfolk CCGs have commissioned a specialist service for adults with ADHD from the NSFT - a unified N&W version of the Shared Care Agreement is published on Knowledge Anglia.

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

consideration in due course.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

Methylphenidate HCl *(Various - see Shared Care Agreement)* TAG recommendation: Mar 1998

for use in: Attention Deficit Hyperactivity Disorder in Children and Adolescents (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of 4-8 wks / stable for 2 reviews.

NICE issued Guidance in: March 2006. There is a shared care protocol approved by TAG.

Specific points: NICE Guidance No. 98 (March 2006):
If a child or adolescent needs treatment with medication for ADHD, methylphenidate, atomoxetine and dexamfetamine are all recommended as possible choices. When deciding which to use, doctors should consider the following:

Whether the child or adolescent has other conditions such as epilepsy.
The side effects of each medicine.
Factors that might make it difficult for the person to take the medicine at the right time (for example, if it is difficult to take a dose during school hours).
The possibility that the medicine might be misused, or passed on to another person for misuse.
The individual preference of the child or adolescent and/or their family or carer.
Where more than one of the medicines is considered to be appropriate for a child or adolescent, their doctor should choose the cheapest one.

Treatment with methylphenidate, atomoxetine or dexamfetamine should only be started after a specialist who is an expert in ADHD has thoroughly assessed the child or adolescent and confirmed the diagnosis. Once treatment has been started it can be continued and monitored by a GP.

November 2007:
The TAG debated the issue regarding continued drug treatment of ADHD in patients diagnosed in childhood who have reached adult age. The TAG agreed that that there are reasonable grounds to continue treatment where it has been assessed as being beneficial. Drug holidays should be considered to check for continued need. The TAG acknowledged the current lack of specialist services available to manage adults requiring treatment for ADHD.

January 2008: The welcomed the news that the NWMHP NHS Trust is currently discussing the service needs of older ADHD patients.

March 2008: The TAG approved the addition of Medikinet XL® to the protocol. Issues related to responsibility for management of patients >18 years as yet unresolved.

September 2008 NICE CG for ADHD published.

May 2009: Shared Care agreement revised in line with NICE CG.

March 2012: Shared Care Agreement revised in line with current clinical practice. Handover period reduced and now states - "Initiation and dose titration and stabilisation for at least two consecutive consultations with no change in dose. Usually 4-8 weeks with patient contact to clarify dosage and side effects."
Available at: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/stimulants_for_adhd.pdf

March 2015: The TAG was advised that Xenidate XL® tablets are a cost-effective option in the treatment of symptoms of ADHD and related

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - CNS stimulants and drugs used for ADHD

disorders with pharmacokinetic equivalence to the brand leader Concerta XL®.
The committee therefore agreed to support use of this product as a cost effective treatment option under the current shared care prescribing arrangements for managing this clinical condition.
i.e. as Amber (Option for GP prescribing under an approved Shared Care Agreement)

March 2015: The NHS Norfolk & Waveney CCGs' D&TCG was advised of the TAG's recommendation to support use of cost-effective and clinically equivalent products to standard treatment, and agreed that where appropriate, clinicians should move their patients to the most cost-effective products at treatment reviews.

March 2017:
An updated version of the shared care agreement was noted and supported by the TAG. The issue of whether GPs should have responsibility for annual review of height, weight, BP and pulse results would be revisited at the May 2017 TAG meeting.

Revised Shared Care Agreement available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

May 2018: The TAG acknowledged NG 87 (March 2018) - Attention deficit hyperactivity disorder: diagnosis and management - which updates and replaces NICE CG72 (September 2008) and NICE technology appraisal guidance 98 (2006) - and noted in particular that baseline ECGs are now required if the treatment being considered may affect the QT interval - this applies to methylphenidate, atomoxetine, lisdexamfetamine (Link), and possibly to dexamfetamine and guanfacine.
The current shared care agreements for stimulants and atomoxetine will be reviewed with reference to NG 87 and returned for the TAG's consideration in due course.

May 2019: The SCAs for use of Stimulants and for Atomoxetine for Children and adolescents with ADHD were reviewed and updated with reference to NG 87.
The TAG agreed that in view of local children's ADHD services being commissioned such that GPs could only refer children from age ≥ 6 years, that the age range as stated within the current SCAs should remain.
The TAG also agreed that the updated documents could be published.

May 2019: Noted and supported by the D&TC

TAG shared care agreement for stimulants for ADHD in children and adolescents available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=j12y-zAhUQY%3d&tabid=913&portalid=1&mid=2043

4.8.1 - control of epilepsy

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.8.1 - control of epilepsy

Cenobamate *(Ontozry®)* TAG recommendation: Mar 2023

for use in: focal onset seizures in epilepsy as per TA753 (x).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until stable.

NICE issued Guidance in: December 2021.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

March 2023 - shared care agreement accepted

4.9.3 - Drugs used in essential tremor, chorea, tics etc.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.9.3 - Drugs used in essential tremor, chorea, tics etc.

Riluzole *(Rilutek®)* TAG recommendation: Jul 2007

for use in: Amyotrophic Lateral Sclerosis (Motor Neurone Disease) (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of 3 months.

NICE issued Guidance in: January 2001. There is a shared care protocol approved by TAG.

Specific points: NICE: Riluzole is recommended for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND).
Riluzole therapy should be prescribed and maintained by a neurological specialist with expertise in the management of MND.

In July 2007 the TAG agreed to support use of a shared care agreement developed by neurologists at the NNUH for use of riluzole in amyotrophic lateral sclerosis.

November 2009: Shared Care Agreement reviewed (no changes) and approved by the TAG.

January 2013: The TAG agreed that on-going monitoring responsibility for patients on riluzole after the initial 3 month period should be returned to the hospital specialist (3-monthly bloods to be taken in primary care but results to be interpreted by the specialist).

May 2013: Confirmation of agreement with the NNUH received. Recommended changes to the Shared Care Agreement made.

September 2015:
In view of there being on-going prescribing by GPs, the TAG recommended that riluzole should remain as a shared care prescribing option. A revised version of the shared care prescribing agreement was recommended for continued use by the TAG.

October 2015:
Use of the revised shared care prescribing agreement was supported by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group.

March 2016: The TAG noted NG 42 (February 2016) Motor neurone disease (MND): assessment and management

January 2018: The TAG agreed to support continued use of the revised shared care agreement for this treatment.

January 2018: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

The document is available on Knowledge Management via
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=AuO3oJhWyg0%3d&tabid=913&portalid=1&mid=2043

4.10 - Drugs used in substance dependence

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.10 - Drugs used in substance dependence

Naltrexone *(Nalorex® / Opizone®)* TAG recommendation: Mar 2012

for use in: Alcohol Use Disorder - maintenance of abstinence only (under an approved shared care agreement) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe until the patient's treatment is stabilised.

NICE issued Guidance in: February 2011. There is a shared care protocol approved by TAG.

Specific points: GPs may be requested to take over prescribing after 4 weeks' treatment when the patient has achieved abstinence from drinking alcohol.
Prescribing responsibility for use of naltrexone for controlled drinking should remain with the specialist service - see separate entry (Red).

(NICE Clinical Guideline 115 (Feb 2011) provides guidance on the diagnosis, assessment and management of harmful drinking and alcohol dependence in adults and in young people aged 10-17 years.)

March 2012: the TAG approved a Shared Care Agreement to support GP prescribing of naltrexone for abstinence in Alcohol Use Disorder. Available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

March 2014: Shared Care Agreement reviewed and supported by the TAG and D&TCG.

November 2016: The TAG supported recommended changes to the Shared Care Prescribing Agreement for Naltrexone for Abstinence in Alcohol Use Disorder. The revised version is published on Knowledge Anglia via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm.

4.11 - Drugs for dementia

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

Donepezil *(Aricept®; Generics available)* TAG recommendation: May 2011

for use in: Mild to moderate Alzheimer's dementia - as per NICE TA 217 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of four months.

NICE issued Guidance in: March 2011.

Specific points: A Dementia Assessment and Treatment Pathway is available via the Knowledge Management service.

May 2011: The TAG noted NICE Technology Appraisal 217 (Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease
Review of NICE technology appraisal guidance 111) which states:
The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the guidance. Specifically:
- donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and
- memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease.

November 2015:
A Shared Care prescribing Agreement for dementia treatments, including donepezil is now available via:
http://nww.knowledgeanglia.nhs.uk/tag/shared_care/dementia_treatments.pdf

November 2015: The TAG and the D&TCG also noted NICE NG 16 (October 2015) Dementia, disability and frailty in later life - mid-life approaches to delay or prevent onset
Main recommendations:
* stop smoking
* be more active
* reduce their alcohol consumption
* improve their diet and,
* lose weight and maintain a healthy weight if necessary.

July 2018:
The TAG acknowledged an update of NICE TA 217 (June 2018) and new guidance NG97 on dementia which updates the TA. The guidance included several recommendations regarding drug treatment of dementia which will necessitate review of current arrangements.The item to be returned to the TAG for further discussion.

July 2018:
The D&TC noted in particular
1.6: Medicines that may cause cognitive impairment - which highlighted the need to consider increased anticholinergic burden related to some medicines used long term and the associated risk of cognitive impairment.

September 2018:
The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia.
The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. Suffolk GP Prescribing Guidance (same guidance

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

used across both CCGs) to be shared and a Task & Finish Group set up to take this item forward.
It was later proposed that this work is discussed by the STP Dementia Group.

November 2018:
The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease.

January 2019: No update on progress was available from the NSFT.

March 2019:
The TAG noted that this item was be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No changes to the current traffic light classifications were agreed.

Sept 2021 - Shared Care Agreement updated in Feb 2021 to include all the dementia drugs in one document. GP to prescribe donepezil, galantamine, rivastigmine or memantine at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

Galantamine *(Reminyl®)* TAG recommendation: May 2011

for use in: Mild to moderate Alzheimer's dementia - as per NICE TA 217 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of four months.

NICE issued Guidance in: March 2011.

Specific points: A Dementia Assessment and Treatment Pathway is available via the Knowledge Management service.

May 2011: The TAG noted NICE Technology Appraisal 217 (Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease
Review of NICE technology appraisal guidance 111) which states:
The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the guidance. Specifically:
- donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and
- memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease.

November 2015:
A Shared Care prescribing Agreement for dementia treatments, including donepezil is now available via:
http://nww.knowledgeanglia.nhs.uk/tag/shared_care/dementia_treatments.pdf

November 2015: The TAG and the D&TCG also noted NICE NG 16 (October 2015) Dementia, disability and frailty in later life - mid-life approaches to delay or prevent onset
Main recommendations:
* stop smoking
* be more active
* reduce their alcohol consumption
* improve their diet and,
* lose weight and maintain a healthy weight if necessary.

July 2018:
The TAG acknowledged an update of NICE TA 217 (June 2018) and new guidance NG97 on dementia which updates the TA. The guidance included several recommendations regarding drug treatment of dementia which will necessitate review of current arrangements.The item to be returned to the TAG for further discussion.

July 2018:
The D&TC noted in particular
1.6: Medicines that may cause cognitive impairment - which highlighted the need to consider increased anticholinergic burden related to some medicines used long term and the associated risk of cognitive impairment.

September 2018:
The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia.
The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. Suffolk GP Prescribing Guidance (same guidance

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

used across both CCGs) to be shared and a Task & Finish Group set up to take this item forward.
It was later proposed that this work is discussed by the STP Dementia Group.

November 2018:
The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease.

January 2019: No update on progress was available from the NSFT.

March 2019:
The TAG noted that this item was be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No changes to the current traffic light classifications were agreed

Sept 2021 - Shared Care Agreement updated in Feb 2021 to include all the dementia drugs in one document. GP to prescribe donepezil, galantamine, rivastigmine or memantine at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

Memantine *(Ebixa® (generics also available))* TAG recommendation: Jul 2011

for use in: Moderate to severe dementia in Alzheimer's Disease - as per NICE TA 217 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of 7 to 8 weeks ('til 2nd review).

NICE issued Guidance in: March 2011. There is a shared care protocol approved by TAG.

Specific points: May 2011: The TAG noted NICE Technology Appraisal 217 (Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease
Review of NICE technology appraisal guidance 111) which states:
The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the guidance. Specifically:
- donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and
- memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease.

July 2011: The TAG agreed to support in principle a Shared Care proposal for use of memantine as per NICE TA 217.

December 2011: Final version of a Shared Care Agreement for use of memantine approved by the NHS N&W Drugs & Therapeutics Commissioning Group.

March 2014: Shared Care Agreement reviewed and supported by the TAG and D&TCG.

November 2015: The TAG and the D&TCG also noted NICE NG 16 (October 2015) Dementia, disability and frailty in later life - mid-life approaches to delay or prevent onset
Main recommendations:
* stop smoking
* be more active
* reduce their alcohol consumption
* improve their diet and,
* lose weight and maintain a healthy weight if necessary.

January 2017:
The Shared Care Agreement for memantine in Alzheimer's Disease was reviewed and updated. The revised version was supported by the TAG and the D&TCG.
This is available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

July 2018:
The TAG acknowledged an update of NICE TA 217 (June 2018) and new guidance NG97 on dementia which updates the TA. The guidance included several recommendations regarding drug treatment of dementia which will necessitate review of current arrangements.The item to be returned to the TAG for further discussion.

July 2018:
The D&TC noted in particular
1.6: Medicines that may cause cognitive impairment - which highlighted the need to consider increased anticholinergic burden related to some

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

medicines used long term and the associated risk of cognitive impairment.

September 2018:
The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia.
The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. Suffolk GP Prescribing Guidance (same guidance used across both CCGs) to be shared and a Task & Finish Group set up to take this item forward.
It was later proposed that this work is discussed by the STP Dementia Group.

November 2018:
The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease.

January 2019: No update on progress was available from the NSFT.

March 2019:
The TAG noted that this item was be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No changes to the current traffic light classifications were agreed.

March 2019:
The D&TC noted the TAG's position and also recommended that the TAG revisits to current recommendation that memantine is restricted to use as monotherapy only, in view of the recommendations within to the 2018 NICE guidance which support adjunctive use with an AChEI.

Sept 2021 - Shared Care Agreement updated in Feb 2021 to include all the dementia drugs in one document. GP to prescribe donepezil, galantamine, rivastigmine or memantine at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

Rivastigmine *(Exelon®)* TAG recommendation: May 2011

for use in: Mild to moderate dementia in Alzheimer's Disease - as per NICE TA 217 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of four months.

NICE issued Guidance in: March 2011.

Specific points: A Dementia Assessment and Treatment Pathway is available via the Knowledge Management service.

May 2011: The TAG noted NICE Technology Appraisal 217 (Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease
Review of NICE technology appraisal guidance 111) which states:
The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the guidance. Specifically:
- donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and
- memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease.

November 2015:
A Shared Care prescribing Agreement for dementia treatments, including donepezil is now available via:
http://nww.knowledgeanglia.nhs.uk/tag/shared_care/dementia_treatments.pdf

November 2015: The TAG and the D&TCG also noted NICE NG 16 (October 2015) Dementia, disability and frailty in later life - mid-life approaches to delay or prevent onset
Main recommendations:
* stop smoking
* be more active
* reduce their alcohol consumption
* improve their diet and,
* lose weight and maintain a healthy weight if necessary.

July 2018:
The TAG acknowledged an update of NICE TA 217 (June 2018) and new guidance NG97 on dementia which updates the TA. The guidance included several recommendations regarding drug treatment of dementia which will necessitate review of current arrangements.The item to be returned to the TAG for further discussion.

July 2018:
The D&TC noted in particular
1.6: Medicines that may cause cognitive impairment - which highlighted the need to consider increased anticholinergic burden related to some medicines used long term and the associated risk of cognitive impairment.

September 2018:
The TAG was asked to reconsider in more detail the updated and new recommendations in the above guidance that will impact on current commissioned arrangements for prescribing and monitoring drug treatments for patients with dementia.
The TAG noted that in Suffolk dementia drugs have been classified as "Green" since 2015. Suffolk GP Prescribing Guidance (same guidance

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

used across both CCGs) to be shared and a Task & Finish Group set up to take this item forward.
It was later proposed that this work is discussed by the STP Dementia Group.

November 2018:
The TAG requested that a proposed treatment pathway be submitted for consideration to enable to group to consider revising the current position regarding drug treatment for Dementia / Alzheimer's Disease.

January 2019: No update on progress was available from the NSFT.

March 2019:
The TAG noted that this item was be managed as part of wider STP-led pathway review work, and therefore agreed to remove it from the TAG's agenda until commissioning arrangements for this patient group were clarified. No changes to the current traffic light classifications were agreed.

March 2019:
The D&TC noted the TAG's position and also discussed how to influence dementia specialists initiating patients on costly rivastigmine transdermal patches. To be raised at NSFT's DTC meeting, and with Mental Health commissioners

Sept 2021 - Shared Care Agreement updated in Feb 2021 to include all the dementia drugs in one document. GP to prescribe donepezil, galantamine, rivastigmine or memantine at the dose advised by the specialist at initiation, or any alternative dose determined by the outcome of monitoring provided by the Memory Assessment and Treatment Service (MATS). Prescribe for up to three months during the initiation phase whilst patient is in the care of the MATS and continue following discharge from specialist service after successful initiation.

5.1.7 - Polymyxin antibiotics

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

5.1.7 - Polymyxin antibiotics

Colistimethate sodium (Nebulised) *(Colomycin®, Promixin®)* TAG recommendation: Jul 2013

for use in: Ps. aeurginosa infection in non-Cystic Fibrosis bronchiectasis (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of one moth.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: Given in-house at NNUH on a case by case basis as approved by microbiology. The TAG considered a request for patients who can tolerate it and for whom it is effective to have on-going treatment provided by Primary Care. Colistemethate is used first-line at the moment. Emerging evidence that nebulised gentamicin is more effective with potential for cost savings.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decision:
Nebulised Colistimethate sodium, or nebulised gentamicin for Ps. aeurginosa infection in non-CF bronchiectasis are commissioned as Red (Hospital /Specialist Only) until a Shared Care Agreement has otherwise been approved via the TAG.

July 2013: NNUH Shared Care Proposal following business application (May 2013) -
Only issue is the provision of syringes in primary care. The document will be reworded to reflect the fact that syringes would be supplied by the Trusts.
Nebulised Colistimethate sodium for (non-CF) bronchiectasis was therefore recommended to be classified as Amber (Option for GP prescribing under an approved shared care agreement).

The D&TCG noted that it was likely that GPs had been prescribing for these patients as for patients with cystic fibrosis.
Costly treatment - use in Primary care will be monitored.

Confirmed as CCG-commissioning responsibility for this indication.
Commissioned as per TAG recommendation.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

January 2019: The TAG noted and supported a revised version of the Shared Care Agreement for use of nebulised colistin for this indication.

Shared Care Agreement available via
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=tz4MVU8QL5Y%3d&tabid=913&portalid=1&mid=2043

January 2019: The TAG acknowledged NICE NG 117 (December 2018) - Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing.

March 219: The TAG considered feedback received from the QEH and the NNUH respiratory specialists which recommended on-going use of the Shared Care Agreement in adults and in children, and also in line with recently published BTS Guidance for Bronchiectasis in Adults, and until a consensus national view by respiratory specialists is available.

The TAG noted that whilst the BTS guidance relates to adults, the local shared care agreement covered use of nebulised colistin in both adults and children, and felt that more work was required on this matter.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

5.1.7 - Polymyxin antibiotics

The TAG agreed that it is necessary to ensure that nebulised colistin is being used only for appropriate reasons. Since this issue is also likely to apply in other areas beyond the Norfolk and Waveney, the TAG recommended that the EoE PAC is requested to consider reviewing this issue.

March 2019:
The D&TC also recommended that the local Antimicrobial Steering Group also be requested to take a view on this matter.

6.1.2.3 - Other antidiabetic drugs

Dapagliflozin *(Forxiga®)* TAG recommendation: Oct 2021

for use in: chronic heart failure with reduced ejection fraction as per TA679 (x).
Prescribing responsibility: Not recommended for routine use.

NICE issued Guidance in: February 2021.

Specific points: March 2021 - awaiting submission of business case

October 2021 - TAG approved the use of SCA and Prescribing Guidance document.

Traffic light classification of AMBER LEVEL 0 - Prescribe drug and perform basic monitoring eg. standard annual review

Empagliflozin *(Jardiance®)* TAG recommendation: Jul 2023

for use in: chronic heart failure with reduced ejection fraction as per TA773 (x).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of first two prescriptions.

NICE issued Guidance in: March 2022. There is a shared care protocol approved by TAG.

Specific points: July 2023 - formulary application accepted. Will be added to Dapagliflozin shared care agreement

6.4.2 - Male sex hormones and antagonists

Testosterone *(Sustanon 250®, Restandol® Testocaps®)* TAG recommendation: Jan 2021

for use in: management of boys with absent/delayed puberty requiring exogenous testosterone therapy (x).
Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: Jan 2021 - The D+TC accepted the SCA proposal and awarded an amber level 2 classification due to the administration requirements. Hospital Specialist to prescribe first injection. Ratified by CCG Governing Body

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.4.2 - Male sex hormones and antagonists

Testosterone *(various)* TAG recommendation: Aug 2022

for use in: Use in women during menopause (x).

Prescribing responsibility: Consultant/Specialist should prescribe until the patient's treatment is stabilised.

NICE has not issued any guidance.

Specific points: No NHS prescribing in primary or secondary care pending review of evidence

Dec 2021 - shared care agreement agreed and Amber 1 classification recommended. Ratified by CCG Governing Body in March 2022

Aug 2022 - amended to Amber level 0

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Denosumab *(Prolia®)* TAG recommendation: Nov 2014

for use in: Prevention of osteoporotic fractures in postmenopausal women as per NICE TA 204 (Shared care in the central Norfolk and Great Yarmouth & Waveney CCGs) (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE issued Guidance in: October 2010. There is a shared care protocol approved by TAG.

Specific points: NICE TA 204 states:
1.1 Denosumab is recommended as a treatment option for the primary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures:
* who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments and
* who have a combination of T-score , age and number of independent clinical risk factors for fracture (see section 1.3) specified in the guidance.
1.2 Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments.
1.3 For the purposes of this guidance, independent clinical risk factors for fracture are parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.
1.4 People currently receiving denosumab for the primary or secondary prevention of osteoporotic fragility fractures who do not meet the criteria specified in recommendations 1.1 or 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

March 2011: The TAG considered applications for use of denosumab from the NNUH and the JPUH as per NICE TA 204 and made the following recommendations:
The TAG agreed to accept the evidence for use of denosumab, and potential benefits for patients, if use and monitoring was supported by a Shared Care Agreement. Denosumab may be used in preference to strontium ranelate and to zoledronic acid as per applications from the NNUH and the JPUH.
Denosumab will be classified as Amber (option for GP prescribing under an approved Shared Care Agreement), with the first dose to be administered in secondary care. Subsequent doses would be given 6-monthly in Primary Care, allowing ample time for communication between the hospital and the GP. The TAG maintains the current recommendation of Red (Hospital Only), until a Shared Care Agreement is approved for use across NHS GtY&W and NHS Norfolk (subject to approval by the PCTs' commissioning decision-making bodies).

July 2011: Shared Care proposal developed by the NNUH with input from specialists at the QEH and the JPUH supported by the TAG.

On December 22nd 2011, the NHS Norfolk Drug & Therapeutics Commissioning Group decided to support the Shared Care Agreement and commissioned use as an 'Amber drug' for primary and secondary prevention in line with NICE TA 204.

March 2014: Shared Care Agreement reviewed and supported by the TAG and D&TCG.

November 2014: The Agreement reviewed and amended in line with the EMA/MHRA safety review which resulted in updated recommendations to minimise osteonecrosis of the jaw (ONJ) and hypocalcaemia during treatment. The TAG made further recommendations regarding new monitoring requirements:
At initiation of treatment the patient's baseline calcium levels must be checked - to be carried out by the secondary care prescriber.
Regarding the follow-up calcium level check required after two weeks, the clinician doing the initial check should also issue an ICE form for the second blood test.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Primary care should then arrange the blood tests required prior to subsequent doses given 6-monthly thereafter.
The TAG supported the shared care agreement with the recommended amendments.

November 2014: The D&TCG noted and supported the TAG recommendation.

The Shared Care Agreement is available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/denosumab.pdf

April 2015: A local agreement exists in West Norfolk CCG whereby the osteoporosis specialist nurse will assess and approve denosumab initiation in primary care for suitable patients i.e. Green (Suitable for GPs to prescribe following specialist recommendation) - see the West Norfolk CCG website for further details.

January 2017: The TAG supported the revised version of the shared care agreement.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

January 2019: The TAG supported the revised shared care agreement. Available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=ecuOI4x_qYE%3d&tabid=913&portalid=1&mid=2043

6.7.2 - Drugs affecting gonadotrophins

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.7.2 - Drugs affecting gonadotrophins

Goserelin *(Zoladex®)* TAG recommendation: Sep 2014

for use in: Management of endometriosis; pre-operative management of uterine fibroids - as per NICE NG 73 (A licensed indication).

Prescribing responsibility: Consultant responsible for the first script.

NICE issued Guidance in: September 2017. There is a shared care protocol approved by TAG.

Specific points: November 2007: Revision of a shared care agreement orginally developed in 2005.
The shared care agreement, "LHRH Agonist Treatment", also covers use of leuprorelin acetate and triptorelin.
GPs may switch their patients to the most appropriate product irrespective of the treatment initated by the hospital.

May 2012: Revised version supported by the TAG and use approved by the NHS N&W D&TCG.

September 2014: The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

September 2017:
The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2017: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Available via the Knowledge Anglia website: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/lhrh_agonists.pdf

November 2017:
The TAG acknowledged NICE NG 73 (September 2017) - Endometriosis: diagnosis and management, which updates and replaces the recommendations on endometriosis in NICE's fertility problems guideline (CG 156), which includes recommendations on fertility tests and treatments such as assisted reproduction.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.7.2 - Drugs affecting gonadotrophins

Leuprorelin acetate *(Prostap® SR)* TAG recommendation: Sep 2014

for use in: Management of endometriosis; pre-operative management of uterine fibroids (A licensed indication).

Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: November 2007: Revision of a shared care agreement orginally developed in 2005.
GPs may switch their patients to the most appropriate product irrespective of the treatment initated by the hospital.

May 2012: Revised version supported by the TAG and use approved by the NHS N&W D&TCG.

November 2017:
The TAG acknowledged NICE NG 73 (September 2017) - Endometriosis: diagnosis and management, which updates and replaces the recommendations on endometriosis in NICE's fertility problems guideline (CG 156), which includes recommendations on fertility tests and treatments such as assisted reproduction.
November 2017;

September 2014: The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

September 2017:
The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2017: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Available in Knowledge Anglia via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/lhrh_agonists.pdf

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.7.2 - Drugs affecting gonadotrophins

Triptorelin *(Decapeptyl® SR; Gonapeptyl® Depot)* TAG recommendation: Sep 2014

for use in: Management of endometriosis; pre-operative management of uterine fibroids (A licensed indication).
Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: November 2007: Revision of a shared care agreement orginally developed in 2005.
The shared care agreement, "LHRH Agonist Treatment", also covers use of goserelin and leuprorelin acetate.
GPs may switch their patients to the most appropriate product irrespective of the treatment initated by the hospital.

May 2012: Revised version supported by the TAG and use approved by the NHS N&W D&TCG.

September 2014: The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

September 2017:
The TAG supported continued use of the revised Shared Care Agreement for this treatment.

September 2017: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Available in Knowledge Anglia via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/lhrh_agonists.pdf

November 2017:
The TAG acknowledged NICE NG 73 (September 2017) - Endometriosis: diagnosis and management, which updates and replaces the recommendations on endometriosis in NICE's fertility problems guideline (CG 156), which includes recommendations on fertility tests and treatments such as assisted reproduction.

8.1.3 - Antimetabolites

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.1.3 - Antimetabolites

Mercaptopurine 50mg tablets *(Puri-Nethol®)* TAG recommendation: Jul 2007

for use in: Steroid-sparing effect in ulcerative colitis and Crohn's disease (Not a licensed indication).
Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: September 2012: Revised version of the Shared Care Agreement approved by the TAG.

September 2014: The TAG supported the continued use of the revised Shared Care Agreement.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

May 2017: The TAG supported the minor changes recommended by the author / editor to the shared care agreement, including avice on handling split tablets when reduced doses are required, and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an approved shared care agreement).

The TAG also clarified that the agreement applies to use in adults, and is for use of 50mg tablets which may be split by the patient using a tablet cutter, if necessary, where a 25mg dose is recommended by the specialist. The patient will be advised about safe handling of split tablets by the specialist team as part counselling about their treatment. This message should be reinforced at the point of dispensing.

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Available via the Knowledge Anglia website: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/mercaptopurine_for_ibd.pdf

8.1.5 - Other antineoplastic drugs

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.1.5 - Other antineoplastic drugs

Hydroxycarbamide (Hydroxyurea) 500mg capsules *(Generics are available - 500mg capsules only)* TAG recommendation: Sep 2017

for use in: CML / Myeloproliferative disorders requiring cytoreduction (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe until the patient's treatment is stabilised.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: March 2008: The TAG recommended that all oral anticancer medicines identified by the National Patient Safety Agency (NPSA) in the Rapid Response Report "Risks of incorrect dosing of oral anti-cancer medicines" (January 2008), for which there are no locally agreed shared care protocols, are classified as Red (Hospital Only).

May 2008:
The TAG approved a shared care protocol for hydroxycarbamide developed by the NNUH, in consultation with QEH and the JPUH.
September 2012: shared care agreement reviewed and approved by the TAG.
Available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2009 - The TAG noted legal guidance stating that PCTs should not be compelled to fund more costly licensed products (i.e. Siklos) over established generic products that do not hold specific marketing authorisation.

November 2014: The shared care agreement was reviewed and was for existing patients as new patients on this treatment are now NHS England (SCG) commissioning responsibility. The TAG agreed that continued use of the shared care agreement was appropriate for the time being. Responsibility for advising patients to avoid becoming dehydrated to be covered by specialist. Other minor changes noted and supported.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

September 2017: The revised draft shared care agreement was reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes were received from the authors / local specialists.
The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

8.2.1 - Antiproliferative immunosuppressants

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

Azathioprine *(Imuran®)* TAG recommendation: May 2016

for use in: As a steroid-sparing effect in patients with Autoimmune Diseases in whom steroids cannot be reduced or are contraindicated, and for maintaining remission in vasculitis (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until stable dose for 6 weeks.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: May 2016: Shared Care Proposal For use as a steroid-sparing effect in patients with Autoimmune Diseases in whom steroids cannot be reduced or are contraindicated, and for maintaining remission in vasculitis - including those with:
* connective tissue diseases e.g. systemic lupus erythematosus and vasculitis, dermatomyositis and polymyositis,
* myasthenia gravis,
* autoimmune hepatitis (including overlap syndromes with primary biliary cirrhosis and primary sclerosing cholangitis),
* autoimmune cytopenias (immune thrombocytopenic purpura and autoimmune haemolytic anaemia),
* Pemphigus vulgaris (Licensed indication), Autoimmune bullous disorders, Atopic eczema, Pyoderma Gangrenosum, Chronic Actinic dermatitis, atopic dermatitis

The TAG noted that initiation of therapy should be by the appropriate specialist team which would be clarified on the shared care document. The TAG supported the shared care proposal and recommended a traffic light classification of Amber (Option for Shared Care Prescribing).

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the Shared Care Agreement for Azathioprine for use as a steroid-sparing effect in patients with Autoimmune Diseases in whom steroids cannot be reduced or are contraindicated, and for maintaining remission in vasculitis and commissioned the treatment as Amber (Option for Shared Care Prescribing) under the approved Shared Care Agreement.

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

Azathioprine *(Generics are available)* TAG recommendation: Jul 2007

for use in: Steroid-sparing effect in ulcerative colitis and Crohn's disease (Not a licensed indication).
Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: September 2012: Revised version of the Shared Care Agreement was approved by the TAG.

September 2014: The TAG supported the continued use of the revised Shared Care Agreement.

September 2014: The Norfolk & Waveney CCGs D&TCG noted a supported the TAG recommendation.

May 2017: The TAG supported the minor changes to the shared care agreement recommended by the authors and agreed to recommend continued use of the revised document as Amber (Option for GP prescribing under an approved shared care agreement).

May 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Available via the Knowledge Anglia website: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/azathioprine_for_ibd.pdf

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

Mycophenolate Mofetil *(Generic)* TAG recommendation: Jan 2017

for use in: For use as an immunosuppressive agent in the treatment of connective tissue disease and other autoimmune conditions managed by Rheumatology, Gastroenterology, Dermatology, Neurology and Nephrology (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until stable dose for 6 weeks.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: November 2016:
The TAG recommended a traffic light classification of Red (Hospital/Specialist only) for use of Mycophenolate Mofetil for use as an immunosuppressive agent in the treatment of connective tissue disease and other autoimmune conditions managed by Rheumatology, Gastroenterology, Dermatology, Neurology and Nephrology, pending the submission and agreement of a revised shared care proposal.

November 2016: The NHS Norfolk & Waveney CCGs' noted the TAG recommendation pending the submission and agreement of a shared care proposal.

January 2017: The TAG supported the revised shared care proposal and recommended a revised classification of Amber (Option for GP prescribing under an approved shared care agreement).
The TAG also noted that patients referred to Papworth Hospital for treatment of interstitial lung disease are likely to be managed with reference to a specific shared care agreement for mycophenolate mofetil from that hospital trust.
Reference to that document to be added to the local shared care proposal with respect to use by respiratory specialists for interstitial lung disease.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation of a revised classification of Amber (Option for GP prescribing under an approved shared care agreement).

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

January 2019: The TAG supported the revised shared care agreement regarding changes to the wording in the document to clarify that use for Interstitial Lung Disease is not limited to patients under Papworth's care.
Available via: https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=rvCVOTFpBfw%3d&tabid=913&portalid=1&mid=2043

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

Mycophenolate mofetil / Mycophenolic acid *(Arzip®, CellCept® / Myfortic®)*

TAG recommendation: Mar 2018

for use in: Immunosuppression in adult renal transplant patients - as per NICE TA 481 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of at least 3 months.

NICE issued Guidance in: September 2004. There is a shared care protocol approved by TAG.

Specific points: NICE TA No. 85 states:
1.3 Mycophenolate mofetil is recommended for adults as an option as part of an immunosuppressive regimen only:
· where there is proven intolerance to calcineurin inhibitors, particularly nephrotoxicity leading to risk of chronic allograft dysfunction, or
· in situations where there is a very high risk of nephrotoxicity necessitating minimisation or avoidance of a calcineurin inhibitor.
1.5 These recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Clinicians prescribing these drugs should ensure that patients are aware of this, and that they consent to their use in such circumstances.

April 2006 NICE No. 99:
NICE has made the following recommendations about the use of immunosuppressive drugs in children and adolescents receiving kidney transplants:
Doctors should consider using mycophenolate mofetil as part of immunosuppressive treatment after kidney transplantation only when a person has to stop taking a calcineurin inhibitor, or has to take a lower dose.

(NICE does not recommend the use of mycophenolate sodium as part of immunosuppressive regimens for children or adolescents undergoing kidney transplantation.)

September 2009: The TAG ratified an updated version of the shared care agreement which included details of the risk of Pure Red Cell Aplasia (PRCA) which was highlighted by the MHRA in July 2009.

September 2012: The TAG ratified a revised version of the agreement which also included Arzip® (MMF) and Myfortic® (mycophenolic acid as mycophenolate sodium). The different salt forms are not interchangeable and should not be switched because of pharmacokinetic differences.

November 2014: The shared care agreement was reviewed and the TAG recommended under "Specialist Monitoring" that an amendment be made stating "the specialist will provide the patient directly with an ICE form to receive phlebotomy from their nearest service. The TAG supported continued use of the agreement subject to the amendments.

November 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Although this treatment is SCG-commissioning responsibility the continued use of a Shared Care Agreement is required until repatriation of prescribing responsibility from primary care is complete (unlikely before April 2016).

Shared care document available via: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

March 2015: The TAG noted and acknowledged the NHSE (Renal Transplant Clinical Reference Group - CRG) SSC 1466 (January 2015) regarding the cost-effective use of transplant immunosuppressants.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.1 - Antiproliferative immunosuppressants

March 2015: The Norfolk & Waveney CCGs' D&TCG noted the NHSE SSC 1466 (January 2015).

May 2016: The TAG and the N&W D&TCG agreed to extend use of the shared care agreement until May 2017 whilst repatriation of patients to specialist care is on-going.

November 2017:
The TAG acknowledged NICE TA 481 (Oct 17) and re-affirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement) for mycophenolate mofetil / mycophenolic acid, which is a SCG-commissioning responsibility treatment, the costs of which are currently being recouped by the CCGs from NHS England to cover any prescribing by GPs.
The use of the current shared care agreement to be extended until the end of March 2018 when use of all local shared care agreements is to be reviewed.

November 2017:
The TAG's recommendation to extend use of the shared care agreement was noted and supported by the D&TCG.

March 2018: The TAG supported a revised version of the shared care agreement which had been updated in line with other SCA for use in autoimmune disease regarding guidance added regarding the need for effective contraception in patients taking MMF and their partners as per MHRA drug safety warning (Feb 2018).

March 2018:
Noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee.

April 2018: Noted and supported by the Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC).

8.2.2 - Corticosteroids and other immunosuppressants

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

Ciclosporin *(Various brands - to be specified by prescribers)* TAG recommendation: Jul 2011

for use in: Rheumatic and dermatological diseases. (A licensed indication).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until stable dose for 6 weeks.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: Guidance developed initially in relation to second-line drugs in the treatment of Rheumatoid Arthritis) and later extended to cover use of ciclosporin in psoriasis. GPs can opt for a shared care arrangement whereby they claim a fee for monitoring patients for whatever indication the patient is taking the medication. Details of claims to be confirmed with individual PCT prescribing advisers.

July 2011: The TAG supported a shared care proposal for use in rheumatology and dermatology developed by the NNUH (with input from the JPUH), subject to recommended amendments being finalised.

The TAG's recommendation was supported and approved by the NHS Norfolk Drug & Therapeutics Commissioning Group on 21st July 2011.

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

Shared Care Agreement available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

Sirolimus *(Rapamune®)* TAG recommendation: Nov 2017

for use in: Immunosuppression in adult renal transplantation - as per NICE TA 481 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of 3 months.

NICE issued Guidance in: October 2017. There is a shared care protocol approved by TAG.

Specific points: November 2005
NICE TA 85 states:
1.4 Sirolimus is recommended for adults as an option as part of an immunosuppressive regimen only in cases of proven intolerance to calcineurin inhibitors (including nephrotoxicity) necessitating complete withdrawal of these treatments.
1.5 These recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Clinicians prescribing these drugs should ensure that patients are aware of this, and that they consent to their use in such circumstances.
In the absence of an locally approved Shared Care Protocol, prescribing responsibility remains with hospital specialists unless Good Practice for Shared Care is followed.

April 2006 NICE No. 99:
NICE made the following recommendations about the use of immunosuppressive drugs in children and adolescents receiving kidney transplants:
NICE does not recommend the use of sirolimus as part of immunosuppressive regimens for children or adolescents undergoing kidney transplantation, except when a patient has had to stop taking calcineurin inhibitors because of their side effects.

September 2012: Shared Care Agreement reviewed and approved by the TAG.

November 2014: The shared care agreement was reviewed and the TAG recommended that under the "Specialist Monitoring" section a change be made regarding the requirement for blood testing. "The specialist will provide the patient directly with an ICE form to receive phlebotomy from their nearest service. The TAG supported the continued use of the agreement subject to the recommended amendments. The agreement to be reviewed in May 2016.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Although this is an SCG commissioning responsibility continued use of the Shared Care Agreement is required until repatriation of prescribing responsibility from primary care is complete (unlikely before April 2016).

Shared care document available via: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

March 2015: The TAG noted and acknowledged the NHSE SSC 1466 (January 2015) regarding the cost-effective use of transplant immunosuppressants.

March 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the NHSE SSC 1466 (January 2015).

May 2016: The TAG and the N&W D&TCG agreed to extend use of the shared care agreement until May 2017 whilst repatriation of patients to specialist care is on-going.

November 2017:

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

The TAG acknowledged NICE TA 481 (Oct 17) and re-affirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement) for sirolimus which is a SCG-commissioning responsibility treatments, the costs of which are currently being recouped by the CCGs from NHS England to cover any prescribing by GPs. The use of the current shared care agreement to be extended until the ned of March 2018.

NICE TA 481 also states that sirolimus, is not recommended as an initial treatment to prevent organ rejection in adults having a kidney transplant.
The TAG therefore also recommended a traffic light classification of Double Red (Not recommended for routine use) for this indication.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

Tacrolimus (oral) *(Various)* TAG recommendation: Nov 2014

for use in: Immunosuppressive therapy to prevent organ rejection in renal transplant in adults - as per NICE TA 481 (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of 3 months.

NICE issued Guidance in: September 2004. There is a shared care protocol approved by TAG.

Specific points: November 2004:
The TAG noted NICE TAG No. 85 which stated:
1.2 Tacrolimus is an alternative to ciclosporin when a calcineurin inhibitor is indicated as part of an initial or a maintenance immunosuppressive regimen in renal transplantation for adults. The initial choice of tacrolimus or ciclosporin should be based on the relative importance of their side-effect profiles for individual people.
1.5 These recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Clinicians prescribing these drugs should ensure that patients are aware of this, and that they consent to their use in such circumstances.

July 2012: The TAG noted Commission on Human Medicines letter:
Oral tacrolimus prescribed/ dispensed by brand to avoid medication errors regarding the importance of ensuring that the same brand is correctly and consistently provided in order to prevent toxicity and rejection.

September 2012: Shared Care Agreement reviewed and approved by the TAG.

November 2014: The Shared Care Agreement was reviewed with a recommendation for a change regarding the requirement for blood testing to state "the specialist will provide the patient directly with an ICE form to receive phlebotomy from their nearest service." The TAG supported continued use of the Agreement subject to the recommended amendments. The Agreement to be reviewed further in May 2016.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

Although SCG commissioning responsibility, continued use of a Shared Care Agreement is required until repatriation of prescribing responsibility from primary care is complete (unlikely before April 2016).

Shared care document available via: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

March 2015: The TAG noted and acknowledged the NHSE SSC 1466 (January 2015) regarding the cost-effective use of transplant immunosuppressants.

March 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted the NHSE SSC 1466 (January 2015).

May 2016: The TAG and the N&W D&TCG agreed to extend use of the shared care agreement until May 2017 whilst repatriation of patients to specialist care is on-going.

November 2017:
The TAG acknowledged NICE TA 481 (Oct 17) and re-affirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement) for immediate-release tacrolimus, which is a SCG-commissioning responsibility treatment, the costs of which

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids and other immunosuppressants

are currently being recouped by the CCGs from NHS England to cover any prescribing by GPs.
The use of the current shared care agreement to be extended until the end of March 2018 when use of all local shared care agreements is to be reviewed.

November 2017:
The TAG's recommendation to extend use of the shared care agreement was noted and supported by the D&TCG.

Tacrolimus (oral) *(Generic option to be used)* TAG recommendation: Jan 2014

for use in: Induction of remission, in combination with steroids, in patients with mild-moderate Ulcerative Colitis which is unresponsive to steroids and 5-ASA preparations (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 4 months (1st review).

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: July 2013:
The TAG noted NICE CG 166 (June 2013)
(Drug recommendations p 14-22)
Azathioprine and mercaptopurine are already options for shared care in Norfolk and Waveney (Amber - option for GP prescribing under an approved shared care agreement).
Other recommended treatments are not specified under TAG traffic lights for use in UC.
e.g. aminosalicylates, corticosteroids, oral tacrolimus, ciclosporin

The NNUH has one or two patients who are being treated in-house with oral tacrolimus for UC. There is currently no shared care agreement in place for this treatment.

January 2014: NNUH business case received and clinical use supported by TAG. Interim classification of Red (Hospital only) recommended with revised shared care proposal to be reviewed by the TAG in March 2014 for agreement and review of traffic light recommendation.
N&W CCGs-D&TCG noted the TAG recommendation and agreed that this is an in-tariff treatment for this indication. Use of the most cost-effective generic treatment is required. Shared Care proposal to be reviewed in line with previous version used for transplant patients. GP monitoring responsibilities to be discussed with GP CCG representatives and LMC.

March 2014: March 2014: Shared Care proposal reviewed and supported by the TAG and D&TCG.

March 2017: The TAG and the NHS Norfolk & Waveney CCGs' D&TCG reviewed and supported continued use of the shared care agreement.

Available for access via Knowledge Anglia at:
http://nww.knowledgeanglia.nhs.uk/tag/shared_care/tacrolimus_ulcerative_colitis.pdf

8.3.4 - Hormone antagonists

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4 - Hormone antagonists

Triptorelin *(Decapeptyl® SR)* TAG recommendation: Nov 2014

for use in: Treatment of precocious puberty, menorrhagia and dysmenorrhoea in children (A licensed indication).

Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: The TAG agreed to support use of a Shared Care Agreement for a licensed product for conditions which develop in small numbers of patients.

November 2009: Shared Care Agreement devleoped by the NNUH reviewed (no changes appplied) and approved for use by the TAG.

November 2012:
Shared Care Agreement devleoped by the NNUH reviewed (no changes appplied) and approved for use by the TAG and the D&TCG.

November 2014: The shared care agreement was reviewed and there were no major changes. The TAG recommended adding a statement that the specialist should be contacted if there are any problems related to this treatment.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

January 2017:
The revised shared care agreement was supported by the TAG and the D&TCG.

Available via the Knowledge Management website:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=u5B_myQ7RyM%3d&tabid=913&portalid=1&mid=2043

9.1.3 - hypopplasmic,

Darbepoetin alfa *(Aranesp)* TAG recommendation: May 2021

for use in: treatment of anaemia in chronic kidney disease (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: D+TC supported the new shared care agreement. They recommended the third tier of monitoring which equates to a traffic light classification of Amber Level 2. Consultant / Specialist to prescribe and arrange ongoing supply via homecare services. GP will be responsible for routine monitoring, as per details in shared care agreement

9.4.1 - Drugs used in platelet disorders

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

9.4.1 - Drugs used in platelet disorders

Anagrelide ▼ *(Xagrid® ▼ / Agrelin® / Agrylin®)* TAG recommendation: Sep 2017

for use in: Thrombocythaemia (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe until the patient's treatment is stabilised until the patient is stable.

NICE has not issued any guidance.

Specific points: November 2012: Shared Care Agreement reviewed and available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/anagrelide_for_thrombocythaemia.htm.

Shared care will continue subject to funds being transferred back from Trusts to cover primary care prescribing of this in-tariff treatment.

November 2014: Minor changes to the shared care agreement were noted and supported. The TAG supported the continued use of the shared care agreement.

November 2014: The NHS Norfolk & waveney CCGs D&TCG noted and supported the TAG recommendation.

September 2017: The revised draft shared care agreement was reviewed and updated in line with the manufacturer's SPCs. No further recommendations for changes were received from the authors / local specialists.
The TAG supported its continued use and confirmed a classification of Amber (Option for GP prescribing under an approved shared care agreement).

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

9.5.1.2 - Hypercalcaemia & hypercalciuria

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

9.5.1.2 - Hypercalcaemia & hypercalciuria

Cinacalcet *(Mimpara®)* TAG recommendation: Mar 2022

for use in: primary hyperparathyroidism where parathyroidectomy is contraindicated, refused by patient or not suitable as per NHSE policy 16034/P (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of.

NICE has not issued any guidance.

Specific points: November 2015: The NHS Norfolk & Waveney CCGs' TAG noted the policy which has been developed by Public Health and recommended that use should be specified as only in patients with symptomatic severe Primary Hyperparathyroidism (PHPT), where normalisation of calcium is desirable, but in whom surgery is not indicated or is contraindicated for medical reasons.
An amended final version of the policy to be disseminated to the Trusts.

The policy states:
Cinacalcet is an effective therapy in patients with symptomatic severe PHPT, in whom normalisation of calcium is desirable, but in whom surgery is not indicated or contraindicated for medical reasons and fulfil one or more of the following criteria:

* Overt manifestation of primary hyperparathyroidism (e.g. nephrolithiasis, osteitis fibrosa cystica, neuromuscular disease)
* Corrected serum calcium >3mmol/L
* Urine Calcium>10mmol/24hours
* Bone density reduced at any site to a T score of <2.5mmol/L (osteoporosis)
* Impaired renal function
* Creatinine clearance reduced by >30%
* Young Age (Age<50years)

November 2015: The D&TCG noted the TAG recommendation and decided on a classification of Red (Hospital/Specialist only) for this treatment.
The policy will be avialable on Knowledge Anglia via http://nww.knowledgeanglia.nhs.uk/ppmm_nor.aspx

November 2016: NHSE has assumed commissioning responsibility for cinacalcet for primary hyperparathyroidism.
The locally approved (CCG-commissioned) policy for this treatment was revoked.
Cinacalcet is now being provided via specialist centres only; the TAG traffic light classification for use of cinacalcet for Primary Hyperparathyroidism, remains as Red (Hospital / Specialist use only), but is now an SCG-commissioned treatment.

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted that Cinacalcet for primary hyperparathyroidism is commissioned by NHS England via specialist centres.
The D&TCG supported the TAG's recommendation of Red (Hospital / Specialist use only) and confirmed that the previously agreed CCG commissioning policy will be revoked.
Individual Funding Requests for this treatment must therefore be submitted to NHSE.

March 2022 - Shared Care Agreement agreed by the TAG and ratified by Governing Body

10.1.3 - Drugs which suppress the rheumatic disease process

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

Leflunomide *(Arava®)* TAG recommendation: Sep 2008

for use in: Rheumatoid arthritis and psoriatic arthritis (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of until dose stable for 6 weeks.

NICE issued Guidance in: February 2009. There is a shared care protocol approved by TAG.

Specific points: April 2000: Use in rheumatoid arthritis supported.
September 2008: Extended use in psoriatic arthritis supported.
November 2008: Revised shared care agreement approved by the TAG.

March 2009: The TAG noted the NICE Clinical Guideline No.79 - Management of Rheumatoid Arthritis in adults.

November 2010: Shared care agreement reapproved with no changes.

January 2013: Shared care agreement reapproved with no changes.

July 2015: Shared care agreement reapproved with no significant changes

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

Shared care prescribing information available via Knowledge Management http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

Methotrexate (oral) *(Matrex® - generics are available)* TAG recommendation: Nov 2003

for use in: Use in severe psoriasis; inflammatory bowel disease; rheumatoid arthritis; connective tissue disease (Various indications).

Prescribing responsibility: Consultant should prescribe for an initial period of until stable dose for 6 weeks.

NICE issued Guidance in: February 2009. There is a shared care protocol approved by TAG.

Specific points: Prescribers should only prescribe, and pharmacies and dispensing practices should only stock 2.5mg strength tablets, with reference to the recommendations arising from the Cambridgeshire enquiry into the circumstances surrounding a death due to methotrexate overdose.
Orginal packs, with tablets blister-packed in foil is also recommended.
Only exception would be use of 10mg tablets in hospital for high doses used in oncology .

February 2009: The TAG noted NICE Clinical Guideline 79 - Rheumatoid Arthritis

January 2013: Indications for Shared Care revised to include Connective Tissue Disease and Felty's Syndrome. Revised Shared Care Agreement supported by the TAG and the D&TCG.

July 2015: Shared Care Agreement reviewed. Clarification that the specialist has responsibility for the first blood test. Also updated in line with current format.

July 2016:
The TAG was advised that revised Arthritis Research UK advice, states that men no longer need to stop taking methotrexate before trying to conceive.

The TAG noted the information provided and agreed that the local shared care agreement should be updated in line with this guidance.

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

March 2018: The TAG agreed revisions to the text regarding specifiying use in Crohn's disease rather than IBD; the need to ensure continuity in injection devices; removal of discontinued pre-filled syringe Methofill; responsibility for dosage changes specified to be of the specialist (not the GP); frequency of recommended monitoring to be specified in the letter to GPs.

May 2018: The TAG supported the addition of a statement supporting GPs to provide varicella vaccination to the very small number of patients who are identified by the specialist service as being non-immune to varicella (chickenpox) prior to them starting treatment with methotrexate.

May 2018: Supported by the D&TC.

The revised SCA available via: http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=fw6_x7LG9cw%3d&tabid=913&portalid=1&mid=2043

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Psoriasis which had been updated with the most recent NICE guidance on all psoriasis treatments to date. The main difference is in the order of treatments.
Other CCGs have accepted use of two biologics treatments but not a third. NICE guidance alludes to third line treatment saying that this can be given by supra-specialists. This has proven problematic for the QEH as they are not able to offer supra-specialist advice.
The pathway provided shows all the NICE-recommended treatments available with discussions to take place regarding the third biologic at either the EoE PAC or regionally.
Switching between apremilast and dimethyl fumarate, which have different mechanisms of action and may be more cost effective than using biologics also needs to be considered in the future.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendation

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

Methotrexate (Parenteral) *(Metoject/Nordimet pens; Zlatal syringes)* TAG recommendation: May 2004

for use in: Subcutaneous use in inflammatory bowel disease, psoriasis; rheumatoid arthritis; connective tissue disease (Various indications).
Prescribing responsibility: Consultant should prescribe for an initial period of until stable dose for 6 weeks.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: Dose errors have caused fatalities. Norfolk shared-care guidelines should be followed to protect staff and patients from this cytotoxic drug. Robust method of communicating dosage alterations is fundamental to patient safety.

Guidelines and a shared care protocol for use of methotrexate in the community were reviewed by TAG in May 2004 and are broadly supported. Education and training of primary care staff in administration of injectable methotrexate is provided NNUH Rheumatology Department. NPSA documentation on safe management of patients on methotrexate is also available.

February 2009: The TAG noted NICE Clinical Guideline 79 - Rheumatoid Arthritis

January 2012: The TAG noted and supported a revised NNUHFT guideline on administration of subcutaneous methotrexate which reflected current use of Metoject® locally.

January 2013: Indications for Shared Care revised to include Connective Tissue Disease and Felty's Syndrome. Revised Shared Care Agreement supported by the TAG and the D&TCG.

July 2015: Shared Care Agreement reviewed. Clarification that the specialist has responsibility for the first blood test. Also updated in line with current format.

July 2016:
The TAG was advised that revised Arthritis Research UK advice, states that men no longer need to stop taking methotrexate before trying to conceive.

The TAG noted the information provided and agreed that the local shared care agreement should be updated in line with this guidance.

Available via: http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2017: The local Shared Care Agreement was updated following the publication of the revised BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying drugs 2017.

March 2018: The TAG agreed revisions to the text regarding specifiying use in Crohn's disease rather than IBD; the need to ensure continuity in injection devices; removal of discontinued pre-filled syringe Methofill; responsibility for dosage changes specified to be of the specialist (not the GP); frequency of recommended monitoring to be specified in the letter to GPs.

May 2018: The TAG supported the addition of a statement supporting GPs to provide varicella vaccination to the very small number of patients who are identified by the specialist service as being non-immune to varicella (chickenpox) prior to them starting treatment with methotrexate.

May 2018: Supported by the D&TC.

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

The revised SCA available via: http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=fw6_x7LG9cw%3d&tabid=913&portalid=1&mid=2043

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

Second-line drugs (DMARDs) *(Various)* TAG recommendation: Mar 1998

for use in: Rheumatoid arthritis (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of until stable dose for 6 weeks.

NICE issued Guidance in: February 2009.

Specific points: GPs in Norfolk are paid an annual fee for agreeing to monitor the use of, and to prescribe these drugs (for whatever indication): ciclosporin, azathioprine, gold, methotrexate, penicillamine. GPs are not offered a fee for prescribing and monitoring sulphasalazine. TAG recommends that a fee is also paid for monitoring patients receiving leflunomide - see separate entry.

March 2009: The noted NICE Clinical Guideline 79 Rheumatoid Arthritis - management in adults

Shared Care Agreements for ciclosporin methotrexate and leflunomide, and also sulphasalazine, are available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations

Amber - 'Option for Shared Care Prescribing'

Drugs for which it has been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, with the GP being asked to prescribe the drug and subject to the good practice described above.

In the absence of a specific decision, general principles apply (see above).

The advice is specific to the indication.

These drugs are generally perceived as being "specialist". As such, the expectation is that the recommendation to use them comes from a consultant, that there is continuing follow-up by a consultant who can advise on dose changes and the appropriate time to stop the drug.

A shared care agreement should indicate responsibilities for prescribing and monitoring - particularly for adverse reactions.

A template is available from the Health Authority Prescribing Support Team.

See the general guidance regarding the interpretation of "consultant initiation". Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.1.3 - Drugs which suppress the rheumatic disease process

Sulfasalazine *(Generics are available)* TAG recommendation: Sep 2017

for use in: Inflammatory Arthritis and Inflammatory Bowel Disease (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until stable dose for 6 weeks.

NICE has not issued any guidance.

Specific points: September 2017: The TAG noted and support the final version of a new shared care agreement which was written in line with the revised BSR and BHPR guidelines 2017 - Link, and confirmed a traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

September 2018:
The TAG noted and a revised Specialist Treatment Pathway for Rheumatoid Arthritis which had been updated with the most recent advice on adalimumab. The place of baricitinib was also clarified.
The TAG was advised that (biosimilar) adalimumab (once available) would remain as the CCGs' preferred 1st line (biologic) treatment option; a JAK inhibitor would be considered only where biologics are contraindicated.
Any further comments from the Trusts regarding the order of use of NICE-recommended therapies within the pathway to be submitted to the CSU's Specialist Interface Pharmacist.
The TAG otherwise agreed with the treatment pathway in principle.

September 2018:
The N&W Drugs & Therapeutics Committee (D&TC) noted and supported the TAG's recommendations.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

Ciclosporin *(Ikervis®)* TAG recommendation: May 2016

for use in: Severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes (Consultant recommendation only) - as per NICE TA 369 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: December 2015.

Specific points: January 2016: The TAG noted NICE TA 369 (December 2015) for the treatment of severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes and recommended a traffic light classification of Red (Hospital/Specialist only) for the CCG-commissioning responsibility treatment.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG's recommendation and decided that the treatment is not commissioned pending submission of a business application and treatment pathway by the local provider Trust. Traffic light classification to be revised to Double Red (Not recommended for routine use/not commissioned).

May 2016: The TAG noted the NNUH's application and recommended a traffic light classification of Green (GP prescribable at the request of Consultant).

May 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the NNUH application for Ciclosporin 0.1% / 1mg/mL Eye Drops (Ikervis®) for treatment of severe keratitis in adults with dry eye disease, which has not improved despite treatment with tear substitutes and commissioned the treatment as Green (GP prescribable at the request of Consultant).

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

FreeStyle Libre BGS sensors (BGS device is "Red") *(FreeStyle Libre)*

TAG recommendation: Apr 2019

for use in: Blood Glucose Monitoring in diabetes - as per NHSE criteria March 2019 (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: May 2016: The TAG and the N&W D&TCG noted and supported Prescribing Reference Group's Devices Advisory Group (DAG) recommendation that due to there being no therapeutic added value in this costly device, its use is classified as Double Red (Not recommended for routine use /Not commissioned).

May 2017: The TAG noted the draft PAC recommendations and reaffirmed its previous recommended traffic light classification of Double Red (Not recommended for routine use) (May 2016).

May 2017: The NHS Norfolk & Waveney's D&TCG noted and supported the TAG's recommendation to support the PAC's recommendations and reaffirmed that use of the Freestyle Libre® Glucose Recording System is Double Red (Not recommended for routine use) / Not commissioned.

November 2017:
The TAG acknowledged the final published version of the EoE PAC's interim recommendations regarding the FreeStyle Libre® Glucose Monitoring System which state:
1. The routine use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not recommended.
2. FreeStyle Libre® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by NICE, is not recommended for routine funding in primary care.
3. This recommendation will be reviewed in the light of new evidence to support the cost effective use of FreeStyle Libre®.

The TAG also acknowledged the Regional Medicines Optimisation Committees (RMOC) (North) Position Statement on FreeStyle Libre, which recommended use under specified criteria.
The TAG considered that the evidence resources used as reference for these recommendations were not as broad or robust as the detailed evidence review undertaken by the EoE PAC. The TAG therefore felt that the RMOC recommendations were not based on any further evidence that would persuade the TAG to change its previous view.

The TAG therefore recommended that the local position for use of FreeStyle Libre should remain in line with the interim EoE PAC recommendations as listed above until further agreement on its use is reached.

Noted and supported by the D&TCG.

May 2018:
The TAG considered recommendations from the East of England Priorities Adviosry Committee (PAC) regarding criteria for use of flash glucose monitoring systems (FGS) in adults and children and young people with Tye 1 diabetes mellitus.

The TAG broadly supported the PAC's guidance and recommended them for consideration by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee (DTC).

May 2018:
The DTC The D&TC acknowledged that the numbers of patients estimated by the specialist clinicians under each agreed criteria for use are small.
The D&TC debated the classification for prescribing responsibility of the sensors - Specialist (Red - possible Homecare provision) as recommended by the PAC, versus GP (Green - specialist recommendation) as recommended by the TAG. The D&TC was uncertain regarding the hospital / specialist's ability to prescribe on-going supplies and any related activity costs to the CCGs, and agreed to investigate further to ensure that the most cost-effective process was recommended.
The issue would be queried with specialist contacts at the PAC and also raised at the next (May 2018) NIDDM and NCH&C D&T meeting and

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

returned to the June 2018 D&TC meeting to ensure that an informed recommendation is made to the JSCC.

June 2018: The June 2018 DTC meeting was cancelled. The item to be discussed further as a matter arising at the July 2018 DTC meeting before referral to the Norfolk and Waveney CCGs' JSCC.

November 2018: The TAG acknowledged the East of England Priority Advisory Committee (PAC)'s published commissioning recommmendations regarding use of FGS in adults, and in children and young adulst aged 4 to 18 years of age, on which previous TAG recommendations were based (May 2018).
The TAG was advised that finance leads at the CCGs' Joint Commissioning and Contracting Executive (JCCE) committee had not supported the prospective costs of using the FGS product, Freestyle Libre, for use within the current financial year. This recommendation would be taken forward to the JSCC for a decision and final sign off.

November 2018: The Norfolk and Waveney CCGs' D&TC recommended that if the CCGs decide not to fund use within this financial year then this decision should be communicated to local stakeholders.
The D&TC also acknowledged NHS England's communication regarding a commitment to make Flash Glucose Monitoring more widely available to people with type 1 diabetes from April 1st 2019.

April 2019: The Norfolk and Waveney CCGs' JSCC commissioned use of Freestyle Libre as follows:

Flash Glucose Sensors (FGS) FreeStyle Libre will only be funded in line with NHSE criteria (March 2019) for patients with type 1 diabetes only, using the following process agreed by the Norfolk and Waveney CCGs:

* Specialist only initiation at the next routine appointment
* Practices should NOT refer specifically for FGS initiation
* The specialist will assess against NHSE criteria and will send the practice a copy of the Patient Contract and FGS Initiation letter giving authority to prescribe
* The specialist will provide the Scanning Device and ONE sensor (14 days)

Practices will be asked to prescribe:
* FreeStyle Libre Sensor x 2 (1 month's supply)
* Maximum Issues: 6 (SIX)
* Do NOT prescribe more than 13 sensors in 6 months

Template should be non- repeatable (untick this option)

Ostomy underwear *(Various)* TAG recommendation: Sep 2017

for use in: Support following stoma surgery for parastomal hernia (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of ostomy underwear in stoma care and agreed that specialist assessment and recommendation for use in pararstomal hernia only would be appropriate.

September 2017:The N&W D&TCG noted and supported the TAG's Green (suitable for GPs to prescribe following specialist recommendation) classification. All other uses not supported .

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

Plantar pressure offloading devices *(Various)* TAG recommendation: Sep 2017

for use in: Prevention and management of diabetic foot problems (x).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of plantar pressure offloading devices for the prevention and management of diabetic foot problems.
The PRG acknowledged the need to feed into work on the diabetic footcare pathway. The PRG otherwise recommended a classification of Green (GP prescribable following specilaist recommendation) in line with an agreed treatment pathway, which the TAG had supported.

September 2017:
Noted and supported by the N&W D&TCG.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

Transanal irrigation /Rectal Irrigation appliances

(Peristeen®, Qufora®, Aquaflush®, IryPump S®)

TAG recommendation: Nov 2019

for use in: Bowel dysfunction; Chronic constipation; Faecal incontinence. Initiation by hospital consultants for adults acro (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2017: The TAG recommended applying a classification of Double Red indication (Not recommended for routine use) until such time as a business application and proposed treatment pathway for use of any these products is submitted. The TAG agreed that such applications should be written and submitted by the interested Trust (not by the product manufacturer).

July 2017: Noted and supported by the D&TCG - Not commissioned until business applications and treatment pathways have been submitted and supported.

September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Anal irrigation (also known as rectal irrigation or trans-anal irrigation) appliances and noted that work on developing local criteria for use within an approved treatment pathway following liaison with local service providers is in progress. .

September 2017:
Noted by the N&W D&TCG.

March 2018: The TAG acknowledged NICE Medical Technologies Guidance (MTG) 36 (Feb 2018) - Peristeen transanal irrigation system for managing bowel dysfunction, and was advised that some prescribing of this product persisted beyond the decision to classify its (and similar TAI products') use as not commissioned. Liaison with local specialist services is in progress and a local formulary and guidelines are under development.

No change to the current classification was recommended in the interim.

March 2018: Noted and supported by the D&TC.
Still recommended as not commissioned, as per previous decision.

April 2018: The D&TC's recommendation was supported by the JSCC.

July 2018: The TAG agreed to support the NCH&C Adult Continence Service's application for use of TAI products and recommended a traffic light classification of Green (GP prescribable following specialist recommendation) for use only in patients managed by the NCH&C Adult Continence Service.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

November 2019 - The TAG approved the business case for the NNUH service for adults and recommended a traffic light classification of Green (GP Prescribable at request of Consultant / Specialist). They felt that service provision should be STP-wide. This was noted and supported by the D+TC and ratified by JSCC

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

- Not listed

Transanal irrigation/Rectal Irrigation appliances *(Peristeen®, Qufora®, IryPump S®)* TAG recommendation: Jul 2018

for use in: Chronic Constipation and Faecal Incontinence (as recommended by the NCH&C Adult Continence Service only) - as an option as per agreed treatment pathways (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2018: The TAG agreed to support the NCHC Adult Continence Service's application for use of TAI products and recommended a traffic light classification of Green (GP prescribable following specialist recommendation) for use only in patients managed by the NCHC Adult Continence Service.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

Transanal irrigation/Rectal Irrigation appliances *(Peristeen®, Qufora®)* TAG recommendation: Sep 2018

for use in: Chronic Constipation and Faecal Incontinence in Paediatrics (as recommended by the NNUH Paediatrics Service) - as per agreed treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2018: The TAG agreed to support the NNUH Paediatric Service application and recommended a traffic light classification of Green (GP prescribable following specialist recommendation).

September 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the NNUH's application for use of TAI in paediatrics.

October 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendation.

1.2 - Antispasmodics & other drugs altering gut motility

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

1.2 - Antispasmodics & other drugs altering gut motility

Eluxadoline ▼ *(Truberzi® ▼)* TAG recommendation: May 2018

for use in: 3rd line option in irritable bowel syndrome with diarrhoea in adults - as per NICE TA 471 and local treatment pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script First 4 weeks.

NICE issued Guidance in: August 2017.

Specific points: September 2017: The TAG acknowledged NICE TA 471 (August 2017) for treating irritable bowel syndrome with diarrhoea in adults, only if:
* the condition has not responded to other pharmacological treatments (for example, anti-motility agents, antispasmodics, tricyclic antidepressants) or
* pharmacological treatments are contraindicated or not tolerated, and
* it is started in secondary care.
* Eluxadoline should be stopped at 4 weeks if thereis inadequate relief of the symptoms of IBS with diarrhoea.
The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment pending the submission and approval of a locally developed business application for its use, and its place in the local treatment pathway clarified.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

May 2018: The TAG considered the NNUH's application and proposed treatment pathway and agreed to support revising the traffic light classification to Green (GP prescribable following specialist recommendation) in line with the proposed treatment pathway and the first 4 weeks are prescribed by the specialist.

May 2018: The D&TC noted that there is an estimated initial dropout rate of ~37% within the first 4 weeks of starting treatment due to adverse effects, and supported the TAG's recommendation that the initial prescription should be provided by the specialist.
The D&TC therefore supported the TAG's recommendation.

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations.

1.3.5 - Proton pump inhibitors

Esomeprazole *(Generic)* TAG recommendation: Nov 2015

for use in: Limited use where other PPI options have been ineffective; Barrett's oesophagus - as per N&W DROP List (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG this treatment is added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Esomeprazole is an isomer of omeprazole which is now off patent. If a PPI is required use a low cost alternative such as omeprazole, lansoprazole or pantoprazole.

Use may only be appropriate under gastroenterologist recommendation if a patient has not responded to other PPIs or for Barrett's oesophagus. Prescribe generically if must be rused.

1.5.2 - Corticosteroids for inflammatory bowel disease

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

1.5.2 - Corticosteroids for inflammatory bowel disease

Beclometasone dipropionate 5mg MR tablets *(Clipper®)*

TAG recommendation: Jan 2016

for use in: Second-line oral corticosteroid option in the treatment of flares in mild-moderate ulcerative colitis in adults - as per local pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2016: The TAG agreed to support the application from the local Trust and recommended a traffic light classification of Green (Specialist initiation / recommendation within the agreed pathway which allows initiation in primary care).
Monitoring of use is recommended to ensure that the numbers being treated are within what was expected in the application.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG considered the information provided by the applicant and agreed to commission use of Clipper® as a second line option, after oral prednisolone, and in line with an amended treatment pathway as Green (Specialist initiation / recommendation within the agreed pathway).

The pathway will be available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

Budenofalk *(Budenofalk®)*

TAG recommendation: Jan 2018

for use in: Crohn's disease in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in:

Specific points: January 2018: PRG recommendation that the TAG considers applying a Green (Suitable for GP prescribing following specialist recommendation) classification to this treatment and that it is supported for possible future addition to the local G-I Formulary:
The TAG agreed to support the PRG's recommendation.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

1.5.2 - Corticosteroids for inflammatory bowel disease

Budenofalk (Budesonide 3mg caps & 9mg granules) *(Budenofalk®)* TAG recommendation: Jul 2018

for use in: Collagenous colitis in adults (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2018:
The TAG acknowledged the QEH's application for use of Budenofalk® (3mg capsules and 9mg ganules) for collagenous colitis in adults.

The TAG acknowledged that there is evidence of effectiveness, it is a licensed indication, and Budenofalk® is a more cost effective brand (11% lower cost) than Entocort® (currently in use).

The TAG therefore recommended a traffic light classification of Green (GP prescribable following specialist recommendation) for Budenofalk® (3mg capsules and 9mg granules) for collagenous colitis in adults.

July 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG & D&TC recommendations.

2.5.1 - Vasodilator antihypertensive drug

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.5.1 - Vasodilator antihypertensive drug

Sildenafil (generic plain tablets only) *(Generic plain tablets)* TAG recommendation: Jan 2019

for use in: Digital ulceration in severe secondary Raynaud's phenomenon associated with systemic sclerosis (Not a licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts 1 month or stable dose.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: March 2009:
Recommended as Red (Hospital only).
Dose: initially 50mg twice daily for one month's trial. Then taken until resolution of symptoms and healing of digital ulceration is achieved, thereafter treatment stopped.
GPs should not be approached to prescribe for this indication due to this product being restricted in the Drug Tariff to use in erectile dysfunction for specifed patient groups, which must be endorsed SLS.
The TAG also agreed a Prescriber's Rating of 3. "Offers an Advantage - the product has some value but does not fundamentally change present therapeutic practice".

September 2015: The TAG noted A13/P/b (A13X04) (July 2015) Treatment of digital ulceration in systemic sclerosis (NHS England document) and recommended a traffic light classification of Red (Specialist use only) for this SCG-commissioning responsibility treatment.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

January 2017:
The TAG acknowledged the significantly lower costs to the NHS and the changes to the Drug Tariff status of generic sildenafil, that have occurred since the original recommendation.

The TAG agreed to support a shared care proposal submitted for secondary Raynaud's phenomenon with digital ulceration, subject to recommended amendments and recommended a revised classification of Amber (Option for GP prescribing under an approved shared care agreement).
Available via: http://nww.knowledgeanglia.nhs.uk/tag/shared_care/index.htm

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation to use the shared care agreement.

January 2019: The TAG considered the revised document and agreed that it would be reasonable to downgrade the traffic light classification from Amber to Green. The document to be retained and adapted as GP Prescribing Guidance.

Document available via: https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=9X5fOEvRC7U%3d&tabid=916&portalid=1&mid=2074

January 2019: The NHS Norfolk& Waveney CCGs' D&TC noted and supported the TAG recommendation.

2.6.3 - Other antianginal drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.6.3 - Other antianginal drugs

Ivabradine ▼ *(Procoralan® ▼)* TAG recommendation: Jan 2013

for use in: Treatment of chronic heart failure (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of until the patient is stabilise.

NICE issued Guidance in: November 2012.

Specific points: the TAG noted NICE TA 267 (November 2012 http://guidance.nice.org.uk/TA267)
which states that:
1.1 Ivabradine is recommended as an option for treating chronic heart failure for people:
with New York Heart Association (NYHA) class II to IV stable chronic heart failure with systolic dysfunction
and
who are in sinus rhythm with a heart rate of 75 beats per minute (bpm) or more
and
who are given ivabradine in combination with standard therapy including beta-blocker therapy, angiotensin-converting enzyme (ACE) inhibitors and aldosterone antagonists, or when beta-blocker therapy is contraindicated or not tolerated
and
with a left ventricular ejection fraction of 35% or less.

1.2 Ivabradine should only be initiated after a stabilisation period of 4 weeks on optimised standard therapy with ACE inhibitors, beta-blockers and aldosterone antagonists.

1.3 Ivabradine should be initiated by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be carried out by a heart failure specialist, or in primary care by either a GP with a special interest in heart failure or a heart failure specialist nurse.

January 2013: TAG recommendation supported by the D&TCG. Commissioned as per treatment pathway outlined in NICE TA 267 http://guidance.nice.org.uk/TA267.
CCGs to ensure that use of ivabradine is audited to check adherence to commissioned pathway.

November 2018: The TAG acknowledged NG 106 - Chronic heart failure in adults: diagnosis and management which includes recommendations on treating heart failure and the place of ivabradine.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.6.3 - Other antianginal drugs

Ranolazine *(Ranexa®)* TAG recommendation: Sep 2012

for use in: Adjunctive use in stable angina unresponsive to other treatments (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: July 2011.

Specific points: NICE CG 126 (July 2011) recommended ranolazine as an option to be considered in line with long-acting nitrates, or ivabradine or nicorandil, to be used in addition to a calcium channel blocker (CCB) or a beta-blocker (BB), or as monotherapy, where CCBs and BBs are contraindicated or not tolerated. The decision on which drug to use to be based on co-morbidities, contraindications, patient preference and drug costs.

Recommended by the TAG for patients who remain symptomatic despite treatment with all other pharmacological anti-anginal therapies and where revascularisation has been considered and undertaken or is not considered appropriate.
Treatment should be initiated by a Cardiologist.
Prescriber's Rating:
Possibly helpful; the product has minimal additional value, and should not change prescribing habits except in rare circumstances.

Supported by the NHS N&W D&TCG providing that GPs review their patient's response to treatment after 1 to 2 months and discontinue if ineffective.

2.6.4 - Peripheral vasodilators and related drugs

Naftidrofuryl oxalate *(Praxilene® (generic available))* TAG recommendation: Jul 2011

for use in: Treatment of intermittent claudication in people with peripheral arterial disease (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: May 2011.

Specific points: July 2011: The TAG noted NICE Technology Appraisal Guidance 223 which recommeded the following:
1.1 Naftidrofuryl oxalate is recommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered appropriate after taking into account other treatment options. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation.
1.2 Cilostazol, pentoxifylline and inositol nicotinate are not recommended for the treatment of intermittent claudication in people with peripheral arterial disease.
1.3 People currently receiving cilostazol, pentoxifylline and inositol nicotinate should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

September 2012: The TAG noted NICE CG 147 (August 2012 http://guidance.nice.org.uk/CG147) - Lower limb peripheral arterial disease.

2.7.2 - Vasoconstrictor sympathomimetic

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.7.2 - Vasoconstrictor sympathomimetic

Midodrine *(Bramox®, Midotense®)* TAG recommendation: Nov 2015

for use in: Treatment of severe orthostatic hypotension due to autonomic dysfunction - second line use after fludrocortisone (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: October 2015.

Specific points: November 2015:
The TAG noted the NICE evidence summary 61 (October 2015) - Midodrine (Bramox®) for treatment of severe orthostatic hypotension due to autonomic dysfunction, and acknowledged that there is long-standing use of unlicensed midodrine for this indication.

The TAG also noted the NNUH's internal policy for use of midodrine 2nd line after fludrocortisone.

The TAG agreed to support use of the recently licensed midodrine product (Bramox) and agreed to support its use as a licensed 2nd line treatment option for orthostatic hypotension after use of fludrocortisone, as per the NNUH Guidelines for management of orthostatic hypotension.

The TAG recommended a classification of Green (GP prescribable at the request of consultant/specialist) for this treatment.

The D&TCG noted and supported the TAG's recommendation and stated that Hospital Specialists' letters recommending GPs to use midodrine should specify the licensed product, Bramox®.

July 2018:
Generic midodrine is now listed in the Drug Tariff as the same price as Bramox®. Midotense® is also now available slighter lower cost (2.5mg tablets only).

2.8.2 - Oral anticoagulants

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Apixaban *(Eliquis®)* TAG recommendation: Jul 2015

for use in: Treatment and secondary prevention of deep vein thrombosis in adults in specified patient groups (see full guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3 weeks.

NICE issued Guidance in: June 2015.

Specific points: July 2015: The TAG recommended a classification of Double Red (Not recommended for routine use/not commissioned) pending the submission of a business case and agreement on treatment pathway, providing this is achieved within NICE's 90-day deadline. NB Dabigatran and rivaroxaban are currently awaiting local agreement on a treatment pathway before prescribing responsibility can be finalised, following positive NICE TAs.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation. Work on finalising commissioning arrangements regarding anticoagulants, including NOACs across a range of NICE-recommended indications to be undertaken by the Norfolk & Waveney Anticoagulation Working Group.

October 2015: Entry updated to Black "In progress - No prescribing recommended until local commissioning arrangements are finalised."

April 2016: The Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) agreed to reclassify use of Apixaban (Eliquis®) from "Black" to "Green" for treatment and secondary prevention of proximal deep vein thrombosis in specified patient groups - as per NICE TA 341 (June 2015) but commissioned only regarding DVT, not PE, as follows:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read: "Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Apixaban *(Eliquis®)* TAG recommendation: Jul 2015

for use in: Treatment and secondary prevention of pulmonary embolism as per NICE TA 341 (where warfarin is not appropriate - see Full Guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2015.

Specific points: July 2015: The TAG recommended a classification of Double Red (Not recommended for routine use/not commissioned) pending the submission of a business case and agreement on treatment pathway, providing this is achieved within NICE's 90-day deadline.
NB Dabigatran and rivaroxaban are currently awaiting local agreement on a treatment pathway before prescribing responsibility can be finalised, following positive NICE TAs.

July 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation. Work on finalising commissioning arrangements regarding anticoagulants, including NOACs across a range of NICE-recommended indications to be undertaken by the Norfolk & Waveney Anticoagulation Working Group.

October 2015: Entry updated to "In progress - No prescribing recommended until local commissioning arrangements are finalised."

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to revise the above commissioning position for use of dabigatran as follows:
Treatment and secondary prevention of proximal deep vein thrombosis in specified patient groups - as per NICE TA 341 (June 2015) but commissioned only regarding DVT, not PE, as follows:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

Regarding commissioning for PE:
The N&W D&TCG was of the view that warfarin should be used first-line for treatment of PE, and for prevention of recurrent PE.
A D/NOAC should only be considered, within its licensed indications, where the patient is known to be allergic to warfarin, or where warfarin therapy has been shown to be outside the time in therapeutic range (TTR) of 60% for 3 months.
Such use of D/NOAC would be classified as Green - GP prescribable at request/ recommendation of Consultant/Specialist

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Dabigatran *(Pradaxa®)* TAG recommendation: Jan 2015

for use in: Treatment and prevention of pulmonary embolism as per NICE TA 327 (where warfarin is not appropriate - see Full Guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: December 2014.

Specific points: January 2015:
The TAG noted NICE TA 327 and recommended that dabigatran is classified in line with previous recommendations for rivaroxaban:

"Red" (Hospital/Specialist only) for:
* Calf Vein DVT - the 6-week treatment course to be supplied by the hospital to avoid inappropriate continuation in Primary Care.

"Green" (Suitable for GPs to prescribe following consultant / specialist recommendation) for:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin.

* "Black" (consideration of classification in progess" - No prescribing recommended for treatment of PE and prevention of recurrent venous thromboembolism until local commissioning arrangements are finalised)

Other treatments are available for these indications. A decision is needed on how this treatment will be used. A commissioning decision on whether the treatment should be included in the treatment pathway is needed before the place in the pathway can be determined.

TAG Traffic light classification to be confirmed in due course once commissioners have finalised a treatment pathway for all clinical indications for use of New Oral Anticoagulants (NOACs).

It is hoped that this will be agreed in September 2015.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to maintain the commissioning position for use of dabigatran as stated above.

Regarding commissioning for PE:
The D&TCG was of the view that warfarin should be used first-line for treatment of PE, and for prevention of recurrent PE.
A D/NOAC should only be considered, within its licensed indications, where the patient is known to be allergic to warfarin, or where warfarin therapy has been shown to be outside the time in therapeutic range (TTR) of 60% for 3 months.
Such use of D/NOAC would be classified as Green - GP prescribable at request/ recommendation of Consultant/Specialist

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Dabigatran etexilate *(Pradaxa®)* TAG recommendation: Jan 2015

for use in: Treatment and secondary prevention of proximal deep vein thrombosis in specified patient groups asper NICE TA 327 and local policy (see Full TAG Guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3 weeks.

NICE issued Guidance in: December 2015.

Specific points: January 2015: The TAG noted NICE TA 327 recommending dabigatran etexilate as an option for treating and preventing recurrent deep vein thrombosis and pulmonary embolism in adults and recommended that dabigatran is classified in line with previous recommendations for rivaroxaban:
Green (Suitable for GPs to prescribe following consultant/specialist recommendation) for:
* Proximal DVT associated with active cancer (total 6 months/26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin.

January 2015: The D&TCG noted and supported the TAG's recommendation pending any changes arising from wider discussions regarding commissioning of anticoagulants across a range of clinical indications (including use in pulmonary embolism which has yet to be agreed upon). It is planned that commissioning decisions regarding use of anticoagulants will finalised in May 2015.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to maintain the commissioning position for use of dabigatran as stated above.

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Edoxaban ▼ *(Lixiana® ▼)* TAG recommendation: Sep 2015

for use in: Treatment and prevention of proximal deep vein thrombosis in specified patient groups (see Full Guidance) (A licensed indication).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3 weeks.

NICE issued Guidance in: August 2015.

Specific points: September 2015:
The TAG acknowledged NICE TA 354 (August 2015) which recommended use of edoxaban, within its marketing authorisation, as an option for treating and preventing recurrent DVT and PE in adults.
The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) pending local commissioning arrangements being finalised, and agreement on a treatment pathway.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to revise the above commissioning position for use of dabigatran as follows:
Treatment and secondary prevention of proximal deep vein thrombosis in specified patient groups - as per NICE TA 354 (August 2015) but commissioned only regarding DVT, not PE, as follows:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Edoxaban ▼ *(Lixiana® ▼)* TAG recommendation: Sep 2015

for use in: Treatment and secondary prevention of pulmonary embolism as per NICE TA 354 (where warfarin is not appropriate - see Full Guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: August 2015.

Specific points: September 2015:
The TAG acknowledged NICE TA 354 (August 2015) which recommended use of edoxaban, within its marketing authorisation, as an option for treating and preventing recurrent DVT and PE in adults.
The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) pending local commissioning arrangements being finalised, and agreement on a treatment pathway.

October 2015:
The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) noted and supported the TAG's recommendation.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to revise the above commissioning position for use of dabigatran as follows:
Treatment and secondary prevention of proximal deep vein thrombosis in specified patient groups - as per NICE TA 354 (August 2015) but commissioned only regarding DVT, not PE, as follows:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

Regarding commissioning for PE:
The D&TCG was of the view that warfarin should be used first-line for treatment of PE, and for prevention of recurrent PE.
A D/NOAC should only be considered, within its licensed indications, where the patient is known to be allergic to warfarin, or where warfarin therapy has been shown to be outside the time in therapeutic range (TTR) of 60% for 3 months.
Such use of D/NOAC would be classified as Green - GP prescribable at request/ recommendation of Consultant/Specialist

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Rivaroxaban *(Xarelto®)* TAG recommendation: Jan 2021

for use in: For preventing atherothrombotic events in people with coronary or peripheral artery disease as per TA607 for a specific group of patients as per pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: October 2019.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. NICE TA607 - October 2019 was noted and afforded a traffic light classification of Double Red (Not recommended for routine use/not commissioned) for this CCG commissioning responsibility treatment pending the provision of a business case, pathway and decision aid.

February 2020: A business case was reviewed and a recommendation made by TAG & D&TC for the traffic light classification of Double Red (Not recommended for routine use/Not commisioned) to remain, pending the provision of a pathway and patient decision aid. The recommendation was agreed by the NHS Norfolk & Waveney CCGs' JSCC.

January 2021 - TAG agreed to recommend Green (GP prescribing following Specialist initiation / recommendation) for appropriate high-risk patients as shown in the pathway. Initiation request letter should be sent to primary care prescriber. This must include HASBLED score and treatment plan. This was supported by D+TC and ratified by Chair's Action on behalf of CCG Governing Body.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Rivaroxaban ▼ *(Xarelto® ▼)* TAG recommendation: Jul 2013

for use in: Treatment and prevention of pulmonary embolism as per NICE TA 261 (where warfarin is not appropriate - see Full Guidance) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2013.

Specific points: July 2013:
Other treatments are available for these indications. A decision is needed on how this treatment will be used. A commissioning decision on whether the treatment should be included in the treatment pathway is needed before the place in the pathway can be determined.

No recommendation for a traffic light classification made by the TAG - to be confirmed in due course once commissioners have finalised a treatment pathway for all clinical indications for use of New Oral Anticoagulants (NOACs).

January 2015:
TAG Traffic light classification to be confirmed in due course once commissioners have finalised a treatment pathway for all clinical indications for use of New Oral Anticoagulants (NOACs).

It is hoped that this will be agreed in September 2015.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to maintain the commissioning position for use of dabigatran as stated above.

Regarding commissioning for PE:
The D&TCG was of the view that warfarin should be used first-line for treatment of PE, and for prevention of recurrent PE.
A D/NOAC should only be considered, within its licensed indications, where the patient is known to be allergic to warfarin, or where warfarin therapy has been shown to be outside the time in therapeutic range (TTR) of 60% for 3 months.
Such use of D/NOAC would be classified as Green - GP prescribable at request/ recommendation of Consultant/Specialist

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.8.2 - Oral anticoagulants

Rivaroxaban ▼ *(Xarelto® ▼)* TAG recommendation: Sep 2012

for use in: Treatment of deep vein thrombosis (except calf vein DVT) and prevention of recurrent DVT in specified patient groups (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of 3 weeks.

NICE issued Guidance in: July 2012.

Specific points: NICE Guidance July 2012 http://guidance.nice.org.uk/TA261 recommends rivaroxaban as an option for these indications.

September 2012:
The TAG considered an NNUH business case for first-line use of rivaroxaban over warfarin and were concerned that there is differing clinical opinion about rivaroxaban between the clinicians across local Acute Trusts. Although rivaroxaban is effective there is no evidence of benefit over warfarin in well-controlled patients. There is also a significant price to the local health economy.

D&TCG decisions October - November 2012:
Rivaroxaban is non-inferior to warfarin. Patients at risk of bleeding (e.g. Hx of GI bleed, SSRI use) are contraindicated.

The first 3 weeks' titration pack will be supplied by the hospital with follow-up treatment prescribed in Primary Care i.e. "Green" (except for the 6 week treatment course for calf vein DVT which will ideally be supplied by the hospital to avoid inappropriate continuation in Primary Care - see separate "Red (Hospital Only)" entry).

Patient groups commissioned as "Green" (GP prescribing following specialist recommendation and initiation) are:

* Proximal DVT associated with active cancer (total 6 months/ 26 wks treatment) - option for individual cases **.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

** January 2015: The TAG revisited the background to this commissioning decision and sought the views of local haematologist following concerns about use of NOACs to treat proximal DVT in patients with active cancer raised by a consultant specialist at the JPUH.
The TAG was satisfied from the information available that there was no reason to overturn this commissioned use.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) confirmed the above commissioning decision regarding use of rivaroxaban for this indication as follows:
Treatment of deep vein thrombosis (except calf vein DVT) and prevention of recurrent DVT in specified patient groups - as per NICE TA 261 (July 2012) but commissioned only regarding DVT, not PE, as follows:
* Proximal DVT associated with active cancer (total 6 months/ 26 weeks' treatment) - option for individual cases.
* Proximal DVT with standard/low recurrence risk (total 13 weeks' treatment) - only if allergic to warfarin.
* Proximal DVT with high recurrence risk/low bleeding risk (long term) - only if allergic to warfarin

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

2.9 - Antiplatelet drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Clopidogrel (with low dose aspirin) *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: Sep 2006

for use in: Post elective percutaneous coronary intervention (PCI) - bare metal stent (Not a licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of in-patient stay.

NICE has not issued any guidance.

Specific points: Refn: Anglia Cardiac Network Guidelines revised version July 2007 http://www.angliacn.nhs.uk/site/Clopidogrel.html.
Patients with bare metal stents are recommended to receive combined treatment with clopidogrel plus low dose aspirin for a total of 4 weeks.
Low dose aspirin should be continued thereafter indefinitely.
Patients with drug-eluting stents are recommended to receive combined treatment with clopidogrel plus low dose aspirin for a total of 12 months.
Low dose aspirin should be continued thereafter indefinitely.
GPs should contact the interventional cardiologist with any queries relating to this therapy.

July 2009: NB pre-procedure prophylaxis with clopidogrel should be provided by the hospital via pre-admission clinics. GPs should not be approached to prescribe treatment that is a part of the hospital procedure.

May 2010: Interaction between Clopidogrel and PPIs:
The April 2010 Drug Safety Update bulletin includes revised advice regarding concomitant use of clopidogrel with proton pump inhibitors. The MHRA states that use of either omeprazole or esomeprazole with clopidogrel should be discouraged but that current evidence does not support to extending this advice to other PPIs.
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON076501
The TAG noted that local hospital specialists plan to adopt this advice and will use lansoprazole. Lansoprazole also offers a cost-effective option in Primary Care.

September 2014: The TAG supported updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Clopidogrel (with low dose aspirin) *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: Apr 2005

for use in: Acute Coronary Syndrome without ST-segment elevation (NSTEMI) (with aspirin) (A licensed indication).
Prescribing responsibility: Consultant responsible for the first script.

NICE issued Guidance in: July 2004.

Specific points: NICE Technology Appraisal Guidance No.80 (Clopidogrel in the treatment of non-ST-segment-elevation acute coronary syndrome) recommends that treatment with clopidogrel in combination with low-dose aspirin should be continued for up to 12 months after the most recent episode of non-ST-segment-elevation ACS. Thereafter standard care, including treatment with low-dose aspirin alone, is recommended.
In September 2004 the TAG agreed that NICE guidance would be interpreted as it would not be expected that patients with non ST-segment elevation ACS would be on clopidogrel and aspirin for more than 12 months.
Patients taking clopidogrel should stop treatment 7 days prior to elective surgery to reduce the risk of severe bleeding.

Local guideline: Anglia Cardiac Network guideline revised July 2007 http://www.angliacn.nhs.uk/site/Clopidogrel.html

May 2010:
The TAG noted NICE Clinical Guideline 96 March 2010 - Unstable MI and NSTEMI which confirmed use of clopidogrel for 12 months.
Interaction between Clopidogrel and PPIs:
The April 2010 Drug Safety Update bulletin includes revised advice regarding concomitant use of clopidogrel with proton pump inhibitors. The MHRA states that use of either omeprazole or esomeprazole with clopidogrel should be discouraged but that current evidence does not support to extending this advice to other PPIs.
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON076501
The TAG noted that local hospital specialists plan to adopt this advice and will use lansoprazole. Lansoprazole also offers a cost-effective option in Primary Care.

September 2014: The TAG supported updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Clopidogrel (with low dose aspirin) *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: Sep 2006

for use in: ST-elevation myocardial infarction (STEMI) (Not a licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of in patient stay; max one month.

NICE has not issued any guidance.

Specific points: Refn: Anglia Cardiac Network Guidelines revised version July 2007 http://www.angliacn.nhs.uk/site/Clopidogrel.html.
Total treatment period should not exceed one month.
Low dose aspirin should be continued thereafter indefinitely.

May 2010: Interaction between Clopidogrel and PPIs:
The April 2010 Drug Safety Update bulletin includes revised advice regarding concomitant use of clopidogrel with proton pump inhibitors. The MHRA states that use of either omeprazole or esomeprazole with clopidogrel should be discouraged but that current evidence does not support to extending this advice to other PPIs.
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON076501
The TAG noted that local hospital specialists plan to adopt this advice and will use lansoprazole. Lansoprazole also offers a cost-effective option in Primary Care.

January 2014: The TAG noted NICE CG 172 (Nov 2013) (update of CG 48) - MI -Secondary prevention in primary and secondary care for patients following a myocardial infarction.

September 2014: The TAG supported updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Prasugrel *(Efient®)* TAG recommendation: Sep 2014

for use in: In combination with aspirin: Prevention of atherothrombotic events in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI) with known intolerance to clopidogrel or who have restenosed whilst on clopidogrel. (A

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: July 2014.

Specific points: November 2009:
NICE TA 182 October 2009 recommends prasugrel, in combination with aspirin, as an option for preventing atherothrombotic events in people with acute coronary syndromes having PCI.

The TAG debated interpretation of NICE guidance against its previous concerns regarding prasugrel i.e. beneficial in high risk groups but more harmful in patients who are higher risk of a bleed.

September 2010: The TAG considered a revised proposal for use of prasugrel from the NNUH and made the following recommendations which were then approved by NHS Norfolk's Drug & Therapeutics Commissioning Programme Board:

Prasugrel, in combination with low dose aspirin, may be used only for the following patient groups for a period of up to 12 months:
* Patients who have been taking aspirin and clopidogrel but who present with stent thrombosis within the 12 month treatment period - Green (GP prescribable following consultant initiation) with an initial prescribing period of one month by the hospital.
* Patients with intracoronary stents who have true intolerance to clopidogrel - Green (GP prescribable following consultant initiation) with an initial prescribing period of one month by the hospital.

NICE TA 317 (July 2014):
Prasugrel is recommended by NICE as an option in the prevention of atherothrombotic events in adults with ACS having primary or delayed PCI.

September 2014: The TAG was advised that the NNUH will continue to use ticagrelor as first line option for this indication.
The TAG otherwise acknowledged NICE TA 317 and affirmed its previous recommendation of a traffic light classification of Green (GP prescribable at the request of Consultant/Specialist).

The TAG also supported related updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/tag/tag_antiplatelets_guidance.pdf

September 2014: The Norfolk & Waveney CCGs D&TCG supported the TAG recommendations. Treatment commissioned in line with NICE TA 317.

See also Summary of Guidance and Clinical Practice on the use of Anti-platelets to prevent occlusive vascular events - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Ticagrelor *(Brilique®)* TAG recommendation: May 2013

for use in: (With aspirin) to prevent atherothrombotic events in patients with ACS as per NICE TA 236 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE issued Guidance in: October 2011.

Specific points: November 2011: NICE TA Guidance 236 (October 2011 http://guidance.nice.org.uk/TA236 Ticagrelor for the treatment of Acute Coronary Syndromes).

The estimated cost is an additional ~£2million for Norfolk (£1.5million for NNUH-treated patients only) for wholesale use of ticagrelor in line with TA 236. A subgroup of patients who would benefit more from ticagrelor has not been identified.

Recommended by the TAG as Green (GP prescribable following specialist/consultant initiation) (subject to commissioning agreement).

January 2013: Commissioned as In Tariff treatment in line with NICE TA 236 but patient groups to be confirmed.

April 2013: The D&TCG agreed to commission ticagrelor for ACS in line with a revised protocol submitted by the NNUH cardiologists following a joint meeting with CCG representatives.

Patients identified for use are:
ACS patients treated by PCI, with the exception of those deemed to be at increased risk of major bleeding (e.g. over 80 years old, previous major bleed, previous stroke, very low body weight, need for concomitant warfarin, pre-existing anaemia).

September 2014: The TAG supported updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/tag/tag_antiplatelets_guidance.pdf

January 2016: Following negotiations between the Trust and the Central Norfolk CCGs and subsequent referral of the cost implications and relative uptake of ticagrelor elsewhere, the NHS Norfolk & Waveney CCGs' D&TCG was advised that the Central Norfolk CCGs' Joint Commissioning Committee had agreed to support use of ticagrelor as per the local Trusts application and revised treatment pathway to use more fully in line with NICE TA 236.

See also - Summary of Guidance and Clinical Practice on the use of Anti-platelets to prevent Occlusive Vascular events - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.9 - Antiplatelet drugs

Ticagrelor *(Brilique®)* TAG recommendation: Jan 2017

for use in: In combination with aspirin for preventing atherothrombotic events who had a myocardial infarction and who are at high risk of a further event as per NICE TA 420 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: December 2016.

Specific points: January 2017: The TAG acknowledged NICE TA 420 (December 2016) for use in combination with aspirin for preventing atherothrombotic events in patients who have had a myocardial infarction and who are at high risk of a further event.
Treatment should be stopped when clinically indicated or at a maximum of 3 years.

The TAG recommended a traffic light classification of Green (GP prescribable following specialist request / recommendation) in line with the NICE clinical pathway for this CCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

May 2018: The TAG considered the NNUH's application for use as part of dual antiplatelet therapy for up to 3 years post MI - as per NICE TA 420.
The TAG clarified that the proposed patient numbers equate to those for the NNUH's catchment population plus the fact that the NNUH is a tertiary centre which may receive referrals from elsewhere across the county. However the estimated number of patients are lower than those estimated by NICE due to the NNUH cardiologists' wish to use in a more considered way. Older People's Medicine numbers have also been included but are low due to the increased risk of bleeding.
The TAG recommended that the dosage regimen and duration of treatment must be specified in the specialist's letter to the GP. The TAG also noted that if treatment is continued beyond a year, then the dose should be revised from 90mg OD to 60mg BD for a maximum of 3 years of extended treatment. GPs would have to set up repeats with a limited and specified number of authorisations in order to ensure safe and appropriate prescribing.
The TAG reaffirmed a traffic light classification of Green (GP prescribable following specialist recommendation) providing that the dosage regimen and duration of treatment is specified in specialists' letters to GPs.

May 2018: The D&TC noted the NNUH cardiologists' considered estimation of patient numbers and was concerned about the financial impact of this treatment of primary care prescribing expenditure. To be referred for consideration by the JSCC.

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) noted the above information without further comment and supported the TAG's recommendations - commissioned as per NICE TA 420.

See also - Summary of Guidance and Clinical Practice on the use of Anti-platelets to prevent Occlusive Vascular events - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

2.12 - lipid-regulating drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.12 - lipid-regulating drugs

Bempedoic acid *(Nilemdo® or Nustendi)* TAG recommendation: Mar 2022

for use in: alone or with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia as per TA694 (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: April 2021.

Specific points: Double Red (Not recommended for routine use / Not commissioned) pending submission of a business case.

March 2022 - Bempedoic acid alone or with ezetimibe commissioned for local use as per lipid pathway - Specialist advice required from primary or secondary care clinician with relevant expertise prior to primary care initiation

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.12 - lipid-regulating drugs

Colesevelam HCl *(Cholestagel®)* TAG recommendation: Mar 2019

for use in: Third-line option for (unlicensed) use in bile salt malabsorption causing diarrhoea (for patients under the NNUH only) (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 8 weeks (for new patients).

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered an NNUH application which proposes initiation and assessment of effectiveness in hospital with transfer to primary care if beneficial.

The TAG considered the application and supporting evidence and was concerned at the low quality of data available.
It was felt that a potentially large number of people could end up on this treatment, long term, as a result of intolerance or unwillingness to adhere to treatment with the first and second line options, cholestyramine and colestipol (which has recently been unavailable).
The TAG noted that NICE evidence summary esuom22 (Oct 2013) indicated that only low level evidence to support use in this indication was available.

September 2017:
The N&W D&TCG noted the TAG's discussions regarding the application for this treatment and decided to apply a classification of Double Red (Not recommended for routine use / Not commissioned) to this indication for use of colesevelam until such time as it is approved.

November 2017:
The TAG noted detail of the RCT referenced in the NNUH's original application and was advised that the patient numbers quoted in the application had been confirmed by the specialist, based on patients who had already responded to the treatment.
The TAG agreed pragmatic support for colesevelam as third-line use in this patient group, and that a shared care approach was reasonable where use was limited to use in patients who remain uncontrolled having tried standard treatment with an opioid (loperamide) and with a bile salt sequestrant (cholestyramine). The specialist should prescribe the first 8 weeks' of treatment to allow transfer of care, having assessed the patient's response within 4 weeks.
The TAG therefore recommended a revised traffic light classification of Amber (Option for GP prescribing under an approved shared care agreement).

November 2017:
The D&TCG considered the information provided by the NNUH and the TAG's revised recommendation, but decided that given the quality of the available evidence, the lack of clarity regarding patient numbers and the current financial cost pressures faced by the CCGs, who have other compelling interests to fund, it is not possible to commission use of this drug.
The D&TCG therefore decided not to support the TAG's recommendations and that the treatment would remain classified as Double Red (Not recommended for routine use) / Not commissioned.

March 2019:
The TAG agreed to re-support the NNUH's revised application and again recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation) for 3rd line use to control diarrhoea caused by bile acid malabsorption providing the specialist prescribes the first 8 weeks of treatment for any new patients.

March 2019: The NHS Norfolk & Waveney CCGs' D&TC agreed to support the revised application, and also the TAG's recommendation. The D&TC recommended that this should apply to use initiated by the NNUH only, with the number of patients to be treated to be capped at the 15 people who have already identified by that Acute Trust.
The other Acute Trusts had not submitted any patient numbers when consulted regarding the revised application.

April 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendations.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

2.12 - lipid-regulating drugs

Icosapent ethyl *(Vazkepa®)* TAG recommendation: Mar 2023

for use in: with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides as per TA805 (x).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: July 2022.

Specific points: No formal application has been made for addition to the formulary. Seek advice from Medicines Optimisation Team before prescribing

March 2023 - application accepted.

Inclisiran *(Leqvio®)* TAG recommendation: Apr 2022

for use in: primary hypercholesterolaemia or mixed dyslipidaemia as per TA733 (x).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: October 2021.

Specific points: CCG Commissioned treatment. Not commissioned yet. No prescribing until confirmation of place in NICE-endorsed pathway

April 2022 - TAG recommended Inclisiran be given an ADVICE - Formulary - Specialist advice required from prior to primary care initiation classification. Must only be prescribed as per approved local pathway and following secondary care assessment

3.3.2 - Leukotriene receptor antagonists

Montelukast *(Singulair®)* TAG recommendation: Apr 2005

for use in: Prophylaxis of asthma - use in children (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2017.

Specific points: Licensed from age 6 months (for initiation by a respiratory paediatrician).
For initiation by GPs as part of the BTS guidelines from age 2 years.
NNUH formulary application for use in adults and children noted and supported by the TAG in September 2004.

January 2018: The TAG noted NICE NG 80 Asthma: diagnosis, monitoring and chronic asthma management (November 2017) which covers use in children and young people aged 5 to 16 years.

3.3.3 - Phosphodiesterase type-4 inhibitors

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

3.3.3 - Phosphodiesterase type-4 inhibitors

Roflumilast ▼ *(Daxas® ▼)* TAG recommendation: Dec 2018

for use in: Adjunct to bronchodilators for maintenance in chronic obstructive pulmonary disease in adults with chronic bronchitis and a history of frequent exacerbations - as per NICE 461 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of one month.

NICE issued Guidance in: July 2017.

Specific points: March 2011: The TAG does not recommend routine use of roflumilast due to a current lack of supporting information and inability to place roflumilast in the current NICE recommended treatment algorithms. This recommendation will be reviewed when further evidence becomes available to support such use.
Prescriber's Rating: Judgement reserved - the Committee postpones its judgement until better data and a more thorough evaluation of the drug are available.

The TAG's recommendation was noted and approved by NHS Norfolk's D&TCG on 17th March 2011.

March 2012: The TAG noted NICE TA 244 which states:
* Roflumilast is recommended only in the context of research as part of a clinical trial for adults with severe chronic obstructive pulmonary disease (COPD) (for the purposes of this guidance defined as forced expiratory volume in 1 second [FEV1] post-bronchodilator less than 50% predicted) associated with chronic bronchitis with a history of frequent exacerbations as an add-on to bronchodilator treatment.
* Such research should be designed to generate robust evidence about the benefits of roflumilast as an add-on to long-acting muscarinic antagonists (LAMA) plus long-acting beta2 agonists (LABA) plus inhaled corticosteroids (ICS), or LAMA plus LABA for people who are intolerant to ICS.
* People receiving roflumilast should have the option to continue treatment until they and their clinicians consider it appropriate to stop.
The TAG noted NICE TA 244 and agreed to maintain the previous recommendation of Double Red (Not recommended for routine use).

Noted by the D&TCG. Roflumilast for the management of severe chronic obstructive pulmonary disease is not commissioned.

July 2017: The TAG acknowledged NICE FAD (June/July 2017) for treating chronic obstructive pulmonary disease as follows:
1.1 Recommended by NICE as an add-on to bronchodilator therapy, as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if:
* the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and
* the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid.
1.2 Treatment with roflumilast should be started by a specialist in respiratory medicine and recommended maintaining the current traffic light classification of Double Red (Not recommended for routine use) for this CCG-commissioning responsibility treatment until the NICE TA guidance is published.

July 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation - Double Red (Not recommended for routine use) / Not Commissioned until the NICE TA has been published and the treatment's place in the COPD treatment pathway agreed. The D&TCG also recommended that there should be agreement on the definition of "a specialist in respiratory medicine" under NICE recommendation 1.2.

September 2017: The TAG acknowledged NICE TA 461 (July 2017) and recommended maintaining the Double Red (Not recommended for routine use) classification for this CCG-commissioning responsibility treatment pending the submission and approval of a business application for its use.
The TAG felt that this was an expensive add-on option with limited supporting evidence of benefit which should be reviewed for assessment of effectiveness / benefit after an agreed time period e.g.one year's use.
The TAG also recognised the need to clarify which local clinicians would be designated as a specialist in respiratory medicine and recommended that initiation of roflumilast should be limited to consultants in respiratory medicine.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted that the SMC (August 2017) had recommended against use of roflumilast

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

3.3.3 - Phosphodiesterase type-4 inhibitors

following a resubmission from the manufacturer.
The TAG's recommendation was noted and supported by the D&TCG, with reiteration that any future use of roflumilast would be limited to initiation by consultants in respiratory medicine only.

January 2018: The TAG considered an application for use by the NNUH in line with NICE TA 461. The TAG felt that the number of patients who would meet theNICE criteria for use was likley to be greater than that estimated in the application. The TAG asked that local specialists be asked to specify which patients would be most likley to benefit fron this treatment, and how such traetment would be reviwed and if ineffective, stopped. If commissioned as Red (Specialist use only) arrangements would have to be made to avoid additional activity costs for the CCGs.
A recommendation on this item was deferred until more information becomes available.

May 2018: May 2018:
The NNUH submitted info on patient numbers based on the NICE resource impact statement as follows:
No significant resource impact is anticipated
We (NICE) do not expect this guidance to have a significant impact on resources; that is, it will be less than £5m per year in England (or £9,100 per 100,000 population). This is because the expected uptake of the technology is small because the therapy should only be started by specialists in secondary care, and the unit cost for the intervention is small.
The NNUH reported that there is limited interest within the Trust's specialists in using roflumilast apart from consultant who has had brief experience of using it elsewhere in the country and would like to have it available as an option. However they are unable to identify criteria of when and how they would decide to use roflumilast or how they would decide to stop it if not beneficial. Adverse effects related to the treatment make it a less desirable option for many physicians.
Despite protracted discussion on how criteria for starting / stopping treatment might be agreed and whether it was appropriate to recommend use within hospital only to start with, the TAG felt unable to comment on the application and as the sub-group of patients could not be identified concerned were expressed around the numbers. The TAG felt unable to consider this any further until more information is received from the clinician.
The TAG recommended that the current traffic light classification of Double Red (Not recommended for routine use) be maintained. A request would be made to the STP respiratory working group to review the evidence for this treatment to see if a sub-group of patients can be identified.

May 2018: The D&TC noted the TAG recommendation but did not agree that the STP respiratory group was the appropriate forum to refer this issue to.
The D&TC instead recommended that the East of England PAC be approached to provide guidance on criteria for use and review of treatment with roflumilast for severe COPD.
The current classification of Not commissioned was therefore recommended to be maintained in the interim.

September 2018:
The TAG noted that the PAC had responded to state that they were unable to undertake this piece of work as it was not a priority for their work plan. Hertfordshire CCGs commissioning policy for roflumilast cited as an example of what had been agreed elsewhere.
Roflumilast could be given only to patients who have had more than two admissions in the previous 12 months. The hospital to provide it for the first 3 months, and if patients tolerated treatment, prescribing responsibility could then be transferred to primary care. Annual data checks would be needed to show that hospital admissions were not increasing. It was considered that stopping criteria would still be difficult to determine as the disease is progressive.

AGEM CSU Business Intelligence unit to be asked to provide the number of patients admitted to hospital for COPD exacerbations 3 times or more in the preceding 12 months to see if they are comparable with NICE estimates.
The figures to be considered by the N&W CCGs' D&TC when available.

October 2018:
The D&TC considered figures produced by the CSU Business Intelliegence team around the number of patients admitted to hospital with COPD exacerbations and it appeared that these were less than initially thought. The costs of using roflumilast would be around £70,000 across all of the local CCGs. There were some patients who were admitted 22 or 23 times and if those admissions could be stopped there would be cost savings. Based on the numbers seen the D&TC agreed to adopt the NICE-recommended criteria. The D&TC recommended that the hospital should provide the first month of treatment (effectively a "Green" classification) and a request be made for the specialists to audit some of the frequent fliers who are admitted 5 times or more in a 12 month period.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

3.3.3 - Phosphodiesterase type-4 inhibitors

The recommendation to go to the next available JSCC meeting for a commissioning decision.

December 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the recommended revised traffic light classification of Green (GP prescribable following hospital specialist initiation) for Roflumilast (Daxas®) for maintenance treatment of severe COPD associated with chronic bronchitis in adults with history of frequent exacerbations as add on to bronchodilator treatment - as per NICE TA 461 where the specialist initiates and provides the first month of treatment.
Hospital specialists to be requested to audit patients who have been admitted to hospital 5 times or more in a 12 month period.

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

4.2.1 - Antipsychotic drugs

Aripiprazole *(Abilify®)* TAG recommendation: Sep 2016

for use in: Moderate to severe manic episodes in adolescents with bipolar I disorder - as per NICE TA 292 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: July 2013.

Specific points: NICE TA 292 (July 2013) Recommended as an "option" for moderate to severe manic episodes in adolescents with bipolar I disorder.
The TAG recommended that the current shared care agreement for Aripiprazole should be updated to reflect TA 292 and that a treatment pathway for bipolar disorder should be submitted to Commissioners to clarify its place in therapy.
November 2013: The TAG considered a proposed treatment pathway which will be finalised imminently and published as part of the revised shared care agreement for Aripiprazole.

November 2013: Treatment pathway supported by the D&TCG and published as part of the revised Shared Care Agreement for aripiprazole available via http://nww.knowledgeanglia.nhs.uk/tag/shared_care/aripiprazole_for_schizophrenia.pdf

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the TAG's recommendations and agreed that use of aripiprazole for schizophrenia and bipolar mood disorder is commissioned as Green (GP prescribing following consultant initiation / recommendation) in line with other antipsychotics.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.2.1 - Antipsychotic drugs

Aripiprazole *(Abilify®)* TAG recommendation: Sep 2016

for use in: Schizophrenia and bipolar mood disorder - as per NICE CG 82 and TA 213 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: March 2009.

Specific points: Shared Care use supported for patients with proven intolerance or who are non-responsive to other second generation antipsychotics. Also considered for patients for whom other antipsychotics are inappropriate - e.g. diabetics, those who are obese.

November 2008: The TAG agreed that consultants would prescribe aripiprazole for at least 4 weeks or until the patient is stabilised before transferring prescribing responsibility to GPs.

March 2009: NICE CG 82 - schizophrenia

November 2010: Revised Shared Care Agreement incorporating updated advice regarding adjunctive use of benzodiazepines for 3 to 4 weeks).

January 2011: NICE Technology Appraisal Guidance 213 - Aripiprazole for the treatment of schizophrenia in people aged 15 to 17 years, states that:

"Aripiprazole is recommended as an option for the treatment of schizophrenia in people aged 15 to 17 years who are intolerant of risperidone, or for whom risperidone is contraindicated, or whose schizophrenia has not been adequately controlled with risperidone."
Commissioned by NHS Norfolk & Waveney.

March 2013: Shared Care Agreement revised to include use in bipolar mood disorder. Supported by the N&W D&TCG.
Available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2016: The TAG agreed and recommended revising the classification for aripiprazole for schizophrenia and bipolar mood disorder in line with other antipsychotics i.e. from Amber (Option for GP prescribing under an approved Shared Care Agreement) to Green (GP prescribing following consultant initiation / recommendation).

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the TAG's recommendations and agreed that use of aripiprazole for schizophrenia and bipolar mood disorder is commissioned as Green (GP prescribing following consultant initiation / recommendation) in line with other antipsychotics.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.2.1 - Antipsychotic drugs

Atypical antipsychotics (except clozapine) *(Various (except Clozaril® (Red))* TAG recommendation: Nov 2001

for use in: As per NICE CG 178 (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of one month.

NICE issued Guidance in: March 2009.

Specific points: 2002:
Consultant initiation only.
Trust will supply atypical antipsychotics for new outpatients for the first three months if there are appropriate reasons to do this, ie unstable or difficult patient, inadequate support available.
NICE produced guidance on use of atypical anitpsychotics in June 2002 (TAG No. 43)

May 2009:
The TAG acknowledged NICE CG 82 Psychosis and schizophrenia: management which replaced TA 43 and CG 1.

May 2014:
The TAG acknowledged NICE CG 178 Psychosis and schizophrenia in adults: prevention and management ,which replaced CG 82

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG supported the TAG's recommendations and agreed that use of aripiprazole for schizophrenia and bipolar mood disorder is commissioned as Green (GP prescribing following consultant initiation / recommendation) in line with other antipsychotics.

July 2018:
The TAG noted and supported GP guidance on Physical Health monitoring related to prescribing in adults with psychoses (and related disorders) which would sit alongside the shared care LES information on Knowledge Anglia.

July 2018:
The D&TC also acknowledged that the monitoring to be undertaken by GPs under the CCGs' Local Enhanced Service agreement for monitoring drug treatments in primary care would be classified as Level "0" since GPs are already funded under the QoF.

Lurasidone ▼ *(Lutada® ▼)* TAG recommendation: Jan 2018

for use in: Third antipsychotic option for schizophrenia in adults aged 18 years and over (A licensed indication).
Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of four weeks.

NICE has not issued any guidance.

Specific points: January 2018: The TAG considered the NSFT application for use as a third antipsychotic option for schizophrenia in adults aged 18 years and over and agreed to recommend a classification of Green (GP prescribable following specialist recommendation) where the consultant would initiate treatment and prescribe for the first 4 weeks of treatment, to assess patient response, before requesting that the GP continues prescribing.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TCG's recommendation.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.2.1 - Antipsychotic drugs

Lurasidone ▼ *(Lutada® ▼)* TAG recommendation: Mar 2015

for use in: Treatment of schizophrenia in adults aged 18 years and over - third-line option under the Early Intervention Treatment Pathway (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of four weeks.

NICE has not issued any guidance.

Specific points: January 2015: The TAG considered the NSFT application and recommended a classification of Red (Hospital/Specialist only) pending the approval of an agreed treatment pathway. The pathway identifying the lurasidone's place in therapy to be brought to the TAG in March 2015.

January 2015: The Norfolk & Waveney CCGs' D&TCG decided to defer the decision on whether to commission this treatment until the TAG have considered the proposed treatment pathway and have clarified lurasidone's place in therapy.

March 2015: The TAG considered the Early Intervention treatment pathway proposed by NSFT and recommended amendments to clarify lurasidone's place as a third-line treatment option.
The TAG agreed to revise the previously recommended classification for lurasidone (Lutada®) for the treatment of schizophrenia in adults aged 18 years and over as a third line option with the Early Intervention Treatment Pathway, from Red (Hospital / Specialist use only) to Green (GP prescribable following consultant initiation), where the specialist has provided the first 4 weeks of treatment in line with the supply arrangements for other oral antispychotics. It was agreed that the specialist will advise the GP of the previous treatments used within the Treatment Pathway when communicating the decision to use lurasidone via a standard letter.

March 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation regarding lurasidone for schizophrenia as part of the Early Intervention Treatment Pathway and agreed to commission the treatment as Green (GP prescribable following consultant initiation) where the specialist provides the first 4 weeks of treatment.

Olanzapine *(Zalasta®, Zyprexa®, ZypAdhera® IM)* TAG recommendation: Nov 2001

for use in: Schizophrenia - 1st line (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of one month.

NICE issued Guidance in: June 2002.

Specific points: Consultant initiation only.
Trust will supply atypical antipsychotics for new outpatients for the first three months if there are appropriate reasons to do this, ie unstable or difficult patient, inadequate support available.
NICE produced guidance on use of atypical anitpsychotics in June 2002 (TAG No. 43)

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.2.1 - Antipsychotic drugs

Olanzapine *(Zalasta®, Zyprexa®, ZypAdhera® IM)* TAG recommendation: Jan 2008

for use in: Maintenance in Bipolar Mania (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of One month.

NICE issued Guidance in: July 2006.

Specific points: Consultant initiation only.
Trust will supply atypical antipsychotics for new outpatients for the first three months if there are appropriate reasons to do this, ie unstable or difficult patient, inadequate support available.

This decision applies to oral medication.
IM olanzapine preparation for acute episodes is also supported.

Quetiapine *(Generics are available)* TAG recommendation: Nov 2001

for use in: Schizophrenia - 1st line (A licensed indication).
Prescribing responsibility: Consultant should prescribe for an initial period of at least one month.

NICE issued Guidance in: March 2014.

Specific points: Consultant initiation only.
Trust will supply atypical antipsychotics for new outpatients for the first three months if there are appropriate reasons to do this, ie unstable or difficult patient, inadequate support available.
NICE produced guidance on use of atypical anitpsychotics in June 2002 (TAG No. 43)

May 2009:
The TAG acknowledged NICE CG 82 Psychosis and schizophrenia: management which replaced TA 43 and CG 1.

May 2014:
The TAG acknowledged NICE CG 178 Psychosis and schizophrenia in adults: prevention and management ,which replaced CG 82

4.2.3 - Antimanic drugs

Lithium *(Various - prescribe branded only)* TAG recommendation: Apr 2005

for use in: Treatment and prophylaxis of mania, bipolar disorder, and recurrent depression; aggressive or self-mutilating behaviour (A licensed indication).
Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance.

Specific points: Ensure that the patient is routinely monitored for serum lithium concentration and thyroid function.

Prescribe by brand only.

4.3.3 - Selective serotonin re-uptake inhibitors

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.3.3 - Selective serotonin re-uptake inhibitors

SSRI antidepressants *(Various)* TAG recommendation: May 2003

for use in: Use for depression in children and young people (only with talking therapies) - as per NICE CG 28 (Not a licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: March 2015.

Specific points: NMHCT has developed a leaflet on the use of SSRIs in children.
Specialists should inform patients and/or carers about the licensed status and evidence base for use.
Specialists must inform GPs of the rationale for treatment in children.

TAG Classification of "Shared Care" with continued consultant supervision - revised from Amber to "Green" following reclassification of the TAG traffic light system in April 2005.
No formal shared care document has been agreed locally.
NICE published its Clinical Guideline on Depression in children and young people in September 2005.

CSM advice (depressive illness in children and adolescents): the balance of risks and benefits for the treatment of depressive illness in individuals under 18 years is considered unfavourable for the SSRIs citalopram, escitalopram, fluvoxamine, paroxetine and sertraline, and for mirtazapine and venlafaxine. Clinical trials have failed to show efficacy and have shown an increase in harmful outcomes. However, it is recognised that specialists may sometimes decide to use these drugs in response to individual clinical need; children and adolescents should be monitored carefully for suicidal behaviour, self-harm or hostility particularly at the beginning of treatment.
Only fluoxetine has been shown in clinical trials to be effective for treating depressive illness in children and adolescents. However, it is possible that in common with the other SSRIs, it is associated with a small risk of self-harm and suicidal thoughts. Overall, the balance of risks and benefits for fluoxetine in the treatment of depressive illness in individuals under 18 years is considered favourable, but children and adolescents must be monitored as above.

November 2011: regarding citalopram, the TAG noted latest safety guidance from the MHRA as follows -
* Citalopram should not be used above 40mg/day in adults (is unlicensed in under 18s)
* Citalopram should not be used above 20mg/day in the elderly and people with reduced hepatic function
* Citalopram is contraindicated in people:
  - with a known QT prolongation or congenital long QT syndrome
  - taking other medicines known to prolong QT interval*
* Citalopram should only be used with caution in people with higher risk of developing Torsades de Pointes e.g. CHF, recent MI, bradyarrhythmias, or hypokalaemia or hypomagnesaemia

May 2015: The TAG noted that NICE CG 28 (March 2015) - Depression in children and young people: Identification and management in primary, community and secondary care, applies to the care of those aged < 18 years. The main recommendation noted was that antidepressants should not be prescribed in this patient group without the support of talking therapies.

The TAG also felt that NICE CG 28 (March 2015) should be drawn to the attention of the CCGs' Mental Health Commissioning Board.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.
No change to current commissioning arrangements.

November 2017:
The TAG noted the upadte of NICE CG 28 - Depression in children and young people: identification and management.

4.4 - Central nervous system stimulants

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.4 - Central nervous system stimulants

Modafinil *(Provigil®)* TAG recommendation: Mar 2001

for use in: Narcolepsy (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Consultant supervision needed.
"Amber" status revised to "Green" following reclassification of the TAG traffic light system in April 2005.

See separate "Double Red" entry regarding use in unlicensed indications.

4.6 - Drugs used in nausea and vertigo

Ondansetron (generic plain tablets) *(Generic plain tablets)* TAG recommendation: Sep 2016

for use in: Drug-induced nausea and vomiting in palliative care (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2016: The TAG agreed to recommend that acute use of ondansetron (plain tablets only) for nausea and vomiting for drug-induced nausea and vomiting in palliative care be
classified as Green (GP prescribing following consultant initiation / recommendation)

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

Ondansetron (generic plain tablets) *(Generic plain tablets)* TAG recommendation: Sep 2016

for use in: Second line option in hyperemesis gravidarum (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2016: The TAG agreed to recommend that acute use of ondansetron (plain tablets only) for nausea and vomiting as a second line option in hyperemesis gravidarum be classified as Green (GP prescribing following consultant initiation / recommendation)

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

4.7.2 - Opioid analgesics

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.7.2 - Opioid analgesics

Buprenorphine (transdermal) *(Butec®, Transtec® patches)* TAG recommendation: Nov 2011

for use in: Patients with renal impairment (eGFR 15-30, CKD 4) who have an accumulation of opiates and a resulting potential for toxicity (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2011: The TAG supported a business case for restricted use of buprenorphine patches by pain specialists at the NNUH.
The TAG's recommendation was supported by the NHS Norfolk & Waveney Drug & Therapeutics Commissioning Group on 17th November, only for limited use in this specific patient group.

July 2012: The TAG noted NICE CG 140 Opioids in Palliative Care

September 2016:
The TAG acknowledged NICE CG 140 (August 2016) - update which includes recommendations on:
* communication
* starting strong opioids and titrating the dose
* first-line maintenance treatment
* first-line treatment using transdermal patches or subcutaneous delivery, if oral opioids are not suitable
* first-line treatment for breakthrough pain in patients who can take oral opioids
* managing constipation, nausea and drowsiness

The D&TCG supported the recommendation that morphine is the gold standard choice when prescribing strong opioids, the use of which should be optimised before considering other strong opioids.

Methadone *(various)* TAG recommendation: Jan 2023

for use in: pain relief in palliative care (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Specialist advice required from primary or secondary care clinician with relevant expertise prior to primary care initiation

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.7.2 - Opioid analgesics

Tapentadol (modified-release) *(Palexia® SR ▼)* TAG recommendation: Dec 2020

for use in: Severe chronic pain in adults with intolerance to m-r morphine, which can be adequately managed only with opioid analgesics (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance. There is a shared care protocol approved by TAG.

Specific points: Tapentadol is a centrally acting analgesic with dual action as a µ-opioid receptor agonist and noradrenaline reuptake inhibitor which has been classified as Schedule 2 controlled drug.

November 2011: The TAG considered an NNUH business case for modified-release tapentadol to be used in an outpatient setting in their Pain Clinic. Tapentadol would not be available for widespread use within the NNUH Trust.
The TAG also acknowledged the opportunity to move towards more effective and appropriate prescribing for pain management through the review of currently available treatments and formulary choices over time.

The NHS Norfolk & Waveney Drugs & Therapeutics Commissioning Group agreed to support the TAG's recommendation providing that the strategy is to aim to reduce overall use of oxycodone across the local health economy.
The committee also recommended that tapentadol SR is not considered for addition to local Pain Management Formulary until at least 6 months' experience of use had passed and that the impact of such use had been reviewed by the committee.

March 2012: The TAG heard that GPs had been requested to prescribe tapentadol SR outside of the local agreement.
Whilst an investigation takes place and until further agreement on use is finalised, the TAG revised its recommendation to Red (Hospital Only) in the interim.
No new patients should be started on treatment in Primary Care and GPs should not be recommended to prescribe tapentadol.

May 2012:
The TAG considered and supported use of an Initiation Check List developed by the NNUH which it was agreed should be completed by the pain specialist and sent to GPs along with letters of recommendation for use. Supporting prescribing information for use of tapentadol SR would also be provided.

The TAG also recommended that immediate-release tapentadol tablets were classified as Double Red (Not recommended for routine use) - please see separate entry.

17th May 2012:
NHS Norfolk & Waveney noted the TAG's recommendations and decided that Tapentadol SR should only be available for prescribing in Primary Care under an approved Shared Care prescribing Agreement i.e. Amber (Option for GPs to prescribe under an approved Shared Care Agreement). To remain as Red (Hospital Only) until a Shared Care Agreement is approved via the Therapeutics Advisory Group (TAG).

July 2012:
The TAG noted NICE CG 140 Opioids in Palliative Care.
The TAG supported a Shared Care Agreement for tapentadol SR to be used in conjunction with the Initiation Checklist when transferring prescribing responsibility to GPs.

July 2014: The TAG reviewed and agreed to support continued use of the Shared Care Agreement for tapentadol SR.

May 2017:
The TAG reviewed and agreed to support continued use of the Shared Care Agreement for tapentadol SR until a more detailed review of the treatment is undertaken at the next TAG meeting.

July 2017: The TAG and the D&TCG agreed to support on-going use of tapentadol modified-release under the terms of the shared care agreement.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.7.2 - Opioid analgesics

Dec 2020 - The TAG agreed to suspend the SCA and amend traffic light classification to Green (GP can prescribe at request of Consultant/Specialist)
Reminder that opioids should not be used routinely in primary care. Supported by D+TC and ratified by CCG Governing Body

4.8.1 - Control of epilepsy

Lacosamide *(Vimpat®)* TAG recommendation: Jan 2013

for use in: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: In January 2011 the TAG agreed to recommend use of lacosamide, and also zonisamide, for second-line adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients with resistant epilepsy aged 16 years and over, and 18 years and over respectively, as Amber (Option for Shared Care), with at least the first month's supply to be the responsibility of hospital specialists.

Prescriber's Rating 4. Possibly helpful - The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

Lacosamide is a black triangle drug ▼which requires reporting of any suspected adverse reactions to the MHRA.

January 2013: Following consultant feedback the TAG agreed to downgrade the classification for lacosamide and zonisamide from Amber to Green.

Lamotrigine *(Lamictal®)* TAG recommendation: Mar 2013

for use in: (Relapse of) Bipolar Depression (as alternative to, or in addition to lithium) (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts 4 weeks.

NICE issued Guidance in: July 2006.

Specific points: Lamotrigine became licensed for use in bipolar depression in the UK 2010.

March 2013: Shared Care Agreement revised to GP Prescribing Guidance.

January 2019: GP prescribing guidance document withdrawn as viewed as being no longer required.

Oxcarbazepine *(Trileptal®)* TAG recommendation: May 2001

for use in: Epilepsy (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Alternative to carbamazepine.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.8.1 - Control of epilepsy

Perampanel *(Fycompa®)* TAG recommendation: Jan 2018

for use in: Second line adjunctive treatment of patients over the age of 12 years with partial seizures with or without secondary generalisation (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script until the dose is stable.

NICE issued Guidance in: January 2012. There is a shared care protocol approved by TAG.

Specific points: March 2014:
Recommended as Red (Hospital/Specialist only) pending the provision of a treatment pathway and agreement on a Shared Care Agreement.

The D&TCG noted and supported the TAG's recommendation of Red (Hospital/Specialist only).
Not for Primary Care prescribing until a treatment pathway has been clarified and shared care agreement approved by the TAG.

November 2014: The TAG supported the proposed treatment pathway in principle subject to recommended amendments and recommended a re-classification to Amber (Option for GP prescribing under an approved shared care agreement) with a review of this arrangement after a period of 12 months.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted the TAG recommendation but decided that the classification will remain as Red (Hospital/Specialist use only) until details within the treatment pathway are clarified and the final version of the shared care agreement is approved by the TAG.

January 2015: The TAG supported the revised treatment pathway and reformatted shared care agreement and recommended re-classification to Amber (Option for GP prescribing under an approved shared care agreement) with a review after a period of 12 months.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

January 2018: The TAG agreed that this treatment could be re-classified as Green (GP prescribable following specialist recommendation) and used as per the previously agreed treatment pathway

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation. The D&TCG also advised that the first supply should continue to be provided by the specialist to cover initial titration of treatment.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the D&TC recommendation.

Pregabalin *(Lyrica®, generic also available)* TAG recommendation: Sep 2005

for use in: Control of epilepsy (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2019: The TAG noted the rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs from April 2019. The TAG also noted that Schedule 2 & 3 Controlled Drugs will become prescribable via the Electronic Prescription Service (EPS) to facilitate the re-classification of gabapentin and pregabalin.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.8.1 - Control of epilepsy

Pregabalin *(Lyrica®; generic also available)* TAG recommendation: May 2007

for use in: Generalised anxiety disorder (GAD) - for use only where all other options have failed. (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: April 2007.

Specific points: For use only after all other appropriate treatment options have been tried. Prescribers are also advised to consider the potential side-effects and cautions related to prescribing this drug, and to consider NICE Guidance which states that cost should be taken into account where equal effectiveness is demonstrated.
(Prescriber's Rating: Possibly Helpful: The product has minimal additional value, and should not change prescribing habits except in rare circumstances.)

March 2019: The TAG noted the rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs from April 2019. The TAG also noted that Schedule 2 & 3 Controlled Drugs will become prescribable via the Electronic Prescription Service (EPS) to facilitate the re-classification of gabapentin and pregabalin.

Zonisamide *(Zonegran®)* TAG recommendation: Jan 2013

for use in: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 18 years and older (A licensed indication).

Prescribing responsibility: Consultant should prescribe for an initial period of one month.

NICE has not issued any guidance.

Specific points: In January 2013 the TAG agreed to recommend use of zonisamide, and also lacosamide, for second-line adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients with resistant epilepsy aged 16 years and over, and 18 years and over respectively, as Amber (Option for Shared Care), with at least the first month's supply to be the responsibility of hospital specialists.

Prescriber's Rating 4. Possibly helpful - The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

Zonisamide is a black triangle drug ▼which requires reporting of any suspected adverse reactions to the MHRA.

January 2013: Following consultant feedback the TAG agreed to downgrade the classification for zonisamide and lacosamide from Amber to Green.

4.9.1 - Catechol-O-methyltransferase inhibitors

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.9.1 - Catechol-O-methyltransferase inhibitors

Opicapone ▼ *(Ongentys® ▼)* TAG recommendation: Nov 2017

for use in: Adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: March 2017.

Specific points: September 2017:
The TAG considered the NNUH application for use of opicapone, alongside the NICE ES9 (March 2017) - Opicapone for Parkinson's disease with end of dose motor fluctuations - which was also provided for the TAG's reference.
The TAG noted that the application had been costed against the prices of branded alternative products rather than the cheaper generic options which are currently in use in primary care in Norfolk & Waveney, and requested that the application is revised with recalculated comparative costs for treatments provided in primary care.

September 2017:
The D&TCG noted the TAG's discussions regarding the application for opicapone and decided to apply a classification of Double Red (Not recommended for routine use / Not commissioned) until such time as its use is approved.

November 2017:
The TAG considered the additional information received from the NNUH consultant neurologist which clarified that opicapone would be used only where entacapone / or its combinations are not tolerated or complied with, and where more expensive options such as tolcapone (which requires intensive hepatic monitoring), apomorphine, and DBS would next be considered.
The TAG acknowledged that such use of opicapone could defer use of apomorphine and therefore save money. Use of opicapone could be audited if necessary.
The TAG therefore recommended a traffic light classification of Green (Suitable for GPs to prescribe following specialist recommendation) for use of opicapone (Ongentys®) as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations and have known intolerance or non-response to entacapone and its combinations.

November 2017:
The D&TCG noted and supported the TAG's recommendations and agreed to revise the traffic light classification from Double Red to Green (Suitable for GPs to prescribe following specialist recommendation).

Pramipexole - Immediate Release *(Mirapexin®)* TAG recommendation: Mar 2011

for use in: Idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: Please also see separate "Double Red" entry relating to prolonged-release pramipexole (Mirapexin Prolonged Release).

The TAG considered the comparative costs of generic IR pramipexole and branded PR pramipexole. PR pramipexole was not judged to offer cost-effective treatment at present, prior to agreement on the patient group and treatment pathway.
The TAG's recommendations were noted and approved by NHS Norfolk's D&TCG on 17th March 2011

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.9.1 - Catechol-O-methyltransferase inhibitors

Pramipexole - Prolonged Release *(Mirapexin® Prolonged Release)* TAG recommendation: Jun 2013

for use in: Idiopathic Parkinson's disease - alone or with levodopa, for patients initiated on treatment prior to mid March 2011 only - no new patients to be started on Pramipexole PR after this date. (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Please also see the separate "Green" entry relating to immediate-release pramipexole and the "Double Red" entry for prolonged release pramipexole for patients initiated on treatment after mid March 2011.

March 2011:
The TAG considered the comparative costs of generic IR pramipexole and branded PR pramipexole. PR pramipexole was not judged to offer cost-effective treatment at present, prior to agreement on the patient group and treatment pathway.
The TAG's recommendations were noted and approved by NHS Norfolk's D&TCG on 17th March 2011.

January 2012: Work on agreeing a treatment pathway is in progress.

June 2013: The Norfolk & Waveney Drugs & Therapeutics Commissioning Group considered concerns raised by the NNUH regarding on-going prescribing responsibility for patients maintained on pramipexole MR whose treatment had been initiated prior to the decision not to commission use in March 2011.

The D&TCG agreed the following:
* There should be no new episodes of treatment with Mirapexin PR started whilst it remains Not Commissioned.
* The Acute Trusts should ensure that all neurology / MFE specialists (including nurses) are aware of the current commissioning position and that there must be no new initiations of treatment.
* GPs can continue to prescribe Mirapexin PR for current patients only i.e. those patients started on treatment prior to mid March 2011 (see separate "Green" entry).
* However there should be active attempts at specialist clinic appointments to review and transfer their treatment to immediate-release pramipexole or other suitable and cost-effective treatment options.

Rasagiline *(Azilect®)* TAG recommendation: Mar 2006

for use in: Idiopathic Parkinson's Disease (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2006.

Specific points: Replaces TAG's previous decision of Double Red (Jan 06).
NB. For third line use only as adjunctive therapy for motor fluctuations where Entacapone not tolerated (reclassification following further evidence).

NICE Clinical Guideline: diagnosis, management and treatment of adults with Parkinson's Disease in primary and secondary care due June 2006.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.9.1 - Catechol-O-methyltransferase inhibitors

Ropinirole *(Adartrel® , Requip®)* TAG recommendation: Mar 1998

for use in: Parkinson's Disease (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Rotigotine *(Neupro® patches)* TAG recommendation: Sep 2008

for use in: Monotherapy for early and adjunct to levodopa in advanced stage Parkinson's disease (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2007: The TAG supported use of rotigotine as monotherapy in doses up to 8mg daily in early-stage parkinson's disease.
September 2008: The TAG agreed to support extended use in advanced stage disease in doses up to 16mg daily.
Responsibility for monitoring for visual abnormalities should be shared by the hospital consultant and the GP. GPs should monitor blood pressure for postural hypotension associated with dopaminergic therapy especially at the beginning of treatment.
The TAG also agreed a revised Prescriber's Rating of 3: "Offers an advantage - the product has some value but does not fundamentally change present therapeutic practice."

Safinamide *(Xadago®)* TAG recommendation: Nov 2019

for use in: Idiopathic Parkinson's disease where existing oral agents are contra-indicated or have failed to improve motor fluctuations/dyskinesia (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: December 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC and TAG recommendations of November 2019. The business case was approved and a traffic light of Green (GP Prescribably at the request of a Consultant/Specialist) was afforded.

4.10 - Drugs used in substance dependence

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.10 - Drugs used in substance dependence

Varenicline *(Champix®)* TAG recommendation: Jul 2007

for use in: Adjunct to smoking cessation in combination with motivational support - Public Health England commissioning responsibility - as per NICE TA 123 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: July 2007.

Specific points: July 2007: The TAG recommended varenicline as GREEN (GP prescribable at the request of a "Consultant"/specialist, where the specialist is a Smoking Cessation Adviser (Level 2 or 3)) as an option for use as monotherapy in smoking cessation in adults, for a 12-week treatment period only, with no return to the Smoking Cessation Service within 6 months.
Varenicline is a Black Triangle Drug ▼ which requires monitoring for adverse reactions. Prescribers should consult the manufacturer's SPC before initiating treatment. Adverse effects reported include nausea and abnormal dreams. The SPC includes special warnings and precautions regarding patients with underlying psychiatric illness (e.g. depression).

The TAG also agreed a Prescriber's Rating: A real advance. The product is an important therapeutic innovation but has certain limitations.

September 2007: The TAG ratified a guidance document for use of varenicline which will form part of the Norfolk Stop Service Smoking Guidelines.

March 2010: The TAG had previously recommended that NRT is the recommended first-line option for most people, over varenicline.
Having considered the NHS Stop Smoking Services - Service & monitoring guidance 2010/11, the TAG agreed that all NICE-recommended stop-smoking pharmacotherapies may be offered as first line options for people who require help to stop smoking and as part of a programme for behavioural or motivational support.

July 2010: The TAG noted NICE CG 101 (June 2010) - management of COPD (update).

July 2013: NICE Public Health guidance 45 (June 2013) Tobacco: harm-reduction in smoking
Public Health are Lead Commissioners.

May 2018: The TAG noted NICE NG 92 (March 2018) - Stop smoking interventions and services , which updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).

Any prescribing in Primary Care is recharged to Public Health as the commissioner.

4.11 - Drugs for dementia

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

4.11 - Drugs for dementia

Rivastigmine *(Use cost-effective generic oral preparations)* TAG recommendation: Jul 2015

for use in: Mild to moderate dementia in Parkinson's disease (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts 6 weeks.

NICE issued Guidance in: March 2011.

Specific points: The TAG noted and accepted the limitations to the quality of the evidence available and the information submitted in an application for use by the NNUH. The TAG acknowledged that GPs are experienced in prescribing rivastigmine.
NSFT's/NHS Suffolk shared care agreement for dementia treatment can be amended to include use in Lewy Body dementia.
The TAG therefore recommended a classification of Amber (Option shared care) following assessment of the patient at 6 weeks and a response being shown. A shared care agreement is being progressed and will follow as soon as possible.

May 2013: N&W CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) decision: Red (Hospital /Specialist Only) until a Shared Care Agreement has been approved via the TAG. GPs should not be asked to prescribe rivastigmine for mild to moderate dementia in Parkinson's disease in the interim period.

July 2015: The TAG considered a first draft of a shared care proposal for dementia treatments including rivastigmine in Parkinson's dementia. The group noted the different supplies being provided by local Trusts for these treatments and agreed to check local commissioning arrangements.

The D&TCG noted the issues around having different handover periods for different treatments and conditions. The committee also acknowledged that there had been specialist initiation and recommendation of use of rivastigmine for Parkinson's dementia to GPs for some time and that this had become part of local clinical practice.
The D&TCG therefore agreed that it was appropriate to revise the previous TAG classification of Red (Hospital / Specialist use only) to Green (GP prescribable following specialist recommendation) providing that the most cost-effective formulations are used first-line (generic capsules) and that transdermal patches are used only where patients are unable to swallow oral formulations.

5.1.7 - Some other antibacterials

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

5.1.7 - Some other antibacterials

Fidaxomicin *(Dificlir®)* TAG recommendation: Jul 2013

for use in: Treatment of mild to moderate C. difficile infection (CDI) in patients who have had two previous episodes in the last 3 months under consultant microbiologist recommendation - as per local policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: For mild to moderate cases being treated in Primary Care following Consultant Microbiologist recommendation.

Prescriber's Rating 3. Offers an advantage - the product has some value but does not fundamentally change present therapeutic practice.

July 2013: The Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG) supported the TAG's recommendation subject to clarification on how Microbiology will test for suitability of fidaxomicin before recommending use to GPs.

August 2013: The D&TCG were reassured of the process for recommendation of use of fidaxomicin and agreed to commission use as per the TAG's recommendation.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

Teicoplanin *(Targocid®)* TAG recommendation: Nov 2000

for use in: Intramuscular treatment at home (A licensed indication).

Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance.

Specific points: Monitoring U&E weekly considered sufficient.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

5.1.9 - Antituberculosis drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

5.1.9 - Antituberculosis drugs

Ethambutol

()

TAG recommendation: Mar 2020

for use in: Non-TB related Mycobacterium infections. (x).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG recommended a traffic light classification of Green (GP Prescribable at request of Consultant / Specialist) for Ethambutol, Rifampicin and Isoniazid. The Trusts would issue the initial prescription with a letter then being sent to the GP asking them to continue prescribing. The letters to GP should clearly state that monitoring of the drug will be undertaken by the Trusts. It would be assumed that if the patient did not attend at the Trust for the required monitoring then the GP would be notified.
This recommendation was supported by the D+TC. The committee would like to emphasise the importance of hospital letters containing accurate information about the indication that is being treated. This recommendation only covers Mycobacterium infections. Treatment for TB will remain Red (Hospital/Specialist use only)

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Isoniazid

()

TAG recommendation: Mar 2020

for use in: Non-TB related Mycobacterium infections (x).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG recommended a traffic light classification of Green (GP Prescribable at request of Consultant / Specialist) for Ethambutol, Rifampicin and Isoniazid. The Trusts would issue the initial prescription with a letter then being sent to the GP asking them to continue prescribing. The letters to GP should clearly state that monitoring of the drug will be undertaken by the Trusts. It would be assumed that if the patient did not attend at the Trust for the required monitoring then the GP would be notified.
This recommendation was supported by the D+TC.
The committee would like to emphasise the importance of hospital letters containing accurate information about the indication that is being treated. This recommendation only covers Mycobacterium infections. Treatment for TB will remain Red (Hospital/Specialist use only)

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Rifampicin

()

TAG recommendation: Mar 2020

for use in: Non-TB related Mycobacterium infections (x).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG recommended a traffic light classification of Green (GP Prescribable at request of Consultant / Specialist) for Ethambutol, Rifampicin and Isoniazid. The Trusts would issue the initial prescription with a letter then being sent to the GP asking them to continue prescribing. The letters to GP should clearly state that monitoring of the drug will be undertaken by the Trusts. It would be assumed that if the patient did not attend at the Trust for the required monitoring then the GP would be notified.
This recommendation was supported by the D+TC.
The committee would like to emphasise the importance of hospital letters containing accurate information about the indication that is being treated. This recommendation only covers Mycobacterium infections. Treatment for TB will remain Red (Hospital/Specialist use only)

May 2020 - Recommendation ratified by the Governing Body for Norfolk and Waveney CCG

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

5.1.13 - Urinary-tract infections

Methenamine *(Hiprex®)* TAG recommendation: Sep 2022

for use in: prophylaxis of uncomplicated lower urinary tract infections (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Specialist advice required from primary or secondary care clinician with relevant expertise prior to primary care initiation. Review at 3 months, then 6 monthly ongoing reviews.

6.1.1.1 - Short-acting insulins

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.1 - Short-acting insulins

Insulin Aspart (Fiasp®) ▼ *(Fiasp® ▼)* TAG recommendation: Apr 2021

for use in: Diabetes mellitus (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: October 2017:
Fiasp® is insulin aspart in a new formulation with a faster onset of action than NovoRapid®.
The Prescribing Reference Group (A sub-group of the TAG) considered the available NHS review of this new insulin formulation, and noted the lack of superiority of other available treatments. The PRG recommended that the TAG considers applying a Double Red (Not recommended for routine use) classification, pending local agreement on a patient group and the product's place in the diabetes treatment pathway.

November 2017:
The TAG noted that local specialists had already been recommending use of Fiasp® to GPs, outside of any local business application and formal consideration for local funding. Anecdotal reports of patients using more units of Fiasp® compared with previous requirements for NovoRapid® were noted with concern regarding potential increased costs for no know benefit.
The TAG agreed to support the PRG's advice and to recommend a traffic light classification of Double Red (Not recommended for routine use) to use of Insulin Aspart (Fiasp®) for any new patients pending local agreement on a patient group and the product's place in the diabetes treatment pathway.

November 2017:
The PRG and the TAG's recommendations were noted and supported by the D&TCG. The D&TCG was also advised that use of Fiasp® would be part of regional level discussions between CCGs and diabetes specialists in December 2017.

September 2018:
The TAG noted a Guidance Statement from the East of England Priorities Advisory Committee (PAC) (July 2018) which included the following recommendations:

1.Faster acting insulin aspart (Fiasp®) is not recommended for routine prescribing in primary or secondary care.
2.It may be of benefit in certain patients under specified criteria, only if first line use of conventional insulin aspart or insulin lispro has been tried and failed
3.It should be initiated by a specialist diabetes team / consultant diabetologist only
4.Return to previous care if no overall improvement in disease control, including HbA1c is seen after 6 months

The TAG noted that the treatment may be used in certain circumstances which have been clearly defined by the PAC.
Locally there had only been limited interest expressed in this therapy, some of which had been patient-led.

It was therefore agreed that the current Double Red (Not recommended for routine use) classification should be maintained, pending the submission of a business case from local clinicians / providers.

September 2018:
The TAG's recommendation was noted and supported by the N&W CCGs' Drugs & Therapeutics Committee.

August 2020 - Returned to TAG for update on business case. The Double Red (Not recommended for routine use / Not commissioned) classification will be maintained pending submission of a business case

Nov 2020 - current Double Red classification to remain

April 2021 - TAG members recommended a classification of Green (GP can prescribe at request of Consultant / Specialist) with the requirement for the Trusts to complete a GPA form to confirm that prescribing is in line with the agreed criteria.
Recommendation would apply across the CCG

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.1 - Short-acting insulins

Insulin glulisine *(Apidra®)* TAG recommendation: May 2010

for use in: Diabetes mellitus (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Use with the SoloStar® pen device simplifies treatment regimens for patients and also provides a cost-effective option.
TAG recommendation approved by the NHS Norfolk Drug & Therapeutics Commissioning Programme Board on 21st July 2010.

September 2015: The TAG noted NICE NG 17 (August 2015) - Type 1 diabetes in adults: diagnosis and management, which covers the care and treatment of adults (aged 18 and over) with type 1 diabetes.
Contains several new recommendations for 2015.
NG 17 updates and replaces the sections for adults in NICE guideline CG15.

September 2015: The TAG noted NG 18 (August 2015) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management - which covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18 years. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

September 2016:
The TAG acknowledged NG 17 (update July 2016) which includes new recommendations on:
* Diagnosis
* Structured education
* Insulin therapy
* Blood glucose management
* Impaired awareness of hypoglycaemia
* Managing complications of diabetes
Recommendation 1.15.1 was also reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

January 2017:
The TAG acknowledged NG 18 (updated November 2016) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management which includes recommendations on:
* diagnosis
* management of type 1 and type 2 diabetes
* diagnosis and management of diabetic ketoacidosis in children and young people with type 1 and type 2 diabetes
* service provision.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.1 - Short-acting insulins

Insulin Lispro *(Lyumjev®)* TAG recommendation: Jun 2023

for use in: adults with type 1 and type 2 diabetes (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Formulary - Specialist advice required from primary or secondary care clinician with relevant expertise prior to primary care initiation

only after trying other rapid-acting insulins

Insulin Lispro ▼ 200units/ml (Humalog KwikPen®) *(Humalog KwikPen®)* TAG recommendation: Mar 2016

for use in: A specific group of adults with diabetes mellitus who require more than 20 units of quick-acting insulin per day (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2016: The TAG agreed to support the application and recommended a traffic light classification of Green (prescribable at request of Consultant/Specialist) for use of insulin lispro (Humalog KwikPen®) 200 units/ml in a specific group of adults with diabetes mellitus who require greater than 20 units of fast-acting insulin and more than 200 units of insulin per day, with poor glycaemic control as defined by having an HbA1c of greater than 75mmol/mol.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

September 2016:
The TAG acknowledged NG 17 (update July 2016) which includes new recommendations on:
* Diagnosis
* Structured education
* Insulin therapy
* Blood glucose management
* Impaired awareness of hypoglycaemia
* Managing complications of diabetes

Recommendation 1.15.1 was also reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

6.1.1.2 - Intermediate and long-acting insulins

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

Insulin degludec *(Tresiba®)* TAG recommendation: May 2018

for use in: RESTRICTED use in Type 1 and Type 2 Diabetes mellitus - consultant initiation only (A licensed indication).
Prescribing responsibility: Consultant/Specialist should prescribe until the patient's treatment is stabilised.

NICE issued Guidance in: August 2015.

Specific points: May 2013:
The TAG agreed that the evidence available for insulin degludec is limited and there is a significant cost involved.

The TAG also noted the Scottish Medicines Consortium's lack of support on pharmacoeconomic grounds and a recent MHRA safety alert highlighting the risks of inappropriate or mistaken use of the two different strengths of insulin degludec.

The TAG therefore recommended a classification of Double Red (Not recommended for routine use) pending consideration of a formulary application to NNUH D&TC and subsequent submission to the TAG and D&TCG.

May 2013: N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) decision: Not commissioned

September 2013: NHS East of England - Priorities Advisory Committee (PAC) Draft Guidance Statement: Commissioning is low priority and not recommended.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) recommended that the previous TAG recommended classification of Double Red (Not recommended for routine use/Not commissioned) be maintained.

January 2014: NHS East of England Priority Advisory Committee's (PAC) Final Policy Statement (September 2013) recommended commissioning is a low priority and not recommended for diabetes mellitus in adults. The TAG acknowledged the PAC statement. Not commissioned by N&W CCGs-D&TCG.

September 2015: The TAG noted NICE NG 17 (August 2015) - Type 1 diabetes in adults: diagnosis and management, which covers the care and treatment of adults (aged 18 and over) with type 1 diabetes.
Contains several new recommendations for 2015.
NG 17 updates and replaces the sections for adults in NICE guideline CG15.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

September 2016:
The TAG noted that in July 2016, recommendation 1.15.1 in NG17 was reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

March 2017: The TAG considered the draft recommendations from the PAC regarding use of insulin degludec in type 1 diabetes and also revisited the QEH's application for niche use in children and young people. The TAG agreed to support the PAC's recommendations for broader use in adults and children, subject to the final version being signed off by the PAC with no significant changes and recommended that the current classification is revised from Double Red (Not recommended for routine use) to Green (GP prescribable following consultant initiation) for use in line with the PAC's recommendations.
The TAG also recommended a Prescriber's Rating of 4. Possibly helpful - The product offers small additional value, and should not change prescribing habits except in rare circumstances.

March 2017: The NHS Norfolk & Waveney CCGs' D&TCG was advised that the draft PAC recommendations considered by the TAG had been finalised by the PAC without any further changes.
The D&TCG therefore noted and supported the TAG's recommendation of a revised traffic light classification of Green (GP prescribable after Consultant initiation) with a Prescriber's Rating of 4 (possibly helpful - The product offers small additional value, and should not change prescribing habits except in rare circumstances) for restricted use of insulin degludec in children and adults with type 1 diabetes used only in line

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

with the PAC's recommendations as follows:
1. Not recommended for routine use in adults or children in either Type 1 or Type 2 diabetic patients.
2. Insulin degludec may be of benefit in certain patients with Type 1 diabetes who fulfil the following criteria:
* Patients with significant nocturnal hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors) and diet (undertaken structured education e.g. DAFNE) and optimising basal insulin/multiple daily injections who fulfil the criteria for insulin pump therapy.
* "Chaotic patients" who may be at significant risk of diabetic ketoacidosis (DKA) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections.
* Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA if daily basal insulin is missed.
* Patients with a diagnosed allergy to either insulin glargine or insulin detemir.
3. Routine commissioning of Insulin degludec is NOT recommended for patients with type 2 diabetes i.e. Double Red (Not recommended for routine use) / Not Commissioned
4. Insulin degludec should be initiated by a consultant led specialist team and is NOT suitable for initiation by GPs or other prescribers in primary care unless under the supervision of a specialist. It is recommended that the initial dose titration and monitoring is closely supervised by a specialist team.
5. Ongoing provision of the insulin may be undertaken in Primary care by agreement between the Specialist and the Patient's GP.
All patients should be reviewed by the initiating specialist team at 6 months and returned to previous treatment if no improvement in overall disease control from baseline is demonstrated.

May 2018:
The TAG considered the PAC's revised guidance, which now also recommended restricted use in Type 2 diabetes and included amendments to the recommended criteria for use, as follows:

1. Insulin degludec is not recommended for routine use in adults or children with either type 1 or type 2 diabetes.

2. Insulin degludec 100 units/ml may be of benefit in certain patients with type 1 or type 2 diabetes who fulfil the following criteria:
* Patients with significant hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE), and basal insulin/multiple daily injections and who fulfil the criteria for insulin pump therapy.
* "Chaotic patients" who may be at significant risk of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) (previously known as hyperosmolar non - ketotic diabetic state or hyper HONK) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections.
* Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA or HHS if daily basal insulin is missed.
* Patients with a diagnosed allergy to either insulin glargine or insulin detemir.

3. High strength insulin degludec 200 units/ml is not recommended for routine use. It should be considered for patients with severe insulin resistance requiring large daily doses of insulin (≥3 units/kg/day), where treatment is initiated by a specialist Consultant Diabetologist.

5. Insulin degludec should be initiated by a Consultant Diabetologist only and is NOT suitable for initiation by GPs or other prescribers in primary care unless under the supervision of a specialist. It is recommended that the initial dose titration and monitoring is closely supervised by a specialist team.

6. All patients should be managed by the initiating specialist team for a minimum of three months or until stable. Patients should be returned to previous treatment if no improvement in overall disease control from baseline is demonstrated.

The TAG agreed to accept the PAC's recommendations as stated above, to revise the Double Red (Not recommended for routine use) classification for routine use in Type 1 AND Type 2 diabetes mellitus, and to extend the classification as Green (GP prescribable following specialist recommendation) where the initial dose titration and monitoring is closely supervised by the initiating specialist for the first three months or until stable, as per the above-listed criteria for use, including use in Type 2 diabetes.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

May 2018: The D&TC noted that the extended criteria relate to T-2 diabetes.
The D&TC supported that PAC's criteria, with the TAG's recommended amendments, providing that local practitioners adhere to them, and that the specialist provides the first prescription.

June 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG and the D&TC's recommendations.

March 2019: The TAG noted that the PAC had amended the wording in their guidance regarding use in patients with disabling hypoglycaemia, which now state:
"Patients with disabling hypoglycaemia (defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life), despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE, DESMOND), and optimisation of basal insulin/multiple daily injections."

The TAG supported continued use of the PAC's revised guidance document with the proviso that the previous local agreement was maintained which related to wording on use for severe insulin resistance, which had been amended to facilitate use of insulin degludec by local acute trust consultant diabetologists for this indication, to avoid the need for unnecessary referral to tertiary centre specialists.

March 2019: The revised wording and the TAG's recommendations were noted and supported by the N&W CCGs' D&TC.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

Insulin detemir *(Levemir®)* TAG recommendation: Jul 2005

for use in: Diabetes in adults & children >1 yrs (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2016.

Specific points: July 2009 - the TAG noted NICE Clinical Guideline 87 May 2009 - Type-2 Diabetes which supersedes previous NICE guidance and agreed to maintain previous TAG recommendations on the use of insulin analogues.

September 2015: The TAG noted NICE NG 17 (August 2015) - Type 1 diabetes in adults: diagnosis and management, which covers the care and treatment of adults (aged 18 and over) with type 1 diabetes.
Contains several new recommendations for 2015.
NG 17 updates and replaces the sections for adults in NICE guideline CG15.

September 2015: The TAG noted NG 18 (August 2015) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management - which covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18 years. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes.

The TAG also acknowledged that continuous glucose monitoring is not routinely commissioned by the CCGs and this aspect of NG 18 could potentially add a cost pressure to the local health economy.
The TAG suggested that a local treatment pathway was needed.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The committee also noted that because NG 17 recommends insulin detemir as the long-acting insulin of choice, this has clinical and cost implications for the local health economy. The D&TCG therefore recommended that local diabetes specialists are liaised with on this issue.

October 2015:
The TAG's recommendation regarding NG 17 also noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The D&TCG therefore recommended that local diabetes specialists are liaised with regarding implementation of NG17.

September 2016:
The TAG noted that in July 2016, recommendation 1.15.1 in NG 17 was reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

January 2017:
The TAG acknowledged NG 18 (updated November 2016) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management which includes recommendations on:
* diagnosis
* management of type 1 and type 2 diabetes
* diagnosis and management of diabetic ketoacidosis in children and young people with type 1 and type 2 diabetes
* service provision.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

Insulin glargine *(Lantus®)* TAG recommendation: Apr 2005

for use in: Diabetes mellitus (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: December 2002.

Specific points: In September 2002, TAG agreed that NICE guidance should be followed, that consultants only should switch patients to insulin glargine, and that there should be no blanket switching of patients.
In September 2003 it was agreed that the Bertram Diabetes Centre should audit prescribing of insulin glargine as per the criteria set out in NICE guidance.

September 2015: The TAG noted NG 18 (August 2015) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management - which covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18 years. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes.

July 2009 - the TAG noted NICE Clinical Guideline 87 May 2009 - Type-2 Diabetes and agreed to maintain previous TAG recommendations on the use of insulin analogues.

September 2015: The TAG noted NICE NG 17 (August 2015) - Type 1 diabetes in adults: diagnosis and management, which covers the care and treatment of adults (aged 18 and over) with type 1 diabetes.
Contains several new recommendations for 2015.
NG 17 updates and replaces the sections for adults in NICE guideline CG15.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).

September 2016:
The TAG noted that in July 2016, recommendation 1.15.1 in NG17 was reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

January 2017:
The TAG acknowledged NG 18 (updated November 2016) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management which includes recommendations on:
* diagnosis
* management of type 1 and type 2 diabetes
* diagnosis and management of diabetic ketoacidosis in children and young people with type 1 and type 2 diabetes
* service provision.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

Insulin glargine 300 units/ml (Toujeo®) *(Toujeo®)*

TAG recommendation: May 2018

for use in: Restricted use in adults aged ≥18 years with diabetes mellitus under specified criteria - see full guidance (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for the first script and until the patient is stabl.

NICE has not issued any guidance.

Specific points: March 2016: The TAG recommended a traffic light classification of Green (prescribable at request of Consultant/Specialist) for use of Toujeo® for diabetes mellitus in a specific group of adults who require greater than 200 units of insulin per day, with poor glycaemic control defined as having an HbA1c of greater than 75mmol/mol.

March 2016: The TAG-recommended traffic light classification of Green (prescribable at request of Consultant/Specialist) for use of Toujeo® for diabetes mellitus in a specific group of adults who require greater than 200 units of insulin per day, with poor glycaemic control defined as having an HbA1c of greater than 75mmol/mol, was noted and supported by the NHS Norfolk & Waveney CCGs' D&TCG.

September 2016:
The TAG acknowledged NG 17 (update July 2016) which includes new recommendations on:
* Diagnosis
* Structured education
* Insulin therapy
* Blood glucose management
* Impaired awareness of hypoglycaemia
* Managing complications of diabetes
Recommendation 1.15.1 was also reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

May 2018: The TAG considered the East of England Priority Advisory Commitee's (PAC) guidance which recommended against routine use in diabetes due to safety concerns with the use of high strength insulins.
PAC-recommended criteria for restricted use in adults aged ≥18 years of age are:
* Patients with significant hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE), and basal insulin/multiple daily injections and who fulfil the criteria for insulin pump therapy.
* "Chaotic patients" who may be at significant risk of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections.
* Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA or HHS if daily basal insulin is missed.
* Patients with a diagnosed allergy to either insulin detemir or insulin degludec.
The PAC also recommended that:
* Insulin glargine 300 units/ml (Toujeo®) could be considered for patients with severe insulin resistance requiring large daily doses of insulin (≥3units/kg/ day), where treatment is initiated by a Consultant Diabetologist
* All patients should be managed by the initiating specialist team for a minimum of three months or until stable. Patients should be returned to their previous treatment if no improvement in overall disease control from baseline is demonstrated.
The TAG agreed to accept the PAC's recommendations as stated above, in addition to the previously commissioned criteria for use, and to maintain the classification as Green (GP prescribable following specialist initiation) where the initial dose titration and monitoring is closely supervised by the initiating specialist for the first three months or until stable, as per the above-listed criteria for use.

May 2018: The NHS Norfolk & Waveney CCGs' D&TC The D&TC supported the PAC's criteria, with the amendments recommended by the TAG, with the proviso that local practitioners must adhere to them, that the specialist will provide the first prescription supply, and that use of Toujeo will be monitored.

May 2018: The NHS Norfolk & Waveney CCGs' JSCC noted and supported the TAG and the D&TC's recommendations.

March 2019: The TAG noted that the PAC had amended the wording in their guidance regarding use in patients with disabling hypoglycaemia,

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.1.2 - Intermediate and long-acting insulins

which now state:
"Patients with disabling hypoglycaemia (defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life), despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education, e.g. DAFNE, DESMOND), and optimisation of basal insulin/multiple daily injections."

The TAG supported continued use of the PAC's revised guidance document with the proviso that the previous local agreement was maintained which related to wording on use for severe insulin resistance, which had been amended to facilitate use of insulin glargine (Toujeo) by local acute trust consultant diabetologists for this indication, to avoid the need for unnecessary referral to tertiary centre specialists.

March 2019: The revised wording and the TAG's recommendations were noted and supported by the N&W CCGs' D&TC.

Insulin glargine biosimilar 100iu/ml (Abasaglar®) *(Abasaglar®)* TAG recommendation: Mar 2016

for use in: Diabetes mellitus (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2016: The TAG noted the information contained within NICE esnm 64 and UKMi evidence and recommended a traffic light classification of Green (prescribable at request of Consultant/Specialist) for use of Abasaglar® in type 1 and type 2 diabetes mellitus.
The TAG also recommended that this insulin glargine product should be prescribed by brand name Abasaglar® in order to ensure that the correct pen device is used and that the most cost-effective option is dispensed.

March 2016: The TAG-recommended traffic light classification of Green (prescribable at request of Consultant/Specialist) for use of Abasaglar®, (prescribed by brand name) in type 1 and type 2 diabetes mellitus was noted and supported by the NHS Norfolk & Waveney CCGs' D&TCG.
CCGs in Norfolk and Waveney will monitor uptake of use of Abasaglar® and may incentivise switching.

September 2016:
The TAG acknowledged NG 17 (update July 2016) which includes new recommendations on:
* Diagnosis
* Structured education
* Insulin therapy
* Blood glucose management
* Impaired awareness of hypoglycaemia
* Managing complications of diabetes
Recommendation 1.15.1 was also reworded to clarify the role of GPs in referring people for eye screening and also to add information on when

6.1.2 - Antidiabetic drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2 - Antidiabetic drugs

Exenatide *(Byetta®)* TAG recommendation: Sep 2013

for use in: Co-use with insulin under specified criteria for T2DM - as per local policy (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2012:
The TAG considered the NNUH's application for use of exenatide for a limited group of patients with type 2 diabetes already receiving insulin with HbA1c >7.5% (58mmol/mol) and BMI >40kg/m2

Exenatide (Byetta) used in combination with insulin became licensed treatment in the UK in April 2012. It is not possible to predict which patients will respond to or be able to tolerate combined treatment. Treatment targets must be reached within 6 months of commencing treatment. If not, treatment with exenatide should be reviewed and ideally stopped.

The TAG supported the business case for exenatide (Byetta) for patients with type 2 diabetes receiving insulin with HbA1c >7.5% (58mmol/mol) and BMI >40kg/m2.

January 2012: The TAG agreed to support a Shared Care proposal for combined use of exenatide (Byetta) in a limited group of patients with type 2 diabetes on pre-existing treatment with insulin. The TAG also recommended that patients should NOT be switched to an analogue insulin after starting treatment with exenatide.
The Norfolk & Waveney Drugs & Therapeutics Commissioning Group approved use of the Shared Care Agreement.

September 2013: The TAG agreed to revise the Amber status for this treatment to Green (GP prescribable at the request of Consultant/Specialist) for all locally recommended indications.
Current Shared Care guidance documents have been withdrawn from use and replaced with GP Prescribing Information.

Approved by the NHS N&W D&TCG.
Available via:
http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2015:
The TAG noted NG 18 (August 2015) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management.

October 2015:
Noted by the Norfolk & Waveney CCGs' Drugs & Therapeutics Commissioning Group (D&TCG).
The D&TCG therefore recommended that local diabetes specialists are liaised with regarding implementation of NG18.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2 - Antidiabetic drugs

Exenatide (prolonged-release) *(Bydureon®)* TAG recommendation: Sep 2013

for use in: in combination with oral antidiabetic therapy for type-2 diabetes - as per NICE TA 248 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: February 2012.

Specific points: March 2012:
NICE TA 248 states that :
Prolonged-release exenatide in triple therapy regimens (that is, in combination with metformin and a sulphonylurea, or metformin and a thiazolidinedione) is recommended as a treatment option for people with type 2 diabetes as described in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, when control of blood glucose remains or becomes inadequate (HbA1c ≥ 7.5% [59 mmol/mol] or other higher level agreed with the individual), and the person has:
* a body mass index (BMI) of ≥ 35 kg/m2 in those of European family origin (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, or
* a BMI < 35 kg/m2, and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related co-morbidities.
* Treatment with prolonged-release exenatide in a triple therapy regimen should only be continued as described in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c [11 mmol/mol] and a weight loss of at least 3% of initial body weight at 6 months).

* Prolonged-release exenatide in dual therapy regimens (that is, in combination with metformin or a sulphonylurea) is recommended as a treatment option for people with type 2 diabetes, as described in 'Liraglutide for the treatment of type 2 diabetes mellitus' (NICE technology appraisal 203); that is, only if:
* the person is intolerant of either metformin or a sulphonylurea, or treatment with metformin or a sulphonylurea is contraindicated, and
* the person is intolerant of thiazolidinediones and dipeptidyl peptidase-4 (DPP-4) inhibitors, or a treatment with thiazolidinediones and DPP-4 inhibitors is contraindicated.
* Treatment with prolonged-release exenatide in a dual therapy regimen should only be continued as described in 'Liraglutide for the treatment of type 2 diabetes mellitus' (NICE technology appraisal guidance 203); that is, if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c [11 mmol/mol] at 6 months).

Bydureon® offers weekly rather than a twice daily dosing regimen (as for Byetta®) at slightly greater cost. It is available as a syringe and needle with the drug requiring reconstitution, rather than in a pre-filled pen device, which may limit its usefulness for some patients and affect ease of administration in Primary Care.

September 2013: The TAG agreed to revise the Amber status for this treatment to Green (GP prescribable at the request of Consultant/Specialist) for all locally recommended indications.
Current Shared Care guidance documents have been withdrawn from use and replaced with GP Prescribing Information.

Approved by the NHS N&W D&TCG.
Available via:
http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2 - Antidiabetic drugs

September 2016:
The TAG noted that recommendation 1.7.17 in NG28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Lixisenatide *(Lyxumia®)* TAG recommendation: Sep 2013

for use in: Treatment of Type 2 diabetes, HbA1c ≥ 58mmol/mol (7.5%), BMI ≥35 kg/m2 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts one one month

NICE has not issued any guidance.

Specific points: Once-daily injectable GLP-1 receptor agonist (Sanofi) which is currently being used adjunctively for patients with type 2 diabetes providing HbA1c targets are met and adequate weight loss is achieved. Use is covered by NICE CG 87. Although there is less evidence related to use of this treatment (than liraglutide and exenatide) no additional safety issues have come to light.

The TAG members agreed they were happy support use of lixisenatide and recommended a traffic light classification of Green (GP prescribable at the request of a Specialist or Consultant) with a Prescriber's Rating of 3. "Offers and advantage, has some value but does not ultimately change therapeutic practice", the advantage being cost-effectiveness.

September 2013: Further discussion and agreement at the TAG and the CCGs' D&TCG has resulted in the current Shared Care Agreement being updated to include us eof lixisenatide and renamed as "Prescribing Guidance" in view of GLP-1agonists being reclassified from Amber (option for shared care prescribing) to Green (GP prescribing following specialist recommendation / initiation).
This is available via http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016:
In July 2016, recommendation 1.7.17 in NG 28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

6.1.2.2 - Biguanides

Metformin *()* TAG recommendation: Mar 2022

for use in: Polycystic ovary syndrome (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Unlicensed treatment

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Canagliflozin ▼ *(Invokana® ▼)* TAG recommendation: Jul 2016

for use in: As a 4th monotherapy option for treating type 2 diabetes - as per NICE TA 390 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: May 2016.

Specific points: July 2016: The TAG noted NICE TA 390 recommending canagliflozin as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:
* a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and
* a sulfonylurea or pioglitazone is not appropriate
and recommended a traffic light classification of Green (GP prescribable following consultant recommendation).

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and commissioned canagliflozin as a 4th line monotherapy option, only after other standard options have been considered, as per the currently commissioned treatment pathway - see local Diabetes Formulary for more information: http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_diabetes.pdf

September 2016:
The TAG acknowledged NG 28 (update July 2016) - Type 2 diabetes in adults: management. This includes recommendations on:
* Individualised care
* Managing blood glucose levels:
  HbA1c measurement and targets
  Self-monitoring of blood glucose
  Drug treatment
* Antiplatelet therapy
* Managing complications

Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Canagliflozin ▼ *(Invokana® ▼)* TAG recommendation: Jul 2014

for use in: In combination therapy for treating type 2 diabetes - as per NICE TA 315 (Prescriber's Rating "Possibly helpful" in certain patients) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2014.

Specific points: NICE TA 315 (June 2014):
Recommended by NICE as an option as follows:
1.1 Canagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if:
- a sulfonylurea is contraindicated or not tolerated or
- the person is at significant risk of hypoglycaemia or its consequences.

1.2 Canagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with:
- metformin and a sulfonylurea or
- metformin and a thiazolidinedione.

1.3 Canagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes.

July 2014: The TAG noted NICE TA 315 and recommended a classification of Green (GP prescribable at the request of a Specialist or Consultant) with a Prescriber's Rating of "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)" in line with the previous recommendation relating to dapagliflozin.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016: The TAG noted that recommendation 1.7.17 in NG28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

January 2017:
The TAG acknowledged NG 18 (updated November 2016) - Diabetes (type 1 and type 2) in children and young people: diagnosis and management which includes recommendations on:
* diagnosis
* management of type 1 and type 2 diabetes
* diagnosis and management of diabetic ketoacidosis in children and young people with type 1 and type 2 diabetes
* service provision.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Dapagliflozin *(Forxiga®)* TAG recommendation: Jan 2017

for use in: Triple therapy for treating type 2 diabetes in adults - as per NICE TA 418 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2016.

Specific points: January 2017: The TAG acknowledged NICE TA 418 (November 2016) and recommended a traffic light classification of Green (GP prescribable following specialist request / recommendation) with a Prescriber's Rating of "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)" for this CCG-commissioning responsibility treatment.

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation. Commissioned as Green (GP prescribable following specialist request / recommendation). Prescriber's Rating: "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)".

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Dapagliflozin ▼ *(Forxiga® ▼)* TAG recommendation: Jul 2013

for use in: Limited use in Type 2 diabetes mellitus - as per NICE TA 288 (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2013.

Specific points: March 2013:
Recommended as Double Red (Not recommended for routine use)
Prescriber's Rating: Not acceptable
Norfolk & Waveney Drugs & Therapeutics Commissioning Group decision: Not commissioned

July 2013:
NICE TA 288 (June 2013) states that
1.1 Dapagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if it is used as described for dipeptidyl peptidase-4 (DPP-4) inhibitors in Type 2 diabetes (NICE clinical guideline 87).
1.2 Dapagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes.
1.3 Dapagliflozin in a triple therapy regimen in combination with metformin and a sulfonylurea is not recommended for treating type 2 diabetes, except as part of a clinical trial.

The TAG therefore recommended re-classification to Green (GP prescribable at the request of a Specialist or Consultant) with a Prescriber's Rating of "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)".

Additional guidance to summarise the benefits and risks of dapagliflozin will be provided for Primary Care prescribers.

Other similar drugs with lesser adverse effects will soon be marketed for the same group of patients, therefore the TAG does not expect there to be significant uptake of dapagliflozin following NICE TA 288.

The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) noted and accepted the TAG's recommendations but also was concerned regarding the risk of adverse effects and the unknown consequences of long-term use of dapagliflozin.
Commissioned for limited use in specific patients.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016:
The TAG noted that recommendation 1.7.17 in NG28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

January 2017: The TAG acknowledged NICE TA 418 (November 2016) for triple therapy for treating type 2 diabetes in adults, and recommended a traffic light classification of Green (GP prescribable following specialist request / recommendation) with a Prescriber's Rating of "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)" for this CCG-commissioning responsibility treatment

January 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation. Commissioned as Green (GP

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

prescribable following specialist request / recommendation). Prescriber's Rating: "Possibly Helpful (has minimal additional value and should not change the prescribing habits except in rare circumstances)".

Dapagliflozin ▼ *(Forxiga® ▼)* TAG recommendation: Jul 2016

for use in: As monotherapy for treating type 2 diabetes - as per NICE TA 390 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: May 2016.

Specific points: July 2016: The TAG noted NICE TA 390 recommending the dapagliflozin as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:
* a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and
* a sulfonylurea or pioglitazone is not appropriate
and recommended a traffic light classification of Green (GP prescribable following consultant recommendation).

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and commissioned dapagliflozin as a 4th line monotherapy option, only after other standard options have been considered, as per the currently commissioned treatment pathway - see local Diabetes Formulary for more information: http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_diabetes.pdf

September 2016:
The TAG acknowledged NG 28 (July 2016) - Type 2 diabetes in adults: management. This includes recommendations on:
* Individualised care
* Managing blood glucose levels:
  HbA1c measurement and targets
  Self-monitoring of blood glucose
  Drug treatment
* Antiplatelet therapy
* Managing complications
Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Dulaglutide ▼ *(Trulicity® ▼)* TAG recommendation: Mar 2021

for use in: Type 2 diabetes mellitus - third line option (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2018: PRG recommendation that the TAG considers applying a Green (Suitable for GP prescribing following specialist recommendation) classification to this treatment and that it is supported for addition to the local Diabetes Formulary as third line option:
The TAG agreed to support the PRG's recommendation.

January 2018: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2018: The NHS Norfolk & Waveney CCGs' JSCC supported the D&TC recommendation.

March 2021 - Business case accepted for 3mg and 4.5mg preparations. Confirmed costs are the same for all strengths

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Empagliflozin ▼ *(Jardiance® ▼)* TAG recommendation: May 2015

for use in: In combination therapy for treating type 2 diabetes - as per NICE TA 336 (Prescriber's Rating - nothing new) (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: March 2015.

Specific points: May 2015: The TAG acknowledged the NICE TA 336 (March 2015) and recommended a classification of Green (GP prescribable following specialist recommendation) for empagliflozin (Jardiance®) in combination therapy for treating type 2 diabetes as follows:
1.1 As dual therapy with metformin only if a sulfonylurea is contraindicated or not tolerated, or the person is at significant risk of hypoglycaemia or its consequences.
1.2 As triple therapy with metformin and a sulfonylurea, or metformin and a thiazolidinedione.
1.3 With insulin with or without other antidiabetic drugs.
The committee also recommended a Prescriber's Rating of 6: Nothing New - The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. (In most cases these are "me-too" products).

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted that use of empagliflozin with pioglitazone is contra-indicated in line with MHRA warnings around heart failure and bladder cancer
The D&TCG otherwise noted and supported the TAG's recommendation.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016:
The TAG noted that recommendation 1.7.17 in NG28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Empagliflozin ▼ *(Jardiance ▼)* TAG recommendation: Jul 2016

for use in: As 4th line monotherapy option for treating type 2 diabetes - as per NICE TA 390 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: May 2016.

Specific points: July 2016: The TAG noted NICE TA 390 recommending empagliflozin as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:
* a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and
* a sulfonylurea or pioglitazone is not appropriate
and recommended a traffic light classification of Green (GP prescribable following consultant recommendation).

July 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation and commissioned empagliflozin as a 4th line monotherapy option, only after other standard options have been considered, as per the currently commissioned treatment pathway - see local Diabetes Formulary for more information: http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_diabetes.pdf

September 2016:
The TAG acknowledged NG 28 (July 2016) - Type 2 diabetes in adults: management. This includes recommendations on:
* Individualised care
* Managing blood glucose levels:
  HbA1c measurement and targets
  Self-monitoring of blood glucose
  Drug treatment
* Antiplatelet therapy
* Managing complications
Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Ertugliflozin *(Steglatro®)* TAG recommendation: May 2019

for use in: As monotherapy or with metformin for treating type 2 diabetes - as per NICE TA 572 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: March 2019.

Specific points: May 2019: The TAG acknowledged NICE TA 572 (March 2019) which states:
1.1 Ertugliflozin monotherapy is recommended as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:
* a dipeptidyl peptidase 4 (DPP 4) inhibitor would otherwise be prescribed and
* a sulfonylurea or pioglitazone is not appropriate.
1.2 Ertugliflozin in combination with metformin is recommended as an option for treating type 2 diabetes, only if:
* a sulfonylurea is contraindicated or not tolerated or
*the person is at significant risk of hypoglycaemia or its consequences.
1.3 If patients and their clinicians consider ertugliflozin to be one of a range of suitable treatments including canagliflozin, dapagliflozin and empagliflozin, the least expensive should be chosen.

and recommended a traffic light classification of Green (GP prescribable at the request of a Specialist or Consultant), in line with other NICE-recommended SGLT2 inhibitors

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Exenatide *(Byetta® and Bydureon® ▼)* TAG recommendation: Sep 2013

for use in: 3rd line use in Type 2 diabetes with metformin + sulphonylurea - as per NICE CG 28 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: December 2015.

Specific points: November 2007: The TAG felt that the place of exenatide in treatment of type 2 diabetes was unclear and noted that local specialists were reserving judgement on this product. It was therefore agreed not to support routine use of exenatide and to review the decision when more comparator and longer term safety data becomes available.
Reports of acute pancreatitis related to use of exenatide were noted with concern.

July 2008: The TAG considered the NICE Clinical Guideline No. 66 (May 2008) - Type 2 diabetes and reviewed the previous recommendation (January 2008) of Double Red (Not recommended for routine use).
The TAG recommended re-classification to Red (Hospital Only) under the following circumstances as per NICE Guidelines:

Consider exenatide as an option only if the person:
* Has body mass index > 35.0 kg/m2 in those of European descent (adjust as appropriate for other ethnic groups), AND
* Has specific psychological, biochemical or physical problems arising from high body weight, AND
* Has inadequate blood glucose control (HbA1c ≥ 7.5%) with conventional oral agents after a trial of metformin and sulfonylurea, AND
* Would otherwise be starting other high-cost medication, such as a thiazolidinedione or insulin.
* Continue exenatide only if beneficial response occurs and is maintained (≥ 1.0 percentage point HbA1c reduction in 6 months and weight loss ≥ 5% at 1 year).

It was also agreed that the NICE criteria for use of exenatide should form the basis for controlled, audited use in secondary care.

Prescriber's Rating: 4. Possibly helpful - This product has minimal additional value, and should not change prescribing habits except in rare circumstances.

July 2009: The TAG considered NICE Clinical Guideline 87 (May 2009) - Type 2 diabetes - newer agents for blood glucose control, which includes exenatide as part of the treatment pathway. The TAG noted that local consultants wish to target use of exenatide to specific patients and support it remaining as Red (Hospital Only). It was also agreed that the emerging side-effect profile of this drug requires that it remains under specialist use for the time being. The TAG therefore agreed to maintain the current classification as Red (Hospital / Specialist Use Only).

March 2010: The TAG agreed that a shared care classification (Amber) would be appropriate for exenatide as a third-line option in combined treatment of type 2 diabetes along with metformin and a sulphonylurea.

July 2010: The TAG agreed to support a Norfolk-wide Shared Care Agreement for use of exenatide (Byetta) in type 2 diabetes.

September 2013: The TAG agreed to revise the Amber status for this treatment to Green (GP prescribable at the request of Consultant/Specialist) for all locally recommended indications.
Current Shared Care guidance documents have been withdrawn from use and replaced with GP Prescribing Information.

Approved by the NHS N&W D&TCG.
Available via:
http://nww.knowledgeanglia.nhs.uk/tag/index.htm

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016
Recommendation 1.7.17 in the guidance was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

GLP-1 agonist Semaglutide *(Ozempic®)* TAG recommendation: May 2019

for use in: Adults with insufficiently controlled type 2 diabetes mellitus (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2019: The TAG acknowledged the PRG's recommendation to have this once-weekly product available on formulary as a 3rd line add-on treatment option and agreed to apply a traffic light classification of Green (suitable for GPs to prescribe following specialist recommendation).

May 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

June 2019: The NHS Norfolk & waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

Liraglutide *(Victoza®)* TAG recommendation: Sep 2013

for use in: Adjunctive use in Type 2 diabetes (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: October 2010.

Specific points: November 2010:
The TAG noted NICE TA 203 which recommends liraglutide 1.2mg as an option for triple (as per exenatide) and dual regimens, but does not recommend the 1.8mg dose as follows:
1.1 Liraglutide 1.2 mg daily in triple therapy regimens (in combination with metformin and a sulphonylurea, or metformin and a thiazolidinedione) is recommended as an option for the treatment of people with type 2 diabetes, only if used as described for exenatide in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, when control of blood glucose remains or becomes inadequate (HbA1c ≥ 7.5%, or other higher level agreed with the individual), and the person has:
* a body mass index (BMI) ≥ 35 kg/m2 in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, or
* a BMI < 35 kg/m2, and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.
1.2 Treatment with liraglutide 1.2 mg daily in a triple therapy regimen should only be continued as described for exenatide in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c and a weight loss of at least 3% of initial body weight at 6 months).
1.3 Liraglutide 1.2 mg daily in dual therapy regimens (in combination with metformin or a sulphonylurea) is recommended as an option for the treatment of people with type 2 diabetes, only if:
* the person is intolerant of either metformin or a sulphonylurea, or treatment with metformin or a sulphonylurea is contraindicated, and
* the person is intolerant of thiazolidinediones and dipeptidyl peptidase-4 (DPP-4) inhibitors, or treatment with thiazolidinediones and DPP-4 inhibitors is contraindicated.
1.4 Treatment with liraglutide 1.2 mg daily in a dual therapy regimen should only be continued if a beneficial metabolic response has been shown (defined as a reduction of at least 1 percentage point in HbA1c at 6 months).
1.5 Liraglutide 1.8 mg daily is not recommended for the treatment of people with type 2 diabetes.
1.6 People with type 2 diabetes currently receiving liraglutide who do not meet the criteria specified in section 1.1 or 1.3, or who are receiving liraglutide 1.8 mg, should have the option to continue their current treatment until they and their clinicians consider it appropriate to stop.

The TAG agreed that liraglutide 1.2mg daily for T2DM should be classified as Amber (option for shared care). The TAG agreed that the term "specialist" should apply to practitioners in both Primary and Secondary care.

September 2013: The TAG agreed to revise the Amber status for this treatment to Green (GP prescribable at the request of Consultant/Specialist) for all locally recommended indications.
Current Shared Care guidance documents have been withdrawn from use and replaced with GP Prescribing Information.

Approved by the NHS N&W D&TCG.
Available via:
http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management, which updated NICE TA 203.
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.1.2.3 - Other antidiabetic drugs

September 2016:
In July 2016, recommendation 1.7.17 in NG28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

Repaglinide *(PRANDIN®)* TAG recommendation: Mar 2020

for use in: to treat CF patients who have diabetes, as an alternative to insulin (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2020 - The TAG considered the business case and recommended a traffic light classification of Green (GP Prescribable at request of Consultant / Specialist) providing this medication is initiated by a CF Specialist.
There are no significant monitoring arrangements associated with the treatment other than the clinicians wishing to carry out the dose titration.
This recommendation was supported by the D+TC.

May 2020 - Recommendation ratified by Governing Body for Norfolk and Waveney CCG

Semaglutide *(Ozempic®)* TAG recommendation: May 2019

for use in: For adults with insufficiently controlled type 2 diabetes mellitus as adjunct to diet and exercise - monotherapy (if metformin inappropriate) or in combination with other antidiabetic drugs as per local Diabetes Formulary guidance - 3rd line option (A licensed

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2019: The TAG considered the Prescribing Reference Group's recommendation to add this once-weekly product available on formulary as a 3rd line add-on treatment option in the Diabetes Formulary.

Semaglutide oral preparations *(Rybelsus®))* TAG recommendation: Nov 2020

for use in: Diabetic patients where GLP1 analogue is indicated but oral preparation is more suitable (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Nov 2020 - TAG recommendation was supported by the D+TC.
It was confirmed that these preparations will have the same prescribing classification as the injections - Green (GP prescribing following Specialist Initiation/recommendation). Ratified by CCG Governing Body

6.2.2 - Anti-thyroid drugs

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.2.2 - Anti-thyroid drugs

Liothyronine / L-tri-iodothyronine sodium (T3) *(Cytomel / Triostat (U.S.))* TAG recommendation: Jan 2019

for use in: RESTRICTED use for long term treatment in rare cases of levothyroxine-induced liver injury, and are assessed by an NHS consultant as requiring treatment - as per RMOC guidance (x).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3 months for new patients.

NICE has not issued any guidance.

Specific points: May 2018:
The TAG considered new recommendations from the East of England Priorities Advisory Committee (PAC) regarding use of liothyronine (T3) which included the following:
2b In rare cases of levothyroxine induced liver injury, long term liothyronine prescribing may be supported but only after initiation and stabilisation by a secondary care specialist. Arrangements for individual prior approval, prescribing and supply should be agreed locally, ensuring that appropriate patient monitoring is in place.

January 2019: The TAG considered guidance from the RMOC (November 2018) and reviewed the previously agreed traffic light classifications. A recommendation was made that the classification be changed to Green - for new patients, NHS Consultant to prescribe for 3 months then GP. For existing patients, NHS consultant to review, then, if appropriate, to the GP.

January 2019: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.2.2 - Anti-thyroid drugs

Liothyronine / L-tri-iodothyronine sodium (T3) *(Cytomel, Triostat (U.S.))* TAG recommendation: Jan 2019

for use in: Liothyronine for NON-ROUTINE use in people with hypothyroidism who continue to suffer with symptoms despite adequate biochemical correction, who have not previously taken or who are currently prescribed Liothyronine by their NHS GP (x).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3 months for new patients.

NICE has not issued any guidance.

Specific points: May 2018:
The TAG considered new recommendations from the East of England Priorities Advisory Committee (PAC) regarding use of liothyronine (T3) which included the following:
3. Initiation and prescribing of liothyronine for patients in place of levothyroxine who continue to suffer with symptoms despite adequate biochemical correction should remain in secondary care under the supervision of an accredited endocrinologist.

May 2018: The The Norfolk and Waveney CCGs' D&TC noted and supported the PAC's, and the TAG's related, recommendations regarding criteria for use of liothyronine.

June 2018: The Norfolk and Waveney CCGs' Joint Strategic Commissioning Committee (JSCC) supported the TAG and the D&TC's recommendations.

January 2019: The TAG considered recent guidance from the RMOC (November 2018) and reviewed the previously agreed traffic light classifications. A recommendation was made that the classification be changed to Green - for new patients, NHS Consultant to prescribe for 3 months then GP.
For existing patients, NHS consultant to review, then, if appropriate, to the GP.

January 2019: The NHS Norfolk & Waveney CCGs' noted and supported the TAG recommendation.

February 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

6.3.2 - Glucocorticoid therapy

Hydrocortisone granules in capsules *(Alkindi®)* TAG recommendation: Mar 2019

for use in: Cortisol replacement therapy for children (0-6 years) with adrenal insufficiency (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2019: The TAG supported the NNUH's proposal for use of a product that would deliver more consistently accurate dose, compared with administering portions of tablets dissolved in water for use, in a young patient group, and at a more cost-effective price than using oral liquid specials. Once older than 6 years, standard tablets can be used to provide necessary dosages.
The TAG agreed to support the application and recommended a traffic light classification of Green (GP prescribing following Specialist initiation/recommendation).

March 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

April 2010: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendatioin.

6.4.1 - Female sex hormones and their modulators

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.4.1 - Female sex hormones and their modulators

Raloxifene *(Evista®)* TAG recommendation: Mar 2014

for use in: Chemoprophylaxis for no more than 5 years for pre- or post-menopausal women at either high or moderate risk of developing breast cancer (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2013.

Specific points: March 2014:
The GY&W CCG Cancer & End of Life (EOL) Board had considered the recommendations contained within NICE CG 164 and had decided to support use of chemoprophylaxis treatment for up to 5 years (tamoxifen first line, then raloxifene) for pre- or post-menopausal women, with or without a uterus who are at high or at moderate risk of developing breast cancer.
The Board now requested a clinical recommendation from the TAG regarding appropriate prescribing responsibility for these treatment options. It was noted that specialist input is required when assessing the level of risk of developing the condition.

The TAG recommended a classification of Green (GP prescribable at the request of the Consultant/Specialist) in line with NICE CG 164.

Noted and supported by the D&TCG - commissioned.

6.4.2 - Male sex hormones and antagonists

Testosterone - various formulations except patches *(Various)* TAG recommendation: Sep 2016

for use in: Androgen deficiency / treatment of transgender patients requiring virilising endocrine therapy (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Cost effectiveness to be taken into consideration.

November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG testosterone transdermal patches to be added on the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List.

Regarding testosterone transdermal patches, these are currently only available as an expensive unlicensed special. Other more cost-effective options are available.

September 2016: The TAG acknowledged publication of NHS England Specialised Services Circular SSC 1620 (22 April 2016) Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Transgender and Non-Binary Adults, regarding the need for testosterone preparations (excluding transdermal patches) to be able to be prescribed by GPs for transgender and non-binary adults on the recommendation of a Gender Identity Clinic specialist.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Denosumab *(Prolia®)* TAG recommendation: Nov 2014

for use in: Prevention of osteoporotic fractures in postmenopausal women as per NICE TA 204 (Specialist Nurse recommendation in West Norfolk CCG only) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: October 2010. There is a shared care protocol approved by TAG.

Specific points: March 2014: Shared Care Agreement reviewed and supported by the TAG and D&TCG.

November 2014: The Agreement reviewed and amended in line with the EMA/MHRA safety review which resulted in updated recommendations to minimise osteonecrosis of the jaw (ONJ) and hypocalcaemia during treatment. The TAG made further recommendations regarding new monitoring requirements:
At initiation of treatment the patient's baseline calcium levels must be checked - to be carried out by the secondary care prescriber.
Regarding the follow-up calcium level check required after two weeks, the clinician doing the initial check should also issue an ICE form for the second blood test.
Primary care should then arrange the blood tests required prior to subsequent doses given 6-monthly thereafter.
The TAG supported the shared care agreement with the recommended amendments.

November 2014: The D&TCG noted and supported the TAG recommendation.

The Shared Care Agreement is available via
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=ecuOI4x_qYE%3d&tabid=913&portalid=1&mid=2043f

April 2015: A local agreement exists in West Norfolk CCG whereby the osteoporosis specialist nurse will assess and approve denosumab initiation in primary care for suitable patients i.e. Green (Suitable for GPs to prescribe following specialist recommendation) - see the West Norfolk CCG website for further details.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Ibandronate / Ibandronic acid

(Oral 50mg tablets - various manufacturers)

TAG recommendation: May 2017

for use in: Daily use for two years to improve survival in post-menopausal women with breast cancer receiving chemotherapy (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2017:
The TAG considered the QEH's application alongside the key reference and agreed to support the application.
The TAG recommended traffic light classifications of Green (GP prescribable following consultant recommendation) for daily oral ibandronate and Red (Hospital use only) for 6-monthly IV zoledronic acid infusions (4 doses) as adjuvant treatment to improve survival in post-menopausal women with breast cancer receiving chemotherapy for 2 years.

May 2017:
The D&TCG noted and supported the TAG's recommendations and decided to commission adjuvant use of 2 years of either 6-monthly IV zoledronic acid infusions (4 doses), or daily oral ibandronate, to improve survival in post-menopausal women with breast cancer receiving chemotherapy as Red (Hospital use only) and Green (GP prescribable following consultant recommendation) respectively.
The D&TCG also recommended that GP prescribing systems and processes should ensure that such use of ibandronic acid is not stopped in advertently or continued beyond two years inappropriately by clearly stating the Indication and duration of use along with an appropriate stop date on the patient's record.

July 2017: GP Prescribing information on the use of ibandronate for this indication is available at:
http://nww.knowledgeanglia.nhs.uk/tag/ibandronic_acid.pdf

Ibandronic Acid, Ibandronate

(Oral product - Bondronat®)

TAG recommendation: May 2014

for use in: Reduction of bone damage in bone metastases in breast cancer (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts Care Agre
ement

NICE has not issued any guidance.

Specific points: January 2006 - Re-classification as Amber - option for GP prescribing under an approved Shared Care Agreement.

November 2007- revised document approved by the TAG.

May 2012: Revised version supported by the TAG and use approved by the NHS N&W D&TCG.

May 2014: TAG recommendation to revise classification from Amber (option for GP prescribing under an approved shared care agreement) to Green (Suitable for GPs to prescribe following specialist recommendation).
Former shared care guidance to be relabelled as GP Prescribing Guidance.

May 2014: TAG recommendation noted ans supported by the Norfolk and Waveney CCG's Drugs & Therapeutics Commissioning Group (D&TCG).

Available via the Knowledge Management website: http://nww.knowledgeanglia.nhs.uk/tag/tag_guidance.htm

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

6.6.2 - Bisphosphonates & drugs affecting bone metabolism

Sodium Clodronate *(Bonefos®/Loron®)* TAG recommendation: May 2014

for use in: Bone pain associated with bony metastases (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

Specific points: Assessment and initiation by a specialist with a shared care agreement ratified by TAG (March 2006).

May 2014: TAG recommendation to revise classification from Amber (option for GP prescribing under an approved shared care agreement) to Green (Suitable for GPs to prescribe following specialist recommendation).
Former shared care guidance to be relabelled as GP Prescribing Guidance.

January 2019: GP prescribing guidance document withdrawn as viewed as being no longer required.

6.7.2 - Drugs affecting gonadotrophins

Leuprorelin acetate *(Prostap®; Lutrate®)* TAG recommendation: Jul 2018

for use in: Prostate cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2018:
Classification reaffirmed by the TAG and the D&TC.

Triptorelin acetate *(Decapeptyl®; Gonapeptyl®)* TAG recommendation: Jul 2018

for use in: Prostate cancer (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2018:
Classification reaffirmed by the TAG and the D&TC.

7.3.1 - Combined contraceptives

Etonogestrel / ethinylestradiol *(NuvaRing®)* TAG recommendation: Nov 2009

for use in: Medium acting reversible contraception where oral and transdermal options are not suitable (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE has not issued any guidance.

October 2005.

Specific points: July 2011:
The NHS Norfolk & Waveney Drug & Therapeutics Commissioning Programme Board approved a business case for use of NuvaRing submitted by Sexual Health and Contraception services in East Coast Health Care CIC.

Patients will be taught to self-administer the treatment by the service.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

7.4.2 - For urinary frequency, enuresis & incontinence

Duloxetine *(Yentreve®)* TAG recommendation: Dec 2020

for use in: Moderate to Severe Stress Urinary Incontinence (SUI) - (but not first- line as per NICE CG 171 - Do Not Do) (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts 6 -8 week s & response assessed

NICE issued Guidance in: October 2006. There is a shared care protocol approved by TAG.

Specific points: September 2012: Shared Care Agreement reviewed (no changes) and approved by the TAG.

September 2014: The TAG supported continued use of the revised Shared Care Agreement.

September 2014: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 171 - Urinary incontinence in women: management which states:

1.7.19 Do not use duloxetine as a first-line treatment for women with predominant stress urinary incontinence.

September 2017: The TAG supported the continued use of the Shared Care Document.

September 2017: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendations.

Dec 2020 - The TAG agreed to suspend the SCA and amend traffic light classification to Green (GP can prescribe at request of Consultant/Specialist). Supported by D+TC and ratified by CCG Governing Body

8.2.2 - Corticosteroids (used in GORD)

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.2.2 - Corticosteroids (used in GORD)

Budesonide orodispersible tablets *(Jorveza®)* TAG recommendation: May 2019

for use in: Eosinophilic oesophagitis in adults (GP may issue a SINGLE follow-up treatment (NOT for repeat) only if deemed necessary following assessment of response to initial treatment by given the hospital) as per TA708 (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script.

NICE issued Guidance in: June 2021.

Specific points: March 2019: The TAG considered the QEH's application for use of this treatment. The TAG noted that Jorveza® is a newly licensed option for a rare condition that occurs in a small number of people, which has been treated to date using budesonide nebules, off-label, mixed to form a slurry to coat the oesophagus.
The Trusts consider that it is necessary to use a licensed product, where available. The TAG considered that the evidence presented indicated that Jorveza® was as effective as the current treatment option and debated whether a more expensive licensed option should necessarily be used. It was noted that there are occasions where treatments of lower cost and equivalent effectiveness have continued to be used off-label instead of a more expensive licensed option.
The TAG acknowledged that the evidence provided indicated higher patient preference for using Jorveza® compared with the slurry prepared from the nebules.
The TAG also debated how the 6-week treatment course for Jorveza® might be managed if an additional 6-week course was deemed necessary as confirmed by histology. In order to avoid patients having to return to hospital, the TAG agreed it was reasonable to recommend a traffic light classification of Red (Hospital/Specialist use only) for the first six weeks of treatment, and Green (GP prescribing following Specialist initiation/recommendation) if an additional six weeks of treatment is required. This would be a one-off, acute prescription from the GP.
The TAG noted the price differential between the current and the proposed treatment options.

March 2019:
The D&TC acknowledged that the proposed treatment schedule would mean that a GPs would be asked to prescribe only a single (follow-up) 6-week treatment course per patient, for a very small number of cases. The D&TC therefore requested sight of the QEH Trust's planned GP communication letter regarding use of Jorveza® before agreeing to recommend that it is commissioned as per the TAG's recommendations. Once approved the letter would have to be used across all the Acute Trusts to ensure a consistent approach.

May 2019: The NHS Norfolk & Waveney CCGs' D&TC considered the QEH's proposed template letter and agreed to support its use with a recommended classifications of Green (GP prescribing following Specialist initiation/recommendation) if an additional six weeks of treatment is required -This would be a one-off, acute prescription from the GP.

May 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

June 2021 - NICE TA published. Supports existing recommendation

8.3.1 - Oestrogens

Diethylstilboestrol *(various)* TAG recommendation: May 2021

for use in: treatment of prostate cancer (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: PRG recommended Green (GP prescribing following Specialist Initiation/recommendation)

8.3.4 - Hormone antagonists

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4 - Hormone antagonists

Anastrozole *(Arimidex®)* TAG recommendation: May 2007

for use in: Breast cancer - as per NICE CG81 (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2006.

Specific points: November 2006: NICE Guidance on hormonal treatments for the adjuvant treatment of early oestrogen-receptor- positive breast cancer - anastrozole recommended as an option for primary adjuvant therapy; exemestane for adjuvant therapy following 2-3 years of adjuvant tamoxifen therapy; letrozole for primary adjuvant therapy and extended adjuvant therapy following standard tamoxifen therapy.

May 2007: The TAG agreed to support a protocol developed by the NNUH Oncologists and Breast Surgeons regarding drug management of oestrogen-receptor-positive early breast cancer in post menopausal women. Regarding anastrozole, advice is as follows:
High risk patients (1-3 Node Positive, High Grade or ≥4 Node Positive Any Grade) - Anastrozole for 5 years.
NB: Other factors may influence risk to patient (e.g. tumour size). Bone health management as per current approved osteoporosis prophylaxis policy should be considered for aromatase inhibitors.

March 2009: The TAG acknowledged NICE Clinical Guideline 80 - Early and locally advanced breast cancer (Feb 2009), which details the place of the aromatase inhibitors (anastrozole, exemestane, letrozole) in adjuvant endocrine therapy for different patient groups.

July 2013: NICE CG 164 (June 2013)
(p34 Section 1.7 Treatment strategies) noted by the TAG.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Exemestane *(Aromasin®)* TAG recommendation: Jul 2003

for use in: Advanced breast cancer in postmenopausal women in whom anti-oestrogen therapy has failed - as per NICE CG 81 (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Consultant initiation only.

For use as second or third line therapy only in hormone positive advanced breast cancer. Only to be used as adjunctive therapy in clinical trials.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4 - Hormone antagonists

Exemestane *(Aromasin®)* TAG recommendation: May 2007

for use in: Adjuvant treatment of oestrogen-receptor-positive early breast cancer - as per NICE TA 112 and CG80/81 (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2006.

Specific points: November 2006: TAG acknowledgment of NICE Guidance on hormonal treatments for the adjuvant treatment of early oestrogen-receptor- positive breast cancer - within marketing authorisations at the time of appraisal - anastrozole recommended as an option for primary adjuvant therapy; exemestane for adjuvant therapy following 2-3 years of adjuvant tamoxifen therapy; letrozole for primary adjuvant therapy and extended adjuvant therapy following standard tamoxifen therapy.

The TAG agreed to support a protocol developed by the NNUH Oncologists and Breast Surgeons regarding drug management of oestrogen-receptor-positive early breast cancer in post menopausal women. Regarding exemestane, advice is as follows:
Intermediate risk patients (Node Negative, High Grade or 1-3 Node positive, Low and Intermediate Grade) - Tamoxifen for 2.5 years then exemestane for 2.5 years.
NB: Other factors may influence risk to patient (e.g. tumour size). Bone health management as per current approved osteoporosis prophylaxis policy should be considered for aromatase inhibitors.

March 2009: The TAG acknowledged NICE Clinical Guideline 80 - Early and locally advanced breast cancer (Feb 2009), which details the place of the aromatase inhibitors (anastrozole, exemestane, letrozole) in adjuvant endocrine therapy for different patient groups.

July 2013: NICE CG 164 (June 2013)
(p34 Section 1.7 Treatment strategies) noted by the TAG.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Goserelin *(Zoladex®)* TAG recommendation: Jan 1996

for use in: Prostate cancer (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Consultant initiation only.
November 2010: View confirmed by the TAG.

July 2018:
Reaffirmed by the TAG and the D&TC.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4 - Hormone antagonists

Letrozole *(Femara®)* TAG recommendation: May 2007

for use in: Adjuvant treatment of early oestrogen-receptor-positive breast cancer in postmenopausal women (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2006.

Specific points: November 2006: TAG acknowledged NICE Guidance on hormonal treatments for the adjuvant treatment of early oestrogen-receptor- positive breast cancer,: within marketing authorisations at the time of appraisal - anastrozole recommended as an option for primary adjuvant therapy; exemestane for adjuvant therapy following 2-3 years of adjuvant tamoxifen therapy; letrozole for primary adjuvant therapy and extended adjuvant therapy following standard tamoxifen therapy.

May 2007: The TAG agreed to support a protocol developed by the NNUH Oncologists and Breast Surgeons regarding drug management of oestrogen-receptor-positive early breast cancer in post menopausal women. Regarding letrozole, advice is as follows:
High risk patients currently on tamoxifen - Letrozole for 3 years following 5 year completion of tamoxifen (extended adjuvant)

Neo-adjuvant patients (locally advanced disease) - Letrozole for four months and continuing for total of 5 years following interventional treatment.
NB: Other factors may influence risk to patient (e.g. tumour size). Bone health management as per current approved osteoporosis prophylaxis policy should be considered for aromatase inhibitors.

March 2009: The TAG acknowledged NICE Clinical Guideline 80 - Early and locally advanced breast cancer (Feb 2009), which details the place of the aromatase inhibitors (anastrozole, exemestane, letrozole) in adjuvant endocrine therapy for different patient groups.

July 2013: NICE CG 164 (June 2013)
(p34 Section 1.7 Treatment strategies) noted by the TAG.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

Tamoxifen *()* TAG recommendation: Mar 2014

for use in: Chemoprophylaxis for no more than 5 years for pre- or post-menopausal women at either high or moderate risk of developing breast cancer (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: June 2013.

Specific points: March 2014:
The GY&W CCG Cancer & End of Life (EOL) Board had considered the recommendations contained within NICE CG 164 and had decided to support use of chemoprophylaxis treatment for up to 5 years (tamoxifen first line, then raloxifene) for pre- or post-menopausal women, with or without a uterus who are at high or at moderate risk of developing breast cancer.
The Board now requested a clinical recommendation from the TAG regarding appropriate prescribing responsibility for these treatment options.
It was noted that specialist input is required when assessing the level of risk of developing the condition.

The TAG recommended a classification of Green (GP prescribable at the request of the Consultant/Specialist) in line with NICE CG 164.

Noted and supported by the D&TCG - commissioned.

8.3.4.1 - Hormone antagonists - breast cancer

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4.1 - Hormone antagonists - breast cancer

Aromatase inhibitors (Various) *(Various)* TAG recommendation: May 2007

for use in: Adjuvant hormonal treatment of early oestrogen-receptor-positive breast cancer in post menopausal women - as per local protocol (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2006.

Specific points: NICE Guidance on hormonal treatments for the adjuvant treatment of early oestrogen-receptor- positive breast cancer, November 2006: anastrozole recommended as an option for primary adjuvant therapy; exemestane for adjuvant therapy following 2-3 years of adjuvant tamoxifen therapy; letrozole for primary adjuvant therapy and extended adjuvant therapy following standard tamoxifen therapy.

May 2007: The TAG agreed to support a protocol developed by the NNUH Oncologists and Breast Surgeons regarding drug management of oestrogen-receptor-positive early breast cancer in post menopausal women. Advice is as follows:
1. Low risk patients (Node Negative, Low and Intermediate Grade) - Tamoxifen for 5 years or nothing as per current practice.
2. Intermediate risk patients (Node Negative, High Grade or 1-3 Node positive, Low and Intermediate Grade) - Tamoxifen for 2.5 years then Exemestane for 2.5 years.
3. High risk patients (1-3 Node Positive, High Grade or ≥4 Node Positive, Any Grade) - Anastrozole for 5 years.
4. High risk patients currently on tamoxifen - Letrozole for 3 years following 5 year completion of tamoxifen (extended adjuvant).
5. Neo-adjuvant patients (locally advanced disease) - Letrozole for four months and continuing for total of 5 years following interventional treatment.

NB: Other factors may influence risk to patient (e.g. tumour size). Bone health management as per current approved osteoporosis prophylaxis policy should be considered for aromatase inhibitors.

July 2013: NICE CG 164 (June 2013)
(p34 Section 1.7 Treatment strategies) noted by the TAG.

September 2014: The TAG noted NICE CG 81 (Update July 2014) - Advanced breast cancer: Diagnosis and treatment

8.3.4.3 - Somatostatin analogues

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4.3 - Somatostatin analogues

Lanreotide *(Somatuline LA®)* TAG recommendation: Sep 2013

for use in: Reducing vomiting in terminal bowel obstruction (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: GPs should ensure that they receive adequate support from Palliative Care team.

May 2013: Commissioning responsibility for cancer-related indications has been transferred to the NHS England SCG which does not support shared care prescribing for cancer-related treatments. Concern was expressed that if reclassified as Red (Hospital/Specialist only) patients would be unable to access treatment, particularly in rural areas.
Existing patients could be repatriated gradually with only new patients coming under a Red classification.

May 2013 N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decisions:
Red (Hospital/Specialist prescribing only) for new patients starting treatment for cancer-related indications from 1st April 2013 onwards.

CCGs will seek reimbursement for any related Primary Care prescribing.

September 2013:
On-going discussion regarding impact on patients.
Recommended as Green (GP prescribable at the request of Consultant/Specialist) for any patients already receiving treatment.

The TAG members agreed that regarding use for terminal bowel obstruction, the SCG's determination to repatriate treatment to secondary care is inappropriate and that the treatment should remain in primary care. Decision rests with commissioners (CCGs) to decide how the repatriation should be dealt with.
Local Acute Trusts have indicated that they would be happy to supply the treatment following a telephone conversation between clinicians and then reclaim the costs from NHS England if necessary.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) supported the revised TAG recommendation.

January 2016:
The TAG noted NG 31 (December 2015) Care of dying adults in the last days of life
This guideline aims to improve end of life care for people in their last days of life by communicating respectfully and involving them, and the people important to them, in decisions and by maintaining their comfort and dignity. It covers how to manage common symptoms without causing unacceptable side effects and maintain hydration in the last days of life.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

8.3.4.3 - Somatostatin analogues

Octreotide *(Sandostatin®)* TAG recommendation: Sep 2013

for use in: Reducing vomiting in terminal bowel obstruction (Not a licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: GPs should ensure that they receive adequate support from Palliative Care team.

May 2013: Commissioning responsibility for cancer-related indications has been transferred to the NHS England SCG which does not support shared care prescribing for cancer-related treatments. Concern was expressed that if reclassified as Red (Hospital/Specialist only) patients would be unable to access treatment, particularly in rural areas.
Existing patients could be repatriated gradually with only new patients coming under a Red classification.

May 2013 N&W CCGs Drugs & Therapeutics Commissioning Group (D&TCG) Decisions:
Red (Hospital/Specialist prescribing only) for new patients starting treatment for cancer-related indications from 1st April 2013 onwards.

CCGs will seek reimbursement for any related Primary Care prescribing.

September 2013:
On-going discussion regarding impact on patients.
Recommended as Green (GP prescribable at the request of Consultant/Specialist) for any patients already receiving treatment.

The TAG members agreed that regarding use for terminal bowel obstruction, the SCG's determination to repatriate treatment to secondary care is inappropriate and that the treatment should remain in primary care. Decision rests with commissioners (CCGs) to decide how the repatriation should be dealt with.
Local Acute Trusts have indicated that they would be happy to supply the treatment following a telephone conversation between clinicians and then reclaim the costs from NHS England if necessary.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) supported the revised TAG recommendation.

Janaury 2016:
The TAG noted NG 31 (December 2015) Care of dying adults in the last days of life
This guideline aims to improve end of life care for people in their last days of life by communicating respectfully and involving them, and the people important to them, in decisions and by maintaining their comfort and dignity. It covers how to manage common symptoms without causing unacceptable side effects and maintain hydration in the last days of life.

9.5.2.2 - Phosphate-binding agents

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

9.5.2.2 - Phosphate-binding agents

Lanthanum carbonate *(Fosrenol®)* TAG recommendation: Sep 2007

for use in: Hyperphosphataemia in end-stage chronic renal failure - if on treatment before 1st April 2013 (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2007:
TAG members agreed that lanthanum carbonate for hyperphosphataemia in end-stage chronic renal failure is recommended as a third line treatment option for patients who have not tolerated or who have had inadequate response to standard phosphate-binding options and sevelamer. However if lanthanum carbonate is used but offers no clinical advantage to patients, treatment options should be discussed with the patient's consultant with a view to reverting to a cheaper previously tried option.

May 2013: The TAG noted that phosphate-binding treatments for renal patients are the commissioning responsibility of Specialised Commissioning (NHS England) from April 2013. The TAG agreed to maintain the current "Green" classification for lanthanum carbonate until clarity is obtained regarding whether prescribing responsibility for this treatment will be returned to hospital specialists.

May 2013: CCGs Commissioning Decision from the Drugs & Therapeutics Commissioning Group (D&TCG) -
For patients already on treatment prior to 1st April 2013 to remain as Green (GP prescribable at the request of a Specialist/Consultant) until patients are reviewed in clinic and repatriated to Red (Hospital / Specialist only).

March 2014: Repatriation of SCG-commissioned treatments is still in progress. This treatment to remain as "Green" for the time being.

June 2021 - Updated to Green for all patients regardless of initiation date. Recharge to NHSE confirmed.

Lanthanum carbonate hydrate *(Fosrenol®)* TAG recommendation: May 2018

for use in: Hyperphosphataemia in end-stage chronic renal failure in patients on renal dialysis (A licensed indication).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is NHS England commissioning responsibility - since April 2013.
Any historical Primary care prescribing is recharged to Commissioner until formal repatriation agreed. Product with lowest procurement cost to be used.

Used under Trust guidelines.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

June 2021 - Updated to Green for all patients regardless of initiation date. Recharge to NHSE confirmed.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

9.5.2.2 - Phosphate-binding agents

Sevelamer *(Renagel®)* TAG recommendation: Mar 2021

for use in: Hyperphosphataemia in chronic renal failure in patients on haemodialysis and on treatment (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2001:
Standard letter providing information on sevelamer should be sent to GPs from hospital consultants (developed by the N&N). All monitoring to be undertaken by the hospital.

May 2013: The TAG noted that phosphate-binding treatments for renal patients are the commissioning responsibility of Specialised Commissioning (NHS England) from April 2013.

May 2013: CCGs Commissioning Decision from the Drugs & Therapeutics Commissioning Group (D&TCG):
For patients already on treatment prior to 1st April 2013 to remain as Green (GP prescribable at the request of a Specialist/Consultant) until patients are reviewed in clinic and repatriated to Red (Hospital / Specialist only).

March 2014: Repatriation of SCG-commissioned treatments still in progress - to remain as "Green" for the time being.

March 2021 - Confirmed recharge to NHSE. Traffic light updated to Green for all patients, not just those initiated before 2013

9.6 - vitamins

DEKAs essential / plus *()* TAG recommendation: Jan 2022

for use in: for use when recommended by specialists for patients with cystic fibrosis (x).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Paravit CF - Vit A,D, E and K *(Paravit CF)* TAG recommendation: Dec 2021

for use in: patients with cystic fibrosis only on the advice of a CF specialist Dietitian following detailed assessment (x).
Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

9.6.4 - Vitamin D

Alfacalcidol *(AlfaD®, One-Alpha®)* TAG recommendation: May 2007

for use in: Preparation for hyperparathyroidectomy (A licensed indication).
Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Part of a secondary care procedure but deemed appropriate for GPs to prescribe.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

10.2.1 - Anticholinesterases

Pyridostigmine *(Mestinon)* TAG recommendation: Jan 2021

for use in: Myasthenia gravis (x).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Jan 2021 - Green (GP prescribing following Specialist initiation / recommendation) recommended for this medication. Ratified by CCG Governing Body

13.5.3 - Drug affecting the immune response

Pimecrolimus 1% Cream *(Elidel® cream)* TAG recommendation: Jan 2005

for use in: Option for 2nd line treatment of moderate atopic eczema on the face and neck in children aged 2 to 16 years not controlled by topical steroids or where there is serious risk of important ADRs from further use of topical steroids - as per NICE CG 57 (A licensed

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: August 2004.

Specific points: May 2003:
Pimecrolimus had been promoted on the basis of it providing a steroid-sparing effect, despite steroids not being recommended for mild to moderate atopic dermatitis. The TAG recommended that use of pimecrolimus was limited to Hospital Only until a suitable Shared Care Protocol was developed by an interested local specialist.
January 2005:
The TAG acknowledged NICE TAG No.82 which stated that -
1.1 Topical tacrolimus and pimecrolimus are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any severity.
1.3 Pimecrolimus is recommended, within its licensed indications, as an option for the second-line treatment of moderate atopic eczema on the face and neck in children aged 2 to 16 years that has not been controlled by topical corticosteroids (see Section 1.4), where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.
1.4 For the purposes of this guidance, atopic eczema that has not been controlled by topical corticosteroids refers to disease that has not shown a satisfactory clinical response to adequate use of the maximum strength and potency that is appropriate for the patient's age and the area being treated.
1.5 It is recommended that treatment with tacrolimus or pimecrolimus be initiated only by physicians (including general practitioners) with a special interest and experience in dermatology, and only after careful discussion with the patient about the potential risks and benefits of all appropriate second-line treatment options.

January 2008: The TAG acknowledged NICE Clinical Guideline No.57 December 2007 which incorporates previous NICE Technology Appraisal Guidance No. 82.

July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 57 - Atopic eczema in under 12s: diagnosis and management which states:

1.5.4.1 Topical tacrolimus and pimecrolimus are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any
severity.

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

13.5.3 - Drug affecting the immune response

Tacrolimus 0.03% Ointment ▼ *(Protopic® ointment ▼)* TAG recommendation: Jan 2005

for use in: Option for 2nd line treatment of moderate to severe atopic eczema in adults and children over 2 years not controlled by topical steroids where there is serious risk of important ADRs further topical steroid use - as per NICE CG 57 (A licensed indication).

Prescribing responsibility: Consultant/Specialist should prescribe for an initial period of 3-4 months (1st review).

NICE issued Guidance in: August 2004.

Specific points: July 2002:
Guidance from local dermatologists was that tacrolimus ointment should only be used when steroid treatment has been tried and shown to fail. TAG therefore recommended that initial prescribing of tacrolimus topical should be by a consultant specialist or a specialist GP, with subsequent prescribing by GPs. A prescribing information sheet is available.
Patients on tacrolimus must be reviewed by a specialist after 3 to 4 months.
January 2005: TAG acknowledged NICE TAG No.82 which recommended that:
1.1 Topical tacrolimus and pimecrolimus are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any severity.
1.2 Topical tacrolimus is recommended, within its licensed indications, as an option for the second-line treatment of moderate to severe atopic eczema in adults and children aged 2 years and older that has not been controlled by topical corticosteroids (see Section 1.4), where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.
1.4 For the purposes of this guidance, atopic eczema that has not been controlled by topical corticosteroids refers to disease that has not shown a satisfactory clinical response to adequate use of the maximum strength and potency that is appropriate for the patient's age and the area being treated.
1.5 It is recommended that treatment with tacrolimus or pimecrolimus be initiated only by physicians (including general practitioners) with a special interest and experience in dermatology, and only after careful discussion with the patient about the potential risks and benefits of all appropriate second-line treatment options.

January 2008: The TAG acknowledged NICE Clinical Guideline No.75 December 2007 which incorporates previous NICE Technology Appraisal Guidance No. 82.

July 2017:
The TAG noted the local Combined Commissioned Drugs List (May 2017) which had been updated to include NICE "Do Not Do" recommendations. These include NICE CG 57 - Atopic eczema in under 12s: diagnosis and management which states:

1.5.4.1 Topical tacrolimus and pimecrolimus are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any
severity.

13.8.1 - Photodamage

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

13.8.1 - Photodamage

Imiquimod Cream *(Aldara® & Zyclara®)* TAG recommendation: Nov 2016

for use in: Non-hypertrophic actinic keratosis (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG noted and supported (subject to agreed amendments) a pharmacological treatment pathway for actinic keratosis which specified the place of imiquimod cream as being suitable for GPs to prescribe following specialist recommendation.

January 2017: The published version of the treatment pathway was noted and supported by the TAG and the NHS Norfolk & Waveney CCGs' D&TCG.

Available via: http://nww.knowledgeanglia.nhs.uk/tag/actinic_keratosis_pathway.pdf

13.12 - Antiperspirants

Glycopyrronium bromide (prescribe as Glycobromag) *(Glycobromag (oral))* TAG recommendation: Mar 2013

for use in: Hyperhidrosis (Not a licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for the first script 3 months.

NICE has not issued any guidance.

Specific points: March 2013:
Unlicensed special. Glycobromag capsules and tablets are available from Temag Pharma (01707 566 008 http://www.temagpharma.co.uk/).
Consultant to initiate treatment and review effectiveness. GPs may take on prescribing for patients who have benefited from and can tolerate treatment.
Patients to nominate a Community Pharmacy which should be given suitable notice in order to organise supplies.

The current most cost-effective formulation to be prescribed. TAG also recommended that a treatment pathway for hyperhidrosis should be agreed locally in consultation with local specialists.

January 2015: The TAG noted and supported the East Of England Priorities Advisory Committee (PAC) Policy Statement and associated Patient Information Leaflet (March 2014) covering various drugs including topical and systemic treatments in the management of hyperhidrosis.

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the PAC Policy Statement and PIL.

15.2 - Local anaesthesia

Green - 'GP prescribable at request of Consultant/Specialist'

Drugs for which it has been deemed reasonable for GPs to prescribe outside a shared-care arrangement following recommendation by a Consultant/Specialist.

The advice is specific to the indication.

Some drugs are recommended to be initiated by a consultant. See the general guidance regarding the interpretation of "consultant initiation".

Unless specified below, TAG has no firm views as to the requirement for consultants to prescribe the first dose.

This list is not exhaustive, but indicates drugs for which a decision has been made.

15.2 - Local anaesthesia

Lidocaine 5% medicated plasters *(Versatis®)*

TAG recommendation: Mar 2016

for use in: Localised neuropathic pain when first line systemic therapies are ineffective or not tolerated as per the local Neuropathic Pain Pathway - Specialist to prescribe for first month (A licensed indication).

Prescribing responsibility: Consultant/Specialist should recommend, but GP can take responsibility for all scripts.

NICE issued Guidance in: November 2013.

Specific points: Already on the Norfolk Restricted List.
Of limited effectiveness and high relative cost.

May 2010: The TAG noted NICE Clinical Guideline 96 March 2010 - Neuropathic pain (adults) - pharmacological management in non-specialist settings and agreed to revisit when local guidance becomes available following publication of the NHS Norfolk Pain Formulary.

January 2014: The TAG noted NICE Clinical Guideline 173 (Nov 2013) Neuropathic pain - pharmacological management (updates NICE CG 96) - which offers evidence-based advice on the pharmacological management of neuropathic pain in non-specialist settings.
The TAG noted that the N&W Neuropathic Pain Pathway is in the process of being finalised by the Prescribing Reference Group and is likely to align with this guidance.

September 2014: The TAG noted the recently updated Analgesics Formulary which includes guidance on the management of pain in line with NICE CG 173, available via: http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_analgesics.pdf

January 2016: Following an application from a local acute trust for specific and restricted use of this treatment, the TAG recommended that the use of lidocaine 5% medicated plasters (Versatis®) in patients with localised neuropathic pain when first line systemic therapies are ineffective or not tolerated is classified as Green (GP prescribable following Consultant/Specialist initiation), with initiation by the Consultant within the Pain Clinic (i.e. the Consultant to give the first prescription).
An audit of usage should be carried out after 6 months and reported back to the CCGs.

January 2016: The D&TCG was concerned about the relative lack of evidence for this expensive product and the potential for inappropriate use outside the terms of agreed criteria and a treatment pathway.
However the committee supported the TAG's recommendation that the treatment should be initiated by the specialist within the pain clinic (first month's supply provided) and its effectiveness assessed before the GP is approached to take over prescribing.
The D&TCG also recommended that the treatment pathway be clarified to indicate that ineffective treatments are stopped before moving to the next option in the pathway, to avoid unnecessary polypharmacy.

March 2016:
The D&TCG noted and supported the incorporation of the pathway into the Pain / Analgesics Formulary and reiterated that only Consultant Pain Specialists should initiate treatment of up to a maximum of two plasters at a time in any one patient.

The neuropathic pain pathway within the N&W Analgesics Formulary (http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_analgesics.pdf) has been updated to reflect this agreement.

January 2018: The TAG noted PrescQIPP Guidance - Bulletin 200 (Nov 2017 v3.0) DROP-List Bulletin which recommended restricting use of lidocaine plasters to people diagnosed with post herpetic neuraligia in whom alternative traetments are contraindicated, not tolerate, or ineffective.
The TAG considered the information prpvided but decided to maintain the wording of the last recommendation for use from March 2016.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

- Not listed in the BNF

Anticoagulant monitoring self test strips *(Various (e.g. CoaguChek))* TAG recommendation: Apr 2005

for use in: Anticoagulant self testing (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: GPs may be approached by patients who have already obtained anticoagulant testing strips for self testing monitors directly from manufacturers.
GPs should consider criteria for "competence of the patient" as detailed by the British Society of Haematologists before deciding whether or not to prescribe self testing strips.

Auto inflation device (Otovent) *(Otovent®)* TAG recommendation: Sep 2017

for use in: Considered use for equalisation of pressure in the middle ear: in otitis media with effusion (glue ear) in children who are able to cooperate with treatment. (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2017:
The TAG considered the Prescribing Reference Group's (PRG) recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of Auto inflation devices e.g. Otovent® for equalisation of pressure in the middle ear: in otitis media with effusion (glue ear).
The TAG agreed with the PRG's advice that the CCGs consider a Double Green (GP prescribable) classification in line with agreed guidance for use, with a view to saving ENT referrals in children.

Autoinflation may be considered during or after an active observation period following diagnosis of otitis media with effusion (OME, or glue ear), in children who are likely to cooperate with the procedure.

September 2017:
Noted and supported by the N&W D&TCG.

May 2018: The TAG acknowledged NG 91 (March 2018) - Otitis media (acute): antimicrobial prescribing

1.3 - Antisecretory drugs and mucosal protectants

GORD - treatments (various) *(Various)* TAG recommendation: Mar 2015

for use in: Treatment of GORD in children and young people - as per NICE NG1 (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: February 2015.

Specific points: March 2015: The TAG noted and acknowledged the pharmacological recommendations contained in NICE NG1 - Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people.

The Norfolk and Waveney CCGs' Drugs & Therapeutics Commissioning Group also noted NICE NG1.

1.3.5 - Proton pump inhibitors

Proton pump inhibitors *(Various)* TAG recommendation: Apr 2005

for use in: Dyspepsia (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2000.

Specific points: See NICE guidance (No. 7) for recommended conditions of use.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

1.6.6 - Peripheral opioid-receptor antagonists

Naloxegol ▼ *(Moventig® ▼)* TAG recommendation: Jan 2016

for use in: Treatment of opioid-induced constipation in adults who have not adequately responded to standard laxatives in line with NICE TA345 and as per the local treatment pathway (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2015.

Specific points: September 2015:
The NHS Norfolk & Waveney CCGs' TAG noted NICE TA 345 (July 2015) which recommended the treatment as an option for patients with opiod induced constipation that has had an inadequate response to laxatives (as defined in guidance). The TAG recommended a traffic light classification of Double Red (Not recommended for routine use) pending the production of a local treatment pathway. The TAG will consider any feedback received from local specialists at its next meeting in November 2015.

October 2015:
The D&TCG noted and supported the TAG's recommendations.

November 2015: The TAG noted the suggested treatment pathway for opioid-induced constipation based on feedback received from local specialists and recommended that they be forwarded to the Prescribing Reference Group for further development.

January 2016:
The TAG considered formulary applications and a proposed treatment pathway from the NNUH's oncology and gastroenterology specialists for use of naloxegol as an option for treating opioid-induced constipation in adults whose constipation has not adequately responded to laxatives in line with NICE TA345. Having discussed this treatment at previous meetings, the TAG was generally supportive but did not specify a recommended traffic light classification for the treatment.

The application and proposed pathway was then forwarded directly to January 2016 Drugs & Therapeutics Commissioning Group as part of local implementation of NICE TA 345. The D&TCG debated whether the proposed treatment pathway included appropriate optimisation of laxative treatment before use of other agents is considered and deferred any decision regarding this treatment until the detail of the treatment pathway was clarified.

The draft pathway was then discussed further at the Prescribing Reference Group, where minor revisions to the pathway were recommended and incorporated into the attached version of the pathway.

The treatment was generally supported as "Double Green" in line with the pathway.

This was acknowledged by the TAG and the D&TCG in March 2016.

The pathway is available via http://nww.knowledgeanglia.nhs.uk/tag/opioid_constipation_pathway.pdf

1.6.7 - Other drugs used in constipation

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

1.6.7 - Other drugs used in constipation

Linaclotide *(Constella®)* TAG recommendation: Nov 2014

for use in: Symptomatic treatment of moderate to severe Irritable Bowel Syndrome with Constipation (IBS-C) in adults - as per local treatment algorithms for IBS-C and Refractory Symptomatic Chronic Constipation in adults (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: February 2015.

Specific points: November 2013: The TAG noted the NNUH application for symptomatic treatment of moderate to severe Irritable Bowel Syndrome with Constipation (IBS-C) in adults. The TAG recommended a Red (Hospital Only) classification for a period of 6 months, to then be reviewed pending the submission of information about the effectiveness of the treatment from local specialists.

Prescriber's rating 4 - possibly helpful

November 2013: Commissioned by the D&TCG. Use to be in line with a locally agreed treatment pathway for IBS-C.

January 2014: NHS East of England-Priorities Advisory Committee (PAC) Final Policy Statement-June 2013 recommend the use under specific criteria for irritable bowel syndrome with constipation (IBS-C). The TAG recommended that the existing classification remain with the treatment to be reconsidered again in July 2014 with NNUH to report back on experience of use. Details of proposed treatment pathway discussed with recommended changes to be communication to specialists. Commissioned by N&W CCGs-D&TCG until reviewed in July 2014 and as per local treatment pathway.

July 2014: The TAG was advised that since the NNUH had only received stock of linaclotide during May 2014, that local specialists would be unable to report on 6 months' experience of using the treatment until January 2015 at the earliest.

November 2014: The TAG considered feedback from the specialist and was satisified that linaclotide had been effective in the small number of patients treated. The TAG supported the previously agreed treatment pathway for IBS-C (January 2014) which clarified the place of linaclotide. The TAG recommended an amended classification of Double Green (Suitable for GPs to initiated and prescribe) in line with the locally agreed treatment pathway.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation to revise the classification.

Treatment pathway for IBS-C available via
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=ZQSvnbgi8Ec%3d&tabid=916&portalid=1&mid=2074

March 2015: The TAG noted and acknowledged NICE CG 61 - Diagnosis and management of irritable bowel syndrome in adults in primary care (update).

March 2015: The Norfolk & Waveney CCGs' D&TCG noted NICE CG 61 (February 2015)

November 2015: The TAG supported use of a combined treatment pathway for adults with symptomiatic chronic constipation.
Available via: https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=6gZURhDXiPE%3d&tabid=916&portalid=1&mid=2074

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

1.6.7 - Other drugs used in constipation

Lubiprostone ▼ *(Amitiza® ▼)* TAG recommendation: Nov 2014

for use in: Treatment of chronic idiopathic constipation - as per local treatment algorithm for Refractory Symptomatic Chronic Constipation in Adults (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2014.

Specific points: NICE TA318 (July 2014):
Recommended by NICE as an option for treatment of chronic idiopathic constipation.

September 2014: The TAG noted NICE TA 318 and recommended a classification of Double Green (Suitable for GPs to initiate and prescribe) subject to lubiprostone being incorporated into a locally agreed treatment pathway.

September 2014: The Norfolk & Waveney CCGs D&TCG noted the TAG recommendation but the treatment remains not commissioned until a pathway clarifying use of lubiprostone is finalised.

November 2014: The TAG considered and supported the NNUH's application, and proposed treatment pathway for the use of lubiprostone in patients with chronic idiopathic constipation.

For use in adults in whom treatment with at least 2 laxatives from different classes, at the recommended doses for at least 6 months, have failed to provide adequate relief and for whom invasive treatment for constipation is being considered.

The TAG also noted clarification from NICE that it supports use of lubiprostone beyond the two-week treatment period stated in the manufacturer's SPC, for patients who respond to treatment.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG's recommendation. The D&TCG noted that lubiprostone offers a useful treatment option in a limited number of patients with chronic idiopathic constipation but agreed that its availability should not affect routine management of this condition in primary care.

November 2015:
The combined treatment pathway for management of refractory symptomatic chronic constipation in men and in women is available on Knowlegde Anglia via https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=6gZURhDXiPE%3d&tabid=916&portalid=1&mid=2074

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

1.6.7 - Other drugs used in constipation

Prucalopride *(Resolor®)* TAG recommendation: Nov 2015

for use in: Chronic constipation in adults - as per local treatment algorithm for Refractory Symptomatic Chronic Constipation in Adults (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: December 2010.

Specific points: January 2011: The TAG noted NICE TA 211 which states the following:
1.1 Prucalopride is recommended as an option for the treatment of chronic constipation only in women for whom treatment with at least two laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and invasive treatment for constipation is being considered.
1.2 If treatment with prucalopride is not effective after 4 weeks, the woman should be re-examined and the benefit of continuing treatment reconsidered.
1.3 Prucalopride should only be prescribed by a clinician with experience of treating chronic constipation, who has carefully reviewed the woman's previous courses of laxative treatments specified in 1.1.

The TAG recommended that prucalopride for treatment of chronic constipation in women as Red (Hospital only) until such time as a business case was for use was supported, with the possibility of being reviewed to Amber (Option for Shared Care) if appropriate.

September 2011: The TAG considered business cases from the NNUH and the JPUH for use of prucalopride and decided that in view of there being no new evidence for use available, and the need to promote effective use of standard laxatives and management strategies for chronic constipation, it was agreed to maintain the current traffic light status of Red (Hospital Only) for the time being.

The TAG also recommended that rational use of standard laxatives should be promoted and that a guideline for use should be drawn up to support care.

November 2013: The TAG considered the application update submitted by NNUH for the symptompatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief and recommended a Double Green classification in line with the proposed treatment pathway.
Prescriber's rating 3 - offers an advantage.

November 2015: The NHS Norfolk & Waveney CCGs' TAG noted the NNUH proposal and agreed that since prucalopride (Restolor®) is now also licensed for use in men, that the pathway be revised to cover the treatment of both men and women. The revised pathway to be reformatted and published.

November 2015: The D&TCG noted and supported the TAG recommendation.

The combined treatment pathway for Refractory Symptomatic Chronic Constipation in Adults is available via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=6gZURhDXiPE%3d&tabid=916&portalid=1&mid=2074

2.2.1 - Thiazides and related diuretics

Indapamide (immediate-release) *(Generic)* TAG recommendation: Nov 2014

for use in: Hypertension (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: August 2011.

Specific points: November 2014: The TAG noted that the treatment is already used in primary care as a treatment alternative to using bendroflumethiazide. A classification of Double Green (Suitable for GPs to initiate and prescribe) was recommended.

November 2014: The NHS Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation providing that only immediate-release products are used.

January 2017:
The TAG acknowledged CG 127 (updated November 2016) - Hypertension in adults: Diagnosis and management.
Recommendation 1.6.7 states:
Do not combine an ACE inhibitor with an ARB to treat hypertension.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.2.1 - Thiazides and related diuretics

Indapamide MR tablets *(Ethibide® XL, Natrilix® SR, Tensaid® XL))* TAG recommendation: Dec 2020

for use in: Essential hypertension (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2015: As recommended by the NHS Norfolk & Waveney CCGs' D&TCG, these products are added to the TAG recommendations list as Double Red (Not recommended for routine use) in line with the Norfolk & Waveney DROP List for most indications.

Expensive and offers no benefit over cheaper immediate-release generic tablets

Dec 2020 - The TAG agreed to amend traffic light classification of Indapamide 1.5mg MR to Double Green in line with the 2.5mg standard release preparation following cost reduction. Supported by D+TC and ratified by CCG Governing Body

2.2.3 - Second-line aldosterone antagonist

Eplerenone *(Inspra®)* TAG recommendation: Jul 2005

for use in: Second-line therapy in patients with heart failure who are intolerant to spironolactone due to hormonal side-effects (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: November 2018.

Specific points: Younger renal patients often subject to spironolactone-induced gynaecomastia.
Black triangle drug ▼ which requires monitoring for adverse drug reactions.

November 2018: The TAG acknowledged NG 106 - Chronic heart failure in adults: diagnosis and management which includes recommendations on treating heart failure.

2.6.3 - Other antianginal drugs

Ivabradine ▼ *(Procoralan® ▼)* TAG recommendation: Jul 2006

for use in: Chronic stable angina when beta-blockers are contra-indicated or not tolerated (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2006:
Recommended for use only where all other appropriate drug therapies have been tried.
Black triangle drug ▼ which requires monitoring for adverse drug reactions.
Prescriber's rating - 4. Possibly helpful - the product has minimal additional value and should not change prescribing habits except in rare circumstances.

July 2015:
The TAG considered the place of ivabradine in a draft joint treatment pathway by West Norfolk CCG and the QEH. The TAG agreed that there was no need to change the previous Double Green classification at the present time but that the draft pathway would be forwarded to the Prescribing Reference Group for their consideration.

2.8.1 - Parenteral anticoagulants

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.1 - Parenteral anticoagulants

Heparin - Low Molecular Weight (LMWH) *(Various)* TAG recommendation: May 1999

for use in: DVT (if suspected out of hours - first dose only) (A licensed indication).
Prescribing responsibility: GP prescribable without restriction for the indication above.

NICE has not issued any guidance.

Specific points: (Dalteparin, Enoxaparin, Tinzaparin)

The TAG recommended that GPs should supply a first dose out-of-hours where investigations for suspected DVT are not available.

The patient will be seen the next day in working hours.
Otherwise the consultant/hospital should prescribe.

2.8.2 - Oral antocoagulants

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.2 - Oral antocoagulants

Apixaban *(Eliquis®)* TAG recommendation: Mar 2013

for use in: Prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation - as per NICE TA 275 and local policy (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: February 2013.

Specific points: NICE TA 275 - Apixaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation states that:
Apixaban is recommended as an option for preventing stroke and systemic
embolism within its marketing authorisation, that is, in people with nonvalvular
atrial fibrillation with 1 or more risk factors such as:
prior stroke or transient ischaemic attack
age 75 years or older
hypertension
diabetes mellitus
symptomatic heart failure.

The decision about whether to start treatment with apixaban should be made after an informed discussion between the clinician and the person about the risks and benefits of apixaban compared with warfarin, dabigatran etexilate and rivaroxaban. For people who are taking warfarin, the potential risks and benefits of switching to apixaban should be considered in light of their level of international normalised ratio (INR) control.

Recommended as Double Green (GPs can initiate and take responsibility for prescriptions where they have experience of initiating warfarin).

March 2013 D&TCG Decision: Commissioned subject to revision and agreement regarding the New Oral Anticoagulants Policy.

March 2014: Revised policy for use of oral anticoagulants for this indication finalised by the TAG and approved by the D&TCG.

July 2014: The TAG noted NICE CG 180 (June 2014) Management of Atrial Fibrillation, including the NICE Patient Decision Aid (PDA).

September 2014: The TAG noted and supported the revised algorithm/combined commissioned pathway for use of anticoagulants for SPAF updated in line with NICE CG 180, to be promoted along with locally developed GP/Patient Decision Support Aid (PDA).

May 2016: The D&TCG agreed to support a revised version of the algorithm/combined commissioned pathway for use of anticoagulants for SPAF.

Available via http://nww.knowledgeanglia.nhs.uk/tag/oral_anticoag_therapy_spaf.pdf

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read: "Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

July 2018:
The TAG noted and supported the revised local treatment pathway which had been reviewed and updated in line with current SPCs and guidance on crushing medicines. Hyperlinks checked and updated.
The TAG agreed that the changes were acceptable and that the revised pathway and prescribing support tool should be published.

July 2018:
Noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee.

May 2019: The use of Anticoagulants for Stroke Prevention in AF guidance was Updated in consultation with STP AF review group.
The TAG agreed that the pathway could be republished with the recommended changes and also recommended that use of oral anticoagulants in patients >120kg / BMI≥40kg/m2 is clarified.

May 2019: The DTC noted the further amendments to the pathway and supported the publication of this version of the document.

Available on Knowledge Anglia via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pq7SFYC_60E%3d&tabid=916&portalid=1&mid=2074

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.2 - Oral antocoagulants

Dabigatran etexilate *(Pradaxa®)* TAG recommendation: Jul 2012

for use in: Stroke and systemic embolism prevention in non-valvular atrial fibrillation -as per NICE TA 249 and local policy (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: March 2012.

Specific points: March 2010:
The TAG had significant concerns regarding safety of dabigatran for prevention of stroke in patients with AF, based on the available trial evidence in terms of the benefit : harm ratio.
The TAG therefore recommended that use of dabigatran for prevention of stroke in AF is classified as Double Red (Not recommended for routine use) until further information and national guidance becomes available.

May 2012:
NICE TA 249 (http://guidance.nice.org.uk/TA249) states that dabigatran etexilate is recommended as an option for the prevention of stroke and systemic embolism within its licensed indication, that is, in people with non-valvular atrial fibrillation with one or more of the following risk factors:
* previous stroke, transient ischaemic attack or systemic embolism
* left ventricular ejection fraction below 40%
* symptomatic heart failure of New York Heart Association (NYHA) class 2 or above
* age 75 years or older
* age 65 years or older with one of the following: diabetes mellitus, coronary artery disease or hypertension.
The decision about whether to start treatment with dabigatran etexilate should be made after an informed discussion between the clinician and the person about the risks and benefits of dabigatran etexilate compared with warfarin. For people who are taking warfarin, the potential risks and benefits of switching to dabigatran etexilate should be considered in light of their level of international normalised ratio (INR) control.

July to November 2012: The TAG noted and supported the development of local guidance on the use of new oral anticoagulants in line with NICE TA 249 and 256 (for rivaroxaban).
The Norfolk and Waveney Drugs & Therapeutics Commissioning Group noted the TAG's recommendation and commissioned dabigatran etexilate in line with Norfolk & Waveney Guidance on New Oral Anticoagulants: Implementation of NICE TA 249 and NICE TA 256.

March 2014: Revised guidance on use of anticoagulants for stroke prevention in AF, including use of apixaban, finalised by the TAG and approved by the D&TCG.

July 2014: The TAG noted NICE CG 180 (June 2014) Management of Atrial Fibrillation, including the NICE Patient Decision Aid (PDA).

September 2014: The TAG noted and supported the revised algorithm/combined commissioned pathway for use of anticoagulants for SPAF updated in line with NICE CG 180, to be promoted along with locally developed GP/Patient Decision Support Aid (PDA).

May 2016: The D&TCG agreed to support a revised version of the algorithm/combined commissioned pathway for use of anticoagulants for SPAF.
Available via: http://nww.knowledgeanglia.nhs.uk/tag/oral_anticoag_therapy_spaf.pdf

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

July 2018:
The TAG noted and supported the revised local treatment pathway which had been reviewed and updated in line with current SPCs and guidance on crushing medicines. Hyperlinks checked and updated.
The TAG agreed that the changes were acceptable and that the revised pathway and prescribing support tool should be published.

July 2018:
Noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee.

May 2019: The use of Anticoagulants for Stroke Prevention in AF guidance was Updated in consultation with STP AF review group.
The TAG agreed that the pathway could be republished with the recommended changes and also recommended that use of oral anticoagulants in patients >120kg / BMI≥40kg/m2 is clarified.

May 2019: The DTC noted the further amendments to the pathway and supported the publication of this version of the document.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.2 - Oral antocoagulants

Available on Knowledge Anglia via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pq7SFYC_60E%3d&tabid=916&portalid=1&mid=2074

Edoxaban ▼ *(Lixiana® ▼)* TAG recommendation: Nov 2015

for use in: For preventing stroke and systemic embolism in people with non valvular atrial fibrillation who have one or more risk factors (as per NICE TA 355) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2015.

Specific points: November 2015: The TAG noted NICE TA 355 (September 2015) for use of this latest Direct Oral Anticoagulant (DOAC) for preventing stroke and systemic embolism in people with non valvular atrial fibrillation who have one or more risk factors, such as:
* Heart failure, high blood pressure or diabetes
* Had a stroke or transient ischaemic attack before
* Aged 75 years or older
and recommended a classification of Double Red (Not recommended for routine use) until such time as the treatment's place in an agreed pathway has been defined.

November 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted that, unlike other DOACs, doses of edoxaban require titration. Therefore it is likely that edoxaban would be a 4th line DOAC option. Although the NHS price of edoxaban is known, local price agreements have yet to be clarified.

The D&TCG otherwise noted and supported the TAG recommendation.

March 2016: As part of discussions regarding use of D/NOACs the TAG considered that use of edoxaban as per NICE TA 355 should be incorporated into the local treatment pathway for stroke prevention on non-valvular atrial fibrilliation (SPAF) as for the other NICE-recommended options.

March 2016: The Norfolk & waveney CCGs; Drugs & Therapeutics Commissioning Group (D&TCG) confirmed that edoxaban should have a Double Green classification for stroke prevention in atrial fibrillation in line with the other options. The local treatment pathway is currently being reviewed.

May 2016: The D&TCG agreed to support a revised version of the algorithm/combined commissioned pathway for use of anticoagulants for SPAF.
Available via: http://nww.knowledgeanglia.nhs.uk/tag/oral_anticoag_therapy_spaf.pdf

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

July 2018:
The TAG noted and supported the revised local treatment pathway which had been reviewed and updated in line with current SPCs and guidance on crushing medicines. Hyperlinks checked and updated.
The TAG agreed that the changes were acceptable and that the revised pathway and prescribing support tool should be published.

July 2018:
Noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee.

May 2019: The use of Anticoagulants for Stroke Prevention in AF guidance was Updated in consultation with STP AF review group.
The TAG agreed that the pathway could be republished with the recommended changes and also recommended that use of oral anticoagulants in patients >120kg / BMI≥40kg/m2 is clarified.

May 2019: The DTC noted the further amendments to the pathway and supported the publication of this version of the document.
Available on Knowledge Anglia via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pq7SFYC_60E%3d&tabid=916&portalid=1&mid=2074

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.2 - Oral antocoagulants

Rivaroxaban ▼ *(Xarelto® ▼)* TAG recommendation: Jul 2012

for use in: Prevention of stroke in patients with atrial fibrillation as per NICE TA 256 and local treatment pathway (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: May 2012.

Specific points: May 2012: NICE TA 256 states that:
1.1 Rivaroxaban is recommended as an option for the prevention of stroke and systemic embolism within its licensed indication, that is, in people with nonvalvular atrial fibrillation with one or more risk factors such as:
* congestive heart failure
* hypertension
* age 75 years or older
* diabetes mellitus,
* prior stroke or transient ischaemic attack.
1.2 The decision about whether to start treatment with rivaroxaban should be made after an informed discussion between the clinician and the person about the risks and benefits of rivaroxaban compared with warfarin. For people who are taking warfarin, the potential risks and benefits of switching to rivaroxaban should be considered in light of their level of international normalised ratio (INR) control.

July to November 2012: The TAG noted and supported the development of local guidance on the use of new oral anticoagulants in line with NICE TA 249 (for dabigatran) and 256 (for rivaroxaban).

The Norfolk and Waveney Drugs & Therapeutics Commissioning Group commissioned rivaroxaban in line with Norfolk & Waveney Guidance on New Oral Anticoagulants: Implementation of NICE TA 249 and NICE TA 256.

March 2014: Revised guidance on use of anticoagulants for stroke prevention in AF, including use of apixaban, finalised by the TAG and approved by the D&TCG.

July 2014: The TAG noted NICE CG 180 (June 2014) Management of Atrial Fibrillation, including the NICE Patient Decision Aid (PDA).

September 2014: The TAG noted and supported the revised algorithm/combined commissioned pathway for use of anticoagulants for SPAF updated in line with NICE CG 180, to be promoted along with locally developed GP/Patient Decision Support Aid (PDA).

May 2016: The D&TCG agreed to support a revised version of the algorithm/combined commissioned pathway for use of anticoagulants for SPAF.
Available via: http://nww.knowledgeanglia.nhs.uk/tag/oral_anticoag_therapy_spaf.pdf

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read: "Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

July 2018:
The TAG noted and supported the revised local treatment pathway which had been reviewed and updated in line with current SPCs and guidance on crushing medicines. Hyperlinks checked and updated.
The TAG agreed that the changes were acceptable and that the revised pathway and prescribing support tool should be published.

July 2018:
Noted and supported by the Norfolk and Waveney CCGs' Drugs & Therapeutics Committee.

May 2019: The use of Anticoagulants for Stroke Prevention in AF guidance was Updated in consultation with STP AF review group.
The TAG agreed that the pathway could be republished with the recommended changes and also recommended that use of oral anticoagulants in patients >120kg / BMI≥40kg/m2 is clarified.

May 2019: The DTC noted the further amendments to the pathway and supported the publication of this version of the document.

Available on Knowledge Anglia via:
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pq7SFYC_60E%3d&tabid=916&portalid=1&mid=2074

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.8.2 - Oral antocoagulants

Warfarin *(Various)* TAG recommendation: Apr 2005

for use in: Various (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

2.9 - Anti-platelet drugs

Clopidogrel *(Plavix®, generics approved for use - Sept 2009)* TAG recommendation: Apr 2005

for use in: Prevention of atherosclerotic events (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: December 2010.

Specific points: May 2010: Interaction between Clopidogrel and PPIs:
The April 2010 Drug Safety Update bulletin includes revised advice regarding concomitant use of clopidogrel with proton pump inhibitors. The MHRA states that use of either omeprazole or esomeprazole with clopidogrel should be discouraged but that current evidence does not support to extending this advice to other PPIs.
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON076501
The TAG noted that local hospital specialists plan to adopt this advice and will use lansoprazole. Lansoprazole also offers a cost-effective option in Primary Care.

January 2011: The TAG noted NICE TA Guidance 210 (December 2010) - Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events (review of TA 90) which replaced NICE technology appraisal guidance 90 issued in May 2005.
The review and re-appraisal of clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events has resulted in a change in the guidance. Specifically:
* Treatment with modified-release dipyridamole in combination with aspirin for people who have had an ischaemic stroke is now recommended only if clopidogrel is contraindicated or not tolerated.
* Treatment with modified-release dipyridamole in combination with aspirin for people who have had an ischaemic stroke or a transient ischaemic attack is no longer limited to 2 years' duration from the most recent event.
* Clopidogrel is no longer recommended only for people who are intolerant of aspirin and have had an occlusive vascular event or have peripheral arterial disease).
* Modified-release dipyridamole alone is now recommended as an option to prevent occlusive vascular events

TA Guidance 210:
1. Clopidogrel is recommended as an option to prevent occlusive vascular events:
* for people who have had an ischaemic stroke or who have peripheral arterial disease or multivascular disease or
* for people who have had a myocardial infarction only if aspirin is contraindicated or not tolerated.
2. Modified-release dipyridamole in combination with aspirin is recommended as an option to prevent occlusive vascular events:
* for people who have had a transient ischaemic attack or
* for people who have had an ischaemic stroke only if clopidogrel is contraindicated or not tolerated.
3. Modified-release dipyridamole alone is recommended as an option to prevent occlusive vascular events:
* for people who have had an ischaemic stroke only if aspirin and clopidogrel are contraindicated or not tolerated or
* for people who have had a transient ischaemic attack only if aspirin is contraindicated or not tolerated.
4. Treatment with clopidogrel to prevent occlusive vascular events should be started with the least costly licensed preparation.

September 2014: The TAG supported updates to the guidance document "Summary of use of Antiplatelets to prevent occlusive vascular events" for reference by GPs - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=RAjKLupT96w%3d&tabid=916&portalid=1&mid=2074

2.12 - Lipid-regulating drugs

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.12 - Lipid-regulating drugs

Ezetimibe and combination products *(Ezetrol® (and combination products Inegy®))* TAG recommendation: Mar 2013

for use in: Lowering cholesterol in at-risk patients - as per NICE TA 385 (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: November 2007.

Specific points: January 2008: the TAG noted and discussed NICE Technology Appraisal Guidance No.132 - "Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia", with respect to previous TAG recommendations regarding ezetimibe.

March 2013: The TAG revised its previous recommendations regarding ezetimibe and recommended that use should be in line with NICE TA 132 (http://guidance.nice.org.uk/TA132) as described in the guidance document "Key Therapeutic topics: Medicine management options for local implementation" (January 2013 http://publications.nice.org.uk/lipid-modifying-drugs-including-ezetimibe-ktt3/) as follows:

1) In patients with Heterozygous Familial Hypercholesterolaemia:

Ezetimibe is an option for monotherapy if statins are contraindicated or not tolerated.
Ezetimibe is an option for combination therapy with a statin if the LDL-C target of <50% of basline is not reached on the initial statin and also changing to an alternative statin is being considered.

2) In patients with non-familial hypercholesterolaemia:

a) Patients without established cardiovascular disease (Primary prevention):
Ezetimibe is an option for monotherapy if statins are contraindicated or not tolerated.

b) Patients with type 2 diabetes, without new or existing CV disease or increased albumin excretion:
Ezetimibe is an option for monotherapy if statins are contraindicated or not tolerated.

c) Patients with type 2 diabetes, with new or existing CV disease or increased albumin excretion:
Ezetimibe is an option for monotherapy if statins are contraindicated or not tolerated.
Ezetimibe is an option for combination therapy with a statin if lipid targets are agreed but not reached on simvastatin alone and also if changing to an alternative statin is being considered.

D) Patients with established cardiovascular disease (Secondary prevention) with or without ACS:
Ezetimibe is an option for monotherapy if statins are contraindicated or not tolerated.

September 2014: The TAG noted NICE CG 181 (July 2014) - Lipid Modification

November 2015: The TAG and the D&TCG noted NICE Quality Standard Cardiovascular risk assessment and lipid modification (September 2015).

March 2016: The TAG noted NICE TA 385 which replaces NICE TA 132 (February 2016) and agreed that the guidance did not require a change in the current traffic light classification of Double Green (suitable for GPs to initiate and prescribe) for this CCG-commissioning responsibility treatment.

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted the TAG recommendation.

NICE TA 385 (which updates and replaces NICE TA 132) states:
For treating primary heterozygous-familial and non-familial hypercholesterolaemia in adults.
Ezetimibe monotherapy is recommended as an option in adults:
* in whom initial statin therapy is contraindicated
* who cannot tolerate statin therapy (as defined under 1.6)
Ezetimibe, given with an initial statin, is recommended as an option when:
* serum total or LDL cholesterol concentration is not appropriately controlled (as defined in section 1.7) either after appropriate dose titration of initial statin therapy or because dose titration is limited by intolerance to the initial statin therapy (as defined under 1.6)
and
* a change from initial statin therapy to an alternative statin is being considered
Ezetimibe co-administered with a statin, ezetimibe should be prescribed on the basis of lowest acquisition cost.
1.6 Intolerance to initial statin therapy is defined as clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy.
1.7 Appropriate control of cholesterol concentrations should be based on individual risk assessment according to national guidance on

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

2.12 - Lipid-regulating drugs

managing cardiovascular disease in the relevant populations.

November 2017:
The TAG acknowledged NICE CG 71 (updated Nov 2017) - Familial hypercholesterolaemia: identification and management. NICE had reviewed the evidence for case finding and diagnosis, identification using cascade testing, and management using statins and added, updated and deleted some recommendations in sections 1.1, 1.2 and 1.3. NICE also removed nicotinic acid from section 1.3 because it no longer has a UK licence.

Noted by the D&TCG.

Statins *(Various)* TAG recommendation: Apr 2005

for use in: Prevention of coronary events in patients with Type II diabetes (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: March 2008.

Specific points: Following the results of the Heart Protection Study, TAG concluded:
1) All Type II diabetics should be assumed to have a CHD risk in excess of 30% over 10 years
2) They should receive an evidence based dose of simvastatin - 40mg or an effective dose of another statin

See also:
NICE Clinical Guideline 67 "Lipid modification - Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease" (March 2008 - reissued March 2010) - http://www.nice.org.uk/nicemedia/pdf/cg67quickrefguide.pdf

and

NICE Clinical Guideline 87 "Type 2 Diabetes" (May 2009 - reissued March 2010) - http://www.nice.org.uk/nicemedia/pdf/CG87quickrefguide.pdf

September 2014: The TAG noted NICE CG 181 which replaces CG 67 and TA 94 Statins for the prevention of cardiovascular events.

September 2014: The Norfolk & Waveney CCGs D&TCG noted and supported the TAG recommendation.

November 2015: The TAG and the D&TCG noted NICE Quality Standard Cardiovascular risk assessment and lipid modification (September 2015).

May 2018: The TAG supported updated prescribing advice on Drug interactions with simvastatin and atorvastatin - http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=FXNti3GQJ5I%3d&portalid=1

May 2018: Noted and supported by the Norfolk and Waveney CCGs' DTC.

3.1.1 - Adrenoceptor agonists

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

3.1.1 - Adrenoceptor agonists

Indacaterol *(Onbrez Breezhaler®)* TAG recommendation: Jul 2012

for use in: Maintenance treatment of obstructive pulmonary disease (COPD) (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: June 2010.

Specific points: Use supported by the TAG in the following circumstances:
Recommended for use in patients who cannot tolerate treatment with other LABAs,
or who cannot comply with the treatment regimen required for other LABAs,
or who are unable to use the inhaler devices available for other LABAs,
and have been assessed as being more likely to be able to use the Onbrez® inhaler device.
Prescriber's Rating 4. "The product has minimal additional value, and should not change prescribing habits except in rare circumstances"

The TAG's recommendation was approved by the Norfolk and Waveney Drugs & Therapeutics Commissioning Group on 19th July 2012.

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

3.1.2 - Antimuscarinic bronchodilators

Aclidinium bromide (Eklira Genuair®) ▼ *(Eklira Genuair® ▼)* TAG recommendation: Jan 2013

for use in: Inhaled treatment for Chronic Obstructive Pulmonary Disease (COPD) (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2013:
Recommended as a 3rd line treatment option in patients unable to tolerate inhaled tiotropium or glycopyrronium, subject to agreement on placement in COPD treatment pathway.

January 2013: TAG recommendation supported by the Norfolk & Waveney Drugs & Therapeutics Commissioning Group.

November 2018: Local Respiratory (COPD) Formulary reflects that as per GOLD guidelines, aclidinium bromide is an equal 1st line LAMA option along with other LAMAs - see https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=fLcXtbWCBZY%3d&tabid=867&portalid=1

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

Glycopyrronium bromide *(Seebri® Breezhaler®)* TAG recommendation: Jan 2013

for use in: Inhaled treatment for Chronic Obstructive Pulmonary Disease (COPD) (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Recommended as a formulary option subject to agreement on placement in COPD treatment pathway.
Inhaler device offers an option for patients who cannot use other devices effectively.

January 2013: TAG recommendation supported by the Norfolk & Waveney Drugs & Therapeutics Commissioning Group.

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

3.1.2 - Antimuscarinic bronchodilators

Tiotropium *(Braltus Zonda® (1st line option);Spiriva Respimat®)* TAG recommendation: Jul 2012

for use in: Maintenance treatment of Chronic Obstructive Pulmonary Disease (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: June 2010.

Specific points: January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

3.1.4 - Compound bronchodilator preparations

Indacaterol / Glycopyrronium inhaler▼ *(Ultibro Breezhaler® ▼)* TAG recommendation: Mar 2014

for use in: Chronic Obstructive Pulmonary Disease (COPD) (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2014:
Recommended as Double Green (GP prescribing appropriate) with the treatment's place in therapy to be identified through the work of the Prescribing Reference Group when reviewing and updating the current local guidance on the management of COPD.

January 2019: The TAG acknowledged NICE NG 115 (December 2018) - Chronic obstructive pulmonary disease in over 16s: Diagnosis and Management.

3.3.2 - Leukotriene receptor antagonists

Montelukast *(Singulair®)* TAG recommendation: Apr 2005

for use in: Adults - Steps 3 and 4 of BTS guidelines (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: See other recommendation for use in children.
NNUH formulary application for use in adults and children noted and supported by the TAG in September 2004.

4.1.1 - Non-benzodiazepine hypnotics and sedatives

Zolpidem *(Stilnoct® / Generics)* TAG recommendation: May 2018

for use in: Short term treatment insomnia (up to 4 weeks) - as per NICE TA 77 (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: April 2004.

Specific points: May 2018:
Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

4.3.3 - Serotonin and noradrenaline re-uptake inhibitors

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.3.3 - Serotonin and noradrenaline re-uptake inhibitors

Duloxetine *(Cymbalta®)* TAG recommendation: Sep 2019

for use in: Depression (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
This treatment is CCG commissioning responsibility. Not commissioned as per Drugs of Low Priority List.

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

September 2019: The traffic light classification was amended in line with local guidance and formularies to Double Green.

4.3.4 - Antidepressants - serotonin modulator & stimulator

Vortioxetine *(Brintellix®)* TAG recommendation: Mar 2016

for use in: Major depressive episodes in adults having a first or recurrent major depressive episode, if the current episode has not responded to two antidepressants as per NICE TA 367 (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: November 2015.

Specific points: January 2016: The TAG noted NICE TA 367 (November 2015) for treating major depressive episodes in adults having a first or recurrent major depressive episode, if the current episode has not responded to two antidepressants and recommended a classification of Double Red (Not recommended for routine use/not commissioned) for this CCG-commissioning responsibility treatment pending the submission of a business application and treatment pathway by the local Trust.

January 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations and confimred that use of vortioxetine is not commissioned pending consideration of a business application and treatment pathway by the local provider Trust.

March 2016: The TAG noted and supported the business application and proposed treatment pathway submitted by the local provider Trust, and recommended a traffic light classification of Double Green (suitable for GPs to initiate and prescribe).

March 2016: The TAG-recommended traffic light classification of Double Green (suitable for GPs to initiate and prescribe) for vortioxetine (Brintellix®) for treatment of major depressive episodes in adults whose condition has responded inadequately to 2 antidepressants within the current episode, as per NICE TA367 (Nov 2015) and in line with the agreed treatment pathway, was noted and supported by the NHS Norfolk & Waveney CCGs' D&TCG.

4.5.1 - Anti-obesity drugs acting on the GI tract

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.5.1 - Anti-obesity drugs acting on the GI tract

Orlistat *(Xenical®)* TAG recommendation: Apr 2005

for use in: Obesity - in adults only (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: November 2014.

Specific points: NICE: Orlistat should only be prescribed for people who have lost at least 2.5 kg in weight by dietary control and increased physical activity alone in the month prior to the first prescription and meet one of the following criteria:
*a body mass index (BMI) of 28 kg/m2 or more in the presence of significant co-morbidities which persist despite standard treatment. (E.g. Type 2 diabetes, high blood pressure and/or high total cholesterol level).
*a BMI of 30 kg/m 2 or more with no associated co-morbidities.
Orlistat should only be prescribed for people between the ages of 18 and 75 years.
In February 2004 NICE announced that it will review its guidance for orlistat (No. 22) and for sibutramine (No. 31) and incorporate it into the on-going NICE Guidance on "Obesity: the prevention, identification, evaluation, treatment and weight maintenance of overweight and obese adults." which is due for release during 2006.

January 2015: The TAG noted and supported NICE CG 189 regarding the following drug treatment recommendations under:
Section 1.8 Pharmacological interventions: outlines the place of orlistat in adults and young people. In children <12 years, drug treatment may be used only in exceptional circumstances if severe comorbidities are present. Prescribing should be started and monitored only in specialist paediatric settings. Drug treatment may be continued in primary care eg with a shared care protocol if local circumstances and/or licensing allow.
Section 1.9 Continued prescribing and withdrawal: Criteria and management strategies for use of orlistat in adults and children are outlined.
The TAG's previous recommendation of Double Green (suitable for GPs to initiate and prescribe) for olistat relates to use in adults only.
The TAG noted NICE CG 189 and recommended a classification of RED (Hospital/Specialist only) for the use of orlistat in children <12 years of age (to be reviewed should a local shared care agreement be agreed upon).

January 2015: The Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendation.

4.7.3 - Neuropathic Pain

Pregabalin *(Lyrica®; Generic supported for use locally)* TAG recommendation: May 2005

for use in: Peripheral neuropathic pain in adults only where other options have failed to provide adequate benefit (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: For use only where all other appropriate treatment options have failed to provide adequate benefit.

See local guidelines on management of Neuropathic Pain via
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/formulary/formulary_analgesics.pdf

March 2019: The TAG noted the rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs from April 2019. The TAG also noted that Schedule 2 & 3 Controlled Drugs will become prescribable via the Electronic Prescription Service (EPS) to facilitate the re-classification of gabapentin and pregabalin.

4.8.1 - Control of epilepsy

Gabapentin *(Neurontin®)* TAG recommendation: Apr 2005

for use in: Neuropathic pain (A licensed indication).

Prescribing responsibility: Consultant should recommend, but GP can take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2019: The TAG noted the rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs from April 2019. The TAG also noted that Schedule 2 & 3 Controlled Drugs will become prescribable via the Electronic Prescription Service (EPS) to facilitate the re-classification of gabapentin and pregabalin.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.9.1 - Dopamine-receptor agonists

Pramipexole *(Mirapexin)* TAG recommendation: Mar 2022

for use in: restless legs syndrome (x).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2022.

Ropinirole *()* TAG recommendation: Mar 2022

for use in: restless legs syndrome (x).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2022.

4.10 - Drugs used in substance dependence

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.10 - Drugs used in substance dependence

Buprenorphine (sublingual & oral lyophilisate) *(Subutex® - generics available / Espranor®)* TAG recommendation: Nov 2016

for use in: Opioid dependence (for use by prescribers with competence in treating opioid dependence) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: January 2007.

Specific points: Pre- 2004:
Most prescribing is managed by secondary-care via TADS. However GPs with special interest and skills in Great Yarmouth and Norwich do prescribe it. GPs should only prescribe if suitably trained and locally accredited. Shared care guidelines available from specialist units.

July 2004: the TAG agreed to support crushing of Subutex tablets during Supervised Consumption Services to avoid "pocketing" of tablets. This was agreed in the interests of supporting clients and pharmacists, and in minimising the availability of street drugs.
GPs in Norfolk can claim payment under Local Enhanced Services for prescribing methadone and buprenorphine under a shared-care agreement with their local specialist agency.
NICE Guidance January 2007 (TAG 114): methadone and buprenorphine (oral formulations), using flexible dosing regimens, are recommended as options for maintenance therapy in the management of opiod dependence. If both drugs are equally suitable, methadone should be prescribed as the first choice. Methadone and buprenorphine should be admininstered daily,under supervision, for at least the first 3 months, as part of a programme of supportive care.

September 2012: The TAG approved revised Guidelines for Sublingual Buprenorphine for treatment of opioid dependence (last updated 2010). Available via http://www.knowledgeanglia.nhs.uk/tag/shared_care/buprenorphine_guidelines.htm

November 2016:
The recommended changes to the Guidelines for Primary Care Prescribers with competence in the treatment of Opioid Dependence - Use of Sublingual Buprenorphine to be finalised and the revised version to be published on Knowledge Anglia. Classification clarified as Double Green (Suitable for GPs (with appropriate competence and as part of the LES) to initiate and prescribe)

November 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the revised guidance.

January 2019:
The TAG re-considered the Guidelines for Primary Care Prescribers with competence in the treatment of Opioid Dependence: Use of Sublingual Buprenorphine and agreed that there is on-going need for this document. It was acknowledged that whilst some local GPs prescribe for patients with opioid dependence under the Local Enhanced Service commissioned by Public Health, or independently, others do not.
Patient numbers / prescription items to be investigated and returned to the TAG.
The document also to be shared with the current local service provider, Change, Grow, Live (CGL).

March 2019:
The TAG was provided with:
* data illustrating prescribing of buprenorphine for opioid dependence by local GP practices over a 12 month period.
* Communications from the DoH and Change, Grow, Live (CGL) regarding a change from using sublingual formulations to Espranor® (buprenorphine as oral lyophilisate, for dissolution on the tongue).
NB Espranor® is not interchangeable with other buprenorphine products and has a different dose regimen from sublingual buprenorphine products.

The TAG noted that CGL is now prescribing Espranor® (buprenorphine as an oral lyophilisate which dissolves on the tongue) to manage rising costs of generic sublingual buprenorphine, which is not interchangeable due to differences in dosage regimen. The TAG supported continued use of the revised document which had been updated in line feedback from CGL.
More practiceshave been asked to sign up to the LES in order for prescribing costs to be recharged to PHE appropriately.

March 2019: The D&TC supported on-going use of the document for practices with competency, working within the LES.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.10 - Drugs used in substance dependence

Bupropion *(Zyban®)* TAG recommendation: Apr 2005

for use in: Adjunct to smoking cessation (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: March 2002.

Specific points: TAG approved updates to the Norfolk Guidelines in September 2003.
NICE: Nicotine replacement therapy (NRT) and bupropion are recommended for smokers who have expressed a desire to quit smoking.
NRT or bupropion should normally only be prescribed as part of an abstinent-contingent treatment (ACT), in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date). Smokers should be offered advice and encouragement to aid their attempt to quit. Ideally, initial prescription of NRT or bupropion should be sufficient to last only until 2 weeks after the target stop date.
Normally, this will be after 2 weeks of NRT therapy, and 3-4 weeks for bupropion, to allow for the different methods of administration and mode of action. Second prescriptions should be given only to people who have demonstrated that their quit attempt is continuing on reassessment.
It is recommended that smokers who are under the age of 18 years, who are pregnant or breastfeeding, or who have unstable cardiovascular disorders, should discuss the use of NRT with a relevant health-care professional before it is prescribed.
Bupropion is not recommended for smokers under the age of 18 years, as its safety and efficacy have not been evaluated for this group. Women who are pregnant or breastfeeding should not use bupropion.
If a smoker's attempt to quit is unsuccessful with treatment using either NRT or bupropion, the NHS should normally fund no further attempts within 6 months. However, if external factors interfere with an individual's initial attempt to stop smoking, it may be reasonable to try again sooner.
There is currently insufficient evidence to recommend the use of an NRT and bupropion in combination.
In deciding which of the available therapies to use and in which order they should be prescribed, practitioners should take into account: a) Intention and motivation to quit, and likelihood of compliance; b) The availability of counselling or support; c) Previous usage of smoking cessation aids; d) Contraindications and potential for adverse effects; e) Personal preferences of the smoker.
Motivational support is being provided by the NHS Stop Smoking services. More information is available from the Cignificant Helpline on 01603 307 307.
The best chance of helping patients give up smoking is likely to involve referring them to the Stop Smoking services. Then consider the place of Nicotine Replacement Therapy or bupropion after your patient has been assessed by these services.
Stop Smoking services are not in a position to prescribe bupropion, but may recommend its use in your patients. GPs should then assess clinical appropriateness (indications, contraindications, drug interactions etc) before prescribing.
Bupropion carries a 1 in 1000 risk of causing seizures. Consider the impact on all drivers.
For elderly or renally impaired patients where bupropion has been prescribed at reduced dose (150mg daily), one original pack of 60 tablets provides an 8-week course.

July 2010: The TAG noted NICE CG 101 (June 2010) - management of COPD (update).

May 2018: The TAG noted NICE NG 92 (March 2018) - Stop smoking interventions and services , which updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).

Methadone *(e.g. Methadose®)* TAG recommendation: May 1999

for use in: Substance dependence (only if the practitioner is suitably trained and accredited to prescribe) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: January 2007.

Specific points: GPs should only prescribe if suitably trained and locally accredited.

GPs in Norfolk can claim payment under Local Enhanced Services for prescribing methadone and buprenorphine under a shared-care agreement with their local specialist agency.

NICE Guidance January 2007 (TA 114): methadone and buprenorphine (oral formulations), using flexible dosing regimens, are recommended as options for maintenance therapy in the management of opioid dependence. If both drugs are equally suitable, methadone should be prescribed as the first choice. Methadone and buprenorphine should be admininstered daily,under supervision, for at least the first 3 months, as part of a programme of supportive care.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

4.10 - Drugs used in substance dependence

Nicotine Replacement Therapy *(Various)* TAG recommendation: Apr 2005

for use in: Smoking cessation (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: March 2002.

Specific points: TAG approved updates of the Norfolk Guidelines in September 2003.

NICE: Nicotine Replacement Therapy (NRT) and bupropion are recommended for smokers who have expressed a desire to quit smoking.
NRT or bupropion should normally only be prescribed as part of an Abstinent-Contingent Treatment (ACT), in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date). Smokers should be offered advice and encouragement to aid their attempt to quit. Ideally, initial prescription of NRT or bupropion should be sufficient to last only until 2 weeks after the target stop date.
Normally, this will be after 2 weeks of NRT therapy, and 3-4 weeks for bupropion, to allow for the different methods of administration and mode of action. Second prescriptions should be given only to people who have demonstrated that their quit attempt is continuing on reassessment.
It is recommended that smokers who are under the age of 18 years, who are pregnant or breastfeeding, or who have unstable cardiovascular disorders, should discuss the use of NRT with a relevant health-care professional before it is prescribed.
If a smoker's attempt to quit is unsuccessful with treatment using either NRT or bupropion, the NHS should normally fund no further attempts within 6 months. However, if external factors interfere with an individual's initial attempt to stop smoking, it may be reasonable to try again sooner.
There is currently insufficient evidence to recommend the use of an NRT and bupropion in combination.
In deciding which of the available therapies to use and in which order they should be prescribed, practitioners should take into account: a) Intention and motivation to quit, and likelihood of compliance; b) The availability of counselling or support; c) Previous usage of smoking cessation aids; d) Contraindications and potential for adverse effects; e) Personal preferences of the smoker.
Motivational support is being provided by the NHS Stop Smoking services. More information is available from the Cignificant Helpline on 01603 307 307.
The best chance of helping patients give up smoking is likely to involve referring them to the Stop Smoking services. Then consider the place of Nicotine Replacement Therapy or bupropion after your patient has been assessed by these services.

July 2010: The TAG noted NICE CG 101 (June 2010) - mamangement of COPD (update).

May 2018: The TAG noted NICE NG 92 (March 2018) - Stop smoking interventions and services , which updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).

5.1.3 - Tetracyclines

Doxycycline *(Vibramycin®)* TAG recommendation: Apr 2005

for use in: Anthrax exposure - as per Public Health guidance (Not a licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

5.1.12 - Quinolones

Ciprofloxacin *(Ciproxin®)* TAG recommendation: Apr 2005

for use in: Anthrax exposure - as per Public Health guidance (Not a licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

5.3.4 - Antiviral drugs

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

5.3.4 - Antiviral drugs

Oseltamivir *(Tamiflu®)* TAG recommendation: Mar 2009

for use in: Treatment of influenza in at-risk people (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: February 2009.

Specific points: March 2009: The TAG noted NICE Technology Appraisal Guidance No. 168 Amantadine, oseltamivir and zanamivir for the treatment of influenza (review of NICE Technology Appraisal Guidance 58):
1.1 Oseltamivir (and zanamivir) are recommended, within their marketing authorisations, for the treatment of influenza in adults and children if all the following circumstances apply:
* national surveillance schemes indicate that influenza virus A or B is circulating
* the person is in an 'at-risk' group as defined in 1.2
* the person presents with an influenza-like illness and can start treatment within 48 hours (or within 36 hours for zanamivir treatment in children) of the onset of symptoms as per licensed indications.

1.2 For the purpose of this guidance, people 'at risk' are defined as those who have one of more of the following:
* chronic respiratory disease (including asthma and chronic obstructive pulmonary disease)
* chronic heart disease
* chronic renal disease
* chronic liver disease
* chronic neurological conditions
* diabetes mellitus.
People who are aged 65 years or older and people who might be immunosuppressed are also defined as 'at-risk' for the purpose of this guidance.
1.3 The choice of either oseltamivir or zanamivir in the circumstances described in 1.1 should be made after consultation between the healthcare professional, the patient and carers. The decision should take into account the patient's preferences regarding drug delivery and potential adverse effects and contraindications. If all other considerations are equal, the drug with the lowest acquisition cost should be offered.
1.4 During localised outbreaks of influenza-like illness (outside the periods when national surveillance indicates that influenza virus is circulating in the community), oseltamivir and zanamivir may be offered for the treatment of influenza in 'at-risk' people who live in long-term residential or nursing homes. However, these treatments should be offered only if there is a high level of certainty that the causative agent in a localised outbreak is influenza (usually based on virological evidence of influenza infection in the initial case).

Oseltamivir *(Tamiflu®)* TAG recommendation: Nov 2008

for use in: Prophylaxis of influenza in at-risk people (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2008.

Specific points: November 2008: The TAG noted NICE Technology Appraisal Guidance No. 158 September 2008: Oseltamivir is recommended, within its marketing authorisation, for post-exposure prophylaxis of influenza if all of the following circumstances apply:
1. National surveillance schemes have indicated that influenza virus is circulating.
2. The person is in an at-risk group as defined in the NICE guidance
3. The person has been exposed, as defined in NICE Guidance, to an influenza-like illness and is able to begin prophylaxis within the timescale specified in the marketing authorisation (within 48 hours of contact with an index case)
4. Exposure to an influenza-like illness is defined as close contact with a person in the same household or residential setting who has had recent symptoms of influenza.
5. The person has not been effectively protected by vaccination, defined as:
* those who have not been vaccinated since the previous influenza season
* those for whom vaccination is contra-indicated, or in whom it has yet to take effect
* those who have been vaccinated with a vaccine that is not well matched (according to information from the Health Protection Agency) to the circulating strain of influenza virus.
6. During localised outbreaks of influenza-like illness (outside periods when national surveillance indicates that influenza virus is circulating generally in the community), oseltamivir may be used for post-exposure prophylaxis in at-risk people living in long-term residential or nursing homes, whether or not they are vaccinated. However, this should be done only if there is a high level of certainty that the causative agent in a localised outbreak is influenza, usually based on virological evidence of infection with influenza in the index case or cases.
7. Oseltamivir is not recommended for seasonal prophylaxis of influenza.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

5.3.4 - Antiviral drugs

Zanamivir *(Relenza®)* TAG recommendation: Nov 2008

for use in: Prophylaxis of influenza in at-risk people as per NICE Guidance (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2008.

Specific points: NICE Technology Appraisal Guidance No. 67 September 2008: Zanamivir is recommended, within its marketing authorisation, for post-exposure prophylaxis of influenza if all of the following circumstances apply:
1. National surveillance schemes have indicated that influenza virus is circulating.
2. The person is in an at-risk group as defined in the NICE guidance
3. The person has been exposed, as defined in NICE Guidance, to an influenza-like illness and is able to begin prophylaxis within the timescale specified in the marketing authorisation (within 36 hours of contact with an index case)
4. Exposure to an influenza-like illness is defined as close contact with a person in the same household or residential setting who has had recent symptoms of influenza.
5. The person has not been effectively protected by vaccination, defined as:
* those who have not been vaccinated since the previous influenza season
* those for whom vaccination is contra-indicated, or in whom it has yet to take effect
* those who have been vaccinated with a vaccine that is not well matched (according to information from the Health Protection Agency) to the circulating strain of influenza virus.
6. During localised outbreaks of influenza-like illness (outside periods when national surveillance indicates that influenza virus is circulating generally in the community), zanamivir may be used for post-exposure prophylaxis in at-risk people living in long-term residential or nursing homes, whether or not they are vaccinated. However, this should be done only if there is a high level of certainty that the causative agent in a localised outbreak is influenza, usually based on virological evidence of infection with influenza in the index case or cases.
7. Zanamivir is not recommended for seasonal prophylaxis of influenza.

Zanamivir *(Relenza®)* TAG recommendation: Mar 2009

for use in: Treatment of influenza in at-risk people as per NICE Guidance (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: February 2009.

Specific points: March 2009: The TAG noted NICE Technology Appraisal Guidance No. 168 Amantadine, oseltamivir and zanamivir for the treatment of influenza (review of NICE Technology Appraisal Guidance 58):
1.1 (Oseltamivir and) zanamivir) are recommended, within their marketing authorisations, for the treatment of influenza in adults and children if all the following circumstances apply:
* national surveillance schemes indicate that influenza virus A or B is circulating
* the person is in an 'at-risk' group as defined in 1.2
* the person presents with an influenza-like illness and can start treatment within 48 hours (or within 36 hours for zanamivir treatment in children) of the onset of symptoms as per licensed indications.

1.2 For the purpose of this guidance, people 'at risk' are defined as those who have one of more of the following:
* chronic respiratory disease (including asthma and chronic obstructive pulmonary disease)
* chronic heart disease
* chronic renal disease
* chronic liver disease
* chronic neurological conditions
* diabetes mellitus.
People who are aged 65 years or older and people who might be immunosuppressed are also defined as 'at-risk' for the purpose of this guidance.
1.3 The choice of either oseltamivir or zanamivir in the circumstances described in 1.1 should be made after consultation between the healthcare professional, the patient and carers. The decision should take into account the patient's preferences regarding drug delivery and potential adverse effects and contraindications. If all other considerations are equal, the drug with the lowest acquisition cost should be offered.
1.4 During localised outbreaks of influenza-like illness (outside the periods when national surveillance indicates that influenza virus is circulating in the community), oseltamivir and zanamivir may be offered for the treatment of influenza in 'at-risk' people who live in long-term residential or nursing homes. However, these treatments should be offered only if there is a high level of certainty that the causative agent in a localised outbreak is influenza (usually based on virological evidence of influenza infection in the initial case).

6.1.2 - Antidiabetic drugs

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.1.2 - Antidiabetic drugs

Sitagliptin *(Januvia®)* TAG recommendation: Jan 2008

for use in: Type 2 diabetes - restricted use as per agreed criteria (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: May 2009.

Specific points: The TAG recommended that sitagliptin (Januvia®) is available for RESTRICTED USE for patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin when diet and exercise, plus metformin, do not provide adequate glycaemic control.
Sitagliptin should ONLY BE USED for patients when the addition of a sulphonylurea is not appropriate, has been ineffective or has not been tolerated.
The efficacy of sitagliptin in reducing HbA1c is similar, but not superior, to sulphonylureas and thiazolidinediones (glitazones) added at this stage in therapy.
Sitagliptin appears to have minimal effects on body weight.
The TAG also noted the current lack of long term outcome and safety data related to this class of drug and also the concerns raised by consultant specialists, particularly at the Norfolk & Norwich University Hospital.
In common with all new drugs sitagliptin (Januvia®) carries a black triangle ▼. Therefore all suspected adverse reactions related to its use should be reported to the CSM.
The TAG agreed a Prescribers' Rating of "Possibly helpful - the product has minimal additional value, and should not change prescribing habits except in rare circumstances."

July 2009 - the TAG noted NICE Clinical Guideline 87 May 2009 - Type-2 Diabetes which supersedes previous NICE guidance and agreed to maintain previous TAG recommendations on the use of sitagliptin.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.1.2 - Antidiabetic drugs

Vildagliptin ▼ *(Galvus® / Eucreas® ▼)* TAG recommendation: Jul 2008

for use in: Type 2 diabetes - see specific criteria for use (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: May 2009.

Specific points: The TAG classified vildagliptin as Double Green (suitable for GPs to initiate and prescribe only under the following circumstances):
* Use is restricted to patients with type 2 diabetes mellitus in combination with metformin, when diet and exercise plus metformin do not provide adequate glycaemic control.
* Vildagliptin should only be used when adding a sulphonylurea is not appropriate, has been ineffective, or has not been tolerated.
* Vildagliptin may be used as an alternative to other agents such as thiazolidinediones (glitazones) in this way.

Other points of note:
* The efficacy of vildagliptin in reducing HbA1c is similar to, but not superior to thiazolidinediones (glitazones) added at this stage in therapy.
* Vildagliptin appears to have minimal effects on body weight.
* The TAG noted the current lack of long term outcome and safety data related to this class of drug and the concerns raised by consultant specialists at the Norfolk & Norwich University Hospital.
* In common with all new drugs vildagliptin carries a black triangle ▼ therefore all suspected adverse reactions related to its use should be reported to the CSM.

The TAG recommended a Prescribers' Rating of 6. Nothing new - the product may be a new substance but it is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases these are "me-too" products.

July 2009 - the TAG noted NICE Clinical Guideline 87 May 2009 - Type-2 Diabetes which supersedes previous NICE guidance and agreed to maintain previous TAG recommendations on the use of vildagliptin.

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

6.1.2.3 - Other antidiabetic drugs

Dapagliflozin *(Forxiga®)* TAG recommendation: Oct 2022

for use in: chronic kidney disease as per TA775 (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: March 2022.

Specific points: Formulary application accepted. Cn be initiated by Prescriber in Primary Care

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.1.2.3 - Other antidiabetic drugs

Ertugliflozin *(Steglatro®)* TAG recommendation: Jul 2019

for use in: With metformin and a depeptidyl peptidase-4 inhibitor for Type 2 diabetes (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: June 2019.

Specific points: July 2019: The TAG noted NICE TA 583 and recommended a traffic light classification of Double Green (suitable for GPs to initiate and prescribe) for this CCG commissioning responsibility treatment.

July 2019: The NHS Norfolk & Waveney CCGs' D&TC noted and supported the TAG recommendation.

August 2019: The NHS Norfolk & Waveney CCGs' JSCC supported the TAG & D&TC recommendation.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.1.2.3 - Other antidiabetic drugs

Pioglitazone *(Actos® (generics approved for use March 2012))* TAG recommendation: Apr 2005

for use in: In combination for type 2 diabetes (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: May 2009.

Specific points: NICE Technology Appraisal Guidance No.63 (Glitazones for the treatment of type 2 diabetes, states:
For people with type 2 diabetes, the use of a glitazone as second-line therapy, added to either metformin or a sulphonlyurea - as an alternative to treatment with a combination of metformin and a sulphonylurea - is not recommended except for those who are unable to take metformin and a sulphonlyurea in combination because of intolerance or a contraindication to one of the drugs. In this instance, the glitazone should replace in the combination the drug that is poorly tolerated or contraindicated.

The TAG noted that at the time of the recommendation, the most cost-effective glitazone option was pioglitazone.

March 2008: The TAG agreed adopt recent guidance from the MHRA (December 2007) regarding cardiovascular safety of glitazones.
Fluid retention and cardiac failure:
(Rosiglitazone and) pioglitazone can cause fluid retention, which may exacerbate or precipitate heart failure. Patients at particular risk are: those who receive concurrent insulin or sulphonylurea; those at risk of heart failure (e.g. previous myocardial infarction or symptomatic coronary artery disease); and those with reduced cardiac reserve.

Advice for healthcare professionals:
* (Rosiglitazone and) pioglitazone should not be used in people with heart failure or history of heart failure (i.e. New York Heart Association class I-IV)
* Incidence of heart failure is increased when (rosiglitazone or) pioglitazone is combined with insulin
* People who are at particular risk of heart failure should start (rosiglitazone or) pioglitazone at the lowest available dose; any dose increase should be done gradually
* Patients should be monitored closely during treatment for signs and symptoms of fluid retention, including weight gain or oedema
* Treatment should be stopped if any deterioration in cardiac status occurs

Myocardial ischaemia:
Analysis of pioglitazone trials did not suggest an increased risk of cardiac ischaemia. However, comparative data do not provide good evidence of a difference between rosiglitazone and pioglitazone for risk of cardiac ischaemia events.

July 2009 - the TAG noted NICE Clinical Guideline 87 May 2009 - Type-2 Diabetes which supersedes previous NICE guidance and agreed to maintain previous TAG recommendations on the use of glitazones.

March 2012: The TAG noted and supported the East of England Priorities Advisory Committee (PAC)'s recommendation that generic versions of pioglitazone may be used across the same range of licensed indications as the branded product.

September 2011:
the noted the MHRA safety warning and advice regarding pioglitazone as follows:
Advice for healthcare professionals:
* patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone
* prescribers should review the safety and efficacy of pioglitazone in individuals after 3-6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg, reduction in glycosylated haemoglobin, HbA1c)
* before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region
* use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age - elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone

January 2016:
The TAG noted NG 28 (December 2015) Type 2 diabetes in adults: management
This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). The guideline focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications.
Also includes a NICE Algorithm for blood glucose lowering therapy in adults with type 2 diabetes.
Plus Patient Decision Aid - Type 2 diabetes in adults: controlling your blood glucose by taking a second medicine - what are your options?

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.1.2.3 - Other antidiabetic drugs

January 2016:
The N&W CCGs' D&TCG noted NG 28 and noted in particluar the changes to advice regarding blood glucose monitoring and HbA1c targets in the frail and elderly.

September 2016:
In July 2016, recommendation 1.7.17 in NG 28 was reworded to clarify GPs' role in referring people for eye screening and also to add info on when this should happen.

6.4.1 - Female sex hormones

Raloxifene HCl *(Evista®)* TAG recommendation: Jan 2009

for use in: Secondary prevention of osteoporotic fragility fractures in postmenopausal women (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.161 October 2008: Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

(Strontium ranelate and) raloxifene are recommended as alternative treatment options for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to comply with the special instructions for the administration of alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (see below) and
* who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see below) as specified in the full guidance (www.nice.org.uk/nicemedia/pdf/TA161guidanceword.doc).

If a woman aged 75 years or older who has one or more independent clinical risk factors for fracture or indicators of low BMD has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

NICE Guidance defines Indicators of low BMD as:
* low body mass index (defined as less than 22 kg/m2)
* medical conditions such as ankylosing spondylitis, Crohn's disease
* conditions that result in prolonged immobility
* untreated premature menopause

NICE Guidance defines Independent Clinical Risk Factors for fracture are:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis

NICE Guidance defines Intolerance of alendronate, risedronate or etidronate as:
* persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment,
and
* that occurs even though the instructions for administration have been followed correctly.

Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

6.4.1.1 - Oestrogens and HRT

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.4.1.1 - Oestrogens and HRT

HRT implants *(Various)* TAG recommendation: Apr 2005

for use in: Hormone replacement therapy (A licensed indication).

Prescribing responsibility: Consultant responsible for the first script.

NICE has not issued any guidance.

Specific points: January 2016:
The TAG noted NG 23 (November 2015) Menopause: diagnosis and management which covers the diagnosis and management of menopause, including in women who have premature ovarian insufficiency. The guideline aims to improve the consistency of support and information provided to women in menopause.

January 2016:
Noted by the N&W CCGs' D&TCG.

6.6.2 - Bisphosphonates (drugs affecting bone metabolism)

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.6.2 - Bisphosphonates (drugs affecting bone metabolism)

Alendronic acid (sodium alendronate) *(Generic available)* TAG recommendation: Sep 2017

for use in: Primary prevention of osteoporotic fragility fractures in postmenopausal women as per NICE criteria (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: August 2017.

Specific points: January 2009:
NICE Technology Appraisal Guidance No.160 October 2008: Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women.
Alendronate is recommended by NICE as a treatment option for the primary prevention of osteoporotic fragility fractures in the following groups:
* Women aged 70 years or older who have an independent clinical risk factor for fracture (see below) or an indicator of low BMD (see below) and who are confirmed to have osteoporosis (that is, a T-score of −2.5 SD or below). In women aged 75 years or older who have two or more independent clinical risk factors for fracture or indicators of low BMD, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.
* Women aged 65 to 69 years who have an independent clinical risk factor for fracture (see below and who are confirmed to have osteoporosis (i.e. a T-score of −2.5 SD or below).
* Postmenopausal women younger than 65 years who have an independent clinical risk factor for fracture (see below) and at least one additional indicator of low BMD (see below) and who are confirmed to have osteoporosis (i.e. a T-score of −2.5 SD or below).
When the decision has been made to initiate treatment with alendronate, the preparation prescribed should be chosen on the basis of the lowest acquisition cost available.

NICE defines Independent Clinical Risk Factors for fracture as:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis

NICE defines Indicators of Low BMD as:
* Low body mass index (defined as less than 22 kg/m2)
* Medical conditions such as ankylosing spondylitis, Crohn's disease
* Conditions that result in prolonged immobility
* Untreated premature menopause

The guidance also states that women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2011: The TAG noted MHRA/CHM Drug Safety Update June 2011 bulletin, in particular the report on safety concerns regarding use of bisphosphonates beyond 5 years' treatment. The TAG acknowledged that there is no clear consensus or advice available on how long these drugs should be used.
Prescribers should aim to review treatment after 5 years and discuss options with their patients. The FRAX risk assessment tool is a useful resource http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9

September 2012: The TAG noted NICE CG 146 (August 2012 http://guidance.nice.org.uk/CG146) - Osteoporosis: Assessing the risk of fragility fracture.

September 2017:
The TAG acknowledged NICE TA 464 (August 2017) - Bisphosphonates (alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid) for treating osteoporosis in adults
- and recommended that the Prescribing Reference Group be requested to consider the implications of this guidance which recommends a lower treatment threshold, for a wider patient group than previously recommended.
The TAG also considered that there should be no case-finding or screening to identify suitable patients outside the terms of the guidance.

November 2017:
The TAG and the D&TCG noted and supported the revised Key Message Bulletins for bisphosphonates in osteoporosis which has been upadted in line with NICE TA 464 - available on Knowledge Anglia via
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/prescribing_sitemap.htm#keymessages

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.6.2 - Bisphosphonates (drugs affecting bone metabolism)

Alendronic acid (sodium alendronate) *(Generics available)* TAG recommendation: Jan 2009

for use in: Secondary prevention of osteoporotic fragility fractures in postmenopausal women - as per NICE criteria (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.161 October 2008: Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

Alendronate is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women who are confirmed to have osteoporosis (that is, a T-score of −2.5 SD or below). In women aged 75 years or older, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.
When the decision has been made to initiate treatment with alendronate, the preparation prescribed should be chosen on the basis of the lowest acquisition cost available.

Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2011: The TAG noted MHRA/CHM Drug Safety Update June 2011 bulletin, in particular the report on safety concerns regarding use of bisphosphonates beyond 5 years' treatment. The TAG acknowledged that there is no clear consensus or advice available on how long these drugs should be used.
Prescribers should aim to review treatment after 5 years and discuss options with their patients. The FRAX risk assessment tool is a useful resource http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9

September 2012: The TAG noted NICE CG 146 (August 2012 http://guidance.nice.org.uk/CG146) - Osteoporosis: Assessing the risk of fragility fracture.

September 2017:
The TAG acknowledged NICE TA 464 (August 2017) - Bisphosphonates (alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid) for treating osteoporosis in adults
- and recommended that the Prescribing Reference Group be requested to consider the implications of this guidance which recommends a lower treatment threshold, for a wider patient group than previously recommended.
The TAG also considered that there should be no case-finding or screening to identify suitable patients outside the terms of the guidance.

November 2017:
The TAG and the D&TCG noted and supported the revised Key Message Bulletins for bisphosphonates in osteoporosis which has been upadted in line with NICE TA 464 - available on Knowledge Anglia via
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/prescribing_sitemap.htm#keymessages

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.6.2 - Bisphosphonates (drugs affecting bone metabolism)

Risedronate sodium *(Actonel® (Once a week, Combi))* TAG recommendation: Jan 2009

for use in: Secondary prevention of osteoporotic fragility fractures in postmenopausal women (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.161 October 2008: Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

Risedronate (and etidronate) are recommended as alternative treatment options for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to comply with the special instructions for the administration of alendronate, or have a contraindication to or are intolerant of alendronate (see below) and
* who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see below) as specified in the full guidance (www.nice.org.uk/nicemedia/pdf/TA161guidanceword.doc)

If a women aged 75 years or older has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.
In deciding between risedronate and etidronate, clinicians and patients need to balance the overall proven effectiveness profile of the drugs against their tolerability and adverse effects in individual patients.

NICE defines Independent Clinical Risk Factors for fracture as:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis.

NICE defines intolerance of alendronate, risedronate or etidronate as:
* persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment
and
* that occurs even though the instructions for administration have been followed correctly

Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2011: The TAG noted MHRA/CHM Drug Safety Update June 2011 bulletin, in particular the report on safety concerns regarding use of bisphosphonates beyond 5 years' treatment. The TAG acknowledged that there is no clear consensus or advice available on how long these drugs should be used.
Prescribers should aim to review treatment after 5 years and discuss options with their patients. The FRAX risk assessment tool is a useful resource http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

6.6.2 - Bisphosphonates (drugs affecting bone metabolism)

Risedronate sodium *(Actonel® (Once a week, Combi))* TAG recommendation: Jan 2009

for use in: Primary prevention of osteoporotic fragility fractures in postmenopausal women (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: October 2008.

Specific points: NICE Technology Appraisal Guidance No.160 October 2008: Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women.

Risedronate (and etidronate) are recommended as alternative treatment options for the primary prevention of osteoporotic fragility fractures in postmenopausal women:
* who are unable to comply with the special instructions for the administration of alendronate, or have a contraindication to or are intolerant of alendronate (see below)
and
* who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see below) as specified in the full NICE guidance (http://www.nice.org.uk/nicemedia/pdf/TA160guidance.doc).

If a woman aged 75 years or older who has two or more independent clinical risk factors for fracture or indicators of low BMD has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.
In deciding between risedronate and etidronate, clinicians and patients need to balance the overall proven effectiveness profile of the drugs against their tolerability and adverse effects in individual patients.

NICE defines Independent Clinical Risk Factors for fracture as:
* parental history of hip fracture
* alcohol intake of 4 or more units per day
* rheumatoid arthritis

NICE defines Indicators of Low BMD as:
* Low body mass index (defined as less than 22 kg/m2)
* Medical conditions such as ankylosing spondylitis, Crohn's disease
* Conditions that result in prolonged immobility
* Untreated premature menopause

NICE guidance defines intolerance of alendronate, risedronate or etidronate as:
* persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.

The guidance also states that women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

July 2011: The TAG noted MHRA/CHM Drug Safety Update June 2011 bulletin, in particular the report on safety concerns regarding use of bisphosphonates beyond 5 years' treatment. The TAG acknowledged that there is no clear consensus or advice available on how long these drugs should be used.
Prescribers should aim to review treatment after 5 years and discuss options with their patients. The FRAX risk assessment tool is a useful resource http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9

7.3.1 - Emergency contraception

Levonorgestrel 1500 micrograms *(Levonelle 1500®)* TAG recommendation: Apr 2005

for use in: Post-coital contraception (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Also available over the counter (OTC) from pharmacists (Feb 2001), the Walk-in Centre in Norwich and A&E departments. Discussions taking place in Norfolk (March 2001) proposing to allow supply on the NHS for low-income or other vulnerable groups. Recommemded product strength revised August 2007.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

7.3.2.3 - Intra-uterine progestogen-only device

Intra-uterine progestogen-only system *(Mirena®)* TAG recommendation: Apr 2005

for use in: Contraception, primary menorrhagia (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Recommended that properly trained GPs should insert coils rather sending patients to Family Planning Clinics.

Levonorgestrel 20micrograms/24hours device *(Benilexa)* TAG recommendation: Sep 2022

for use in: Alternative to Mirena® for contraception (x).
Prescribing responsibility: GP prescribable without restriction for the indication above.

NICE has not issued any guidance.

7.3.5 - Emergency Contraception

Ulipristal acetate *(EllaOne®)* TAG recommendation: Jan 2011

for use in: Emergency contraception from 72 to 120 hours following unprotected sexual intercourse (A licensed indication).
Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2011: The TAG considered a business case for use of EllaOne from the NNUH Family Planning Service.
Key points discussed were:
* Efficacy and superiority of ulipristal over levonorgestrel is demonstrated only in the proposed time window of 72 to 120 hours post USI.
* EllaOne is the only licensed option for women presenting for emergency oral contraception from 72 hours onwards.
* Current NHS costs are 30mg ulipristal tablet (1) £16.95 compared with Levonelle® 1500 tablet (1) £5.20.
* Levonelle® remains as the first-line Emergency Hormonal Contraception (EHC) option for use up to 72 hours post USI.
* EllaOne can be offered as a second line option from 72 to 120 hours post USI for patients who are unable to accept use of an IUD.
Prescriber's Rating agreed as 4. Possibly helpful. The product has minimal additional value and should not change prescribing habits except in rare circumstances.

7.4.2 - For urinary frequency, enuresis & incontinence

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

7.4.2 - For urinary frequency, enuresis & incontinence

Fesoterodine M-R *(Toviaz®)* TAG recommendation: Nov 2011

for use in: Increased urinary frequency and/or urgency and/or urgency incontinence) in Overactive Bladder Syndrome (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2013.

Specific points: November 2011: The NNUH Urologists wish to use once daily fesoterodine instead of tolterodine on the basis of it being more effective but may cause more adverse effects.

Prescriber's Rating of 6. Nothing New - The product may be a new substance but is superfluous because it does add to the clinical possibilities offered by previous products available. In most cases these are "me-too" products.

The TAG also recommended that work on developing a treatment formulary for incontinence should be progressed.

The NHS Norfolk and Waveney Drugs & Therapeutics Commissioning Group agreed to support the TAG's recommendation as stated above.

September 2012: The TAG noted NICE CG 148 (August 2012 http://guidance.nice.org.uk/CG148) - Urinary incontinence in neurological disease

November 2013: The TAG noted NICE CG 171 and agreed that the local treatment pathway for overactive bladder is line with the NICE guidance.

July 2015: the TAG and the d&TCG noted NICE CG 97 - Lower Urinary Tract Symptoms (LUTS) in men: assessment and management

Mirabegron *(Betmiga®)* TAG recommendation: Jul 2013

for use in: 3rd line option for overactive bladder (OAB) symptoms where antimuscarinics are contraindicated or not tolerated (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2013.

Specific points: NICE TA 290 (June 2013)
Recommended as an "option" by NICE for treating the symptoms of overactive bladder only for people in whom anti-muscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects.

Use of mirabegron as a 3rd line option after use of two antimuscarinincs or where these are contraindicated is illustrated in a locally agreed treatment pathway for management of the symptoms of overactive bladder. Available via
http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=w3NwLoOOukA%3d&tabid=916&portalid=1&mid=2074

Recommended by the TAG as Double Green (suitable for initiation and prescribing by GPs)
Prescriber's Rating - 4. "Possibly helpful - the product has minimal additional value, and should not change prescribing habits except in rare circumstances."

November 2013: The TAG noted NICE CG 171 (September 2013) and agreed that the local treatment pathway for overactive bladder is line with the NICE guidance.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

7.4.2 - For urinary frequency, enuresis & incontinence

Solifenacin *(Vesicare®)* TAG recommendation: Jul 2006

for use in: Urge incontinence - only where all other appropriate drug therapies have been tried (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: October 2006.

Specific points: For use only where all other appropriate drug therapies have been tried.
Prescriber's Rating - 4. Possibly helpful - the product has minimal additional value and should not change prescribing habits except in rare circumstances.

September 2012: The TAG noted NICE CG 148 (August 2012 http://guidance.nice.org.uk/CG148) - Urinary incontinence in neurological disease

July 2015: The TAG noted and supported guidance for supporting switching patients from solifenacin to a more cost-effective choice, tolterodine MR.

7.4.5 - Drugs for erectile dysfunction

Alprostadil cream *(Vitaros®)* TAG recommendation: May 2015

for use in: Erectile dysfunction (as per SLS conditions only) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: December 2013.

Specific points: May 2015: The NHS Norfolk & Waveney CCGs' PRG accepted that the topical route is of equivalent efficacy to the injection and therefore supported use of this product as follows:
For use as per conditions specified in Part XVII of the Drug Tariff (SLS) only. Maximum recommended quantity to be supplied on NHS prescription to equate to four doses per month.
The TAG also noted that Vitaros® cream has no safety data for use beyond 9 months or for use in anal or oral sex. The manufacturer's SPC states that use without a condom can cause mucosal irritation for the sexual partner.
The TAG supported the PRG's advice and recommended a classification of Double Green (suitable for GPs to initiate and prescribe) as per SLS conditions specified in the Drug Tariff and with the cautions stated above.

May 2015: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG's recommendations.

Erectile dysfunction drugs *(Various)* TAG recommendation: Sep 2014

for use in: Erectile dysfunction - limited categories of patients under SLS for certain drugs (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Drugs affected include Alprostadil, branded Sildenafil (Viagra) (but not generic sildenafil as from August 2014), Tadalalfil, Vardenafil.

Prescriptions must be endorsed SLS.

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

7.4.5 - Drugs for erectile dysfunction

Sildenafil (as Viagra®) *(Viagra®)* TAG recommendation: Apr 2005

for use in: Erectile dysfunction - limited categories under SLS (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Limited availability on the NHS. Refer to HSC 1999/148.
Viagra® can be only be prescribed for patients with impotence caused by Diabetes, Multiple Sclerosis, Parkinson's Disease, Poliomyelitis, prostate cancer, prostatectomy, radical pelvic surgery, renal failure treated by transplant or dialysis, severe pelvic injury,single gene neurological disease, spinal cord injury, spina bifida.
Also for patients who were receiving a course of NHS drug treatment for erectile dysfunction on 14 September 1998.
If your patient does not have these conditions, treatment on the NHS may be possible if the GP considers the patient is suffering from "Severe Distress". Refer to HSC 1999/177 and details in the "Red - Hospital only" section.
Prescriptions for Viagra® must be endorsed SLS.

Sildenafil (generic) *(Generic sildenafil)* TAG recommendation: Sep 2014

for use in: Erectile dysfunction (any cause) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: From 1st August 2014 generic sildenafil was removed from the list requiring 'SLS' criteria. This may now be prescribed on FP10 for any patient with a clinical need.

Vardenafil, Tadalafil, Viagra® and Avanafil, are only available on the NHS providing 'SLS' criteria indicated in Drug Tariff Part XVIIIB are met. For all other circumstances a private prescription should be issued. It is fraudulent to endorse SLS if it is for reasons other than those specified under SLS.

Drugs included in the SLS list for erectile dysfunction are only allowed on NHS prescriptions in men who:
* Have:-
  o diabetes,
  o multiple sclerosis,
  o Parkinson's disease,
  o poliomyelitis,
  o prostate cancer,
  o severe pelvic injury,
  o single gene neurological disease,
  o spina bifida,
  o or spinal cord injury;
* Are receiving dialysis for renal failure;
* Have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate), or kidney transplant;
* Were receiving Caverject®, Erecnos®, MUSE®, Viagra®, or Viridal® for erectile dysfunction at the expense of the NHS, on 14th September 1998;
* Are suffering severe distress as a result of impotence (prescribed in specialist centres ONLY via FP10 (HP) i.e. fraudulent for GPs to prescribe on FP10)

Tadalafil 10mg & 20mg strength tablets for prn use *(Cialis®; Generics are available)* TAG recommendation: Jul 2018

for use in: Erectile dysfunction - as required use as per SLS criteria - max 4 doses per month (NOT regular daily use) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2018:
The TAG considered and supported the Prescribing Reference Group recommendation to apply a Double Green (Suitable for GPs to initiate and prescribe) classification to these products for prn use in erectile dysfunction as per SLS criteria, and that they should be substituted in the Urology Formulary in place of vardenafil (max 4 doses per month to be supplied on the NHS).

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

7.6.1 - Not listed in the BNF

Gluten-free bread or flour *(Various)* TAG recommendation: Jan 2016

for use in: Gluten-sensitive enteropathies in children up to 18 years of age (West Norfolk CCG area only) (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: July 2010:
Diagnosis of celiac disease should be by serology and biopsy as per NICE CG 86 - Coeliac Disease. G-F products should not be prescribed for patients unless diagnosis in line with the guidance.
NHS Norfolk supported provision of BASIC FOODSTUFF only (bread (not fresh UNLESS the patient agrees to immediate collection and freezer storage of loaves), pasta, bread and pastry mixes).
Order quantities are as per the units recommended by age and gender.

July to December 2015: CCGs in central Norfolk have decided to no longer support routine NHS provision of any gluten-free foods.

West Norfolk CCG still offers provision of G-F bread and flour for children and young people aged up to 18 years - http://www.westnorfolkccg.nhs.uk/news/gluten-free-statement

November 2015:
The TAG and the D&TCG noted NICE NG 20 (September 2015) - Coeliac disease: recognition, assessment and management
Includes recommendations on:
* Referral of people with suspected coeliac disease
* Information and support
* Advice on dietary management
* Non-responsive and refractory coeliac disease
* Monitoring and review in people with coeliac disease

March 2016:
Great Yarmouth and Waveney CCG revised their previous policy to no prescribing of any G-F products on FP10 for adults or children.
http://www.greatyarmouthandwaveneyccg.nhs.uk/news_item.asp?fldID=776

9.4.1 - Foods for psecial diets

Phenylketonuria (PKU) Foods *(Various)* TAG recommendation: Jan 2018

for use in: Guidance on the recommended quantities of specialist PKU foods for patients diagnosed with phenylketonuria (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2018:
The TAG supported guidance for GPs on the recommended number of food units that may be issued per month for PKU foods.

January 2018:
Noted and supported by the N&W D&TCG.

April 2018: Agreed for commissioning by the Norfolk CCGs JSCC.

Available via: http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=W5PwAKDbiqQ%3d&tabid=808&portalid=1&mid=955

Guidance available at: http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=W5PwAKDbiqQ%3d&portalid=1

9.4.2 - Enteral nutrition -

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

9.4.2 - Enteral nutrition -

Enteral nutrition *(Various)* TAG recommendation: May 2012

for use in: PEG and NG tube feeding (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: Guidance is available via:
http://nww.knowledgeanglia.nhs.uk/KMS/Norwich/Home/ClinicalInformation/Other/DieteticsandNutrition.aspx

Guidance re prescribing for patients with enteral tubes is available via
http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=DWRnoAmViYM%3d&portalid=1

9.6.4 - Vitamin D

Colecalciferol (Vitamin D) *(Licensed Vitamin D products)* TAG recommendation: Nov 2017

for use in: Treatment of vitamin D deficiency in adults and children - as per local policies (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: March 2016: The TAG noted and supported the document - Revised Guidance for Diagnosis and Management of Vitamin D Deficiency in Primary Care (Feb 2016). Prescribing colecalciferol in line with the guidance is recommended as Double Green (Suitable for GPs to initiate and prescribe)

March 2016: The NHS Norfolk & Waveney CCGs' D&TCG noted and supported the TAG recommendation.

March 2016: The TAG also noted NG 34 (February 2016) - Sunlight exposure: risks and benefits.

September 2016: The TAG and the D&TCG noted the The Scientific Advisory Committee on Nutrition (SACN) - recommendations on vitamin D (July 2016)
(which updates national guidance in NICE PH 56 Vitamin D: increasing supplement use in at-risk groups (Nov 14)).
The D&TCG supported the TAG's recommendation that vitamin D supplementation for the general population should not be supplied by the NHS, irrespective of the sector people are being seen within.

Local guidance for Diagnosis and Management of Vitamin D Deficiency in adults in Primary Care is available via:
http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=vRToGbY4FPw%3d&tabid=916&portalid=1&mid=2074

October - November 2017:
The Prescribing Reference Group (a sub-group of the TAG), the TAG, and the D&TCG noted and supported new guidance for the Diagnosis and Management of Vitamin D Deficiency in children and adolescents.
Available on Knowledge Anglia at: http://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=bT-NFcRQpLs%3d&tabid=916&portalid=1&mid=2074

10.1.1 - Non-steroidal anti-inflammatory drugs

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

10.1.1 - Non-steroidal anti-inflammatory drugs

COX II Inhibitors *(Various)* TAG recommendation: Apr 2005

for use in: Pain and inflammation in osteoarthritis or rheumatoid arthritis - as per local Analgesics Formulary (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: April 2009.

Specific points: NICE CG 79 Rheumatoid arthritis (April 2009) revised the above the clarify that for symptom control in RA,
1.4.4.1 Offer analgesics (for example, paracetamol, codeine or compound analgesics) to people with RA whose pain control is not adequate, to potentially reduce their need for long-term treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or cyclo-oxygenase-2 (COX-2) inhibitors.
1.4.4.2 Oral NSAIDs/COX-2 inhibitors should be used at the lowest effective dose for the shortest possible period of time.
1.4.4.3 When offering treatment with an oral NSAID/COX-2 inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor. In either case, these should be coprescribed with a proton pump inhibitor (PPI), choosing the one with the lowest acquisition cost.
1.4.4.4 All oral NSAIDs/COX-2 inhibitors have analgesic effects of a similar magnitude but vary in their potential gastrointestinal, liver and cardio-renal toxicity; therefore, when choosing the agent and dose, healthcare professionals should take into account individual patient risk factors, including age. When prescribing these drugs, consideration should be given to appropriate assessment and/or ongoing monitoring of these risk factors.
1.4.4.5 If a person with RA needs to take low-dose aspirin, healthcare professionals should consider other analgesics before substituting or adding an NSAID or COX-2 inhibitor (with a PPI) if pain relief is ineffective or insufficient

April 2011: NHS Norfolk & Waveney issued its NSAIDs Formulary - http://nww.knowledgenorfolk.nhs.uk/prescribing_nhsn/formulary/formulary_nhsn_nsaids.pdf - which specifies prescribing related to use of COX II Inhibitors.

September 2018:
The TAG noted NICE NG 100 (July 2018) - Management of rheumatoid arthritis in adults, which included new and updated recommendations on:
* investigations following diagnosis
* treat-to-target strategy and initial pharmacological management
* symptom control and monitoring
and also:
* investigations for diagnosis and referral from primary care
* non-pharmacological management and the multidisciplinary team
* communication and education

September 2018:
NICE NG 100 (July 2018) was noted by the N&W CCGs' Drugs & Therapeutics Committee

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

10.1.1 - Non-steroidal anti-inflammatory drugs

Meloxicam *(Mobic®)* TAG recommendation: Apr 2005

for use in: Osteoarthritis - short-term (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: July 2001.

Specific points: In January 2004 TAG members agreed:
1. to no longer recommend one preferred COX-2 inhibitor drug over the others.
2. Prescribers should consider which subgroup(s) of patients who might receive a COX-2 inhibitor.
3. Prescribers should consider the adverse effects of the COX IIs and the patient risk factors that might increase their incidence.
4. There are options other than COX-2 inhibitors
5. For acute pain post-operatively, use of COX-2 inhibitors should not be carried on into primary care they should not be included in discharge supplies with patients leaving hospital.

NICE Guidance: Cox II selective inhibitors and other non-steroidal anti-inflammatory drugs (NSAIDs) are indicated for pain and stiffness in inflammatory rheumatoid arthritis and for the short-term management of pain in osteoarthritis. Cox II selective inhibitors are not recommended for routine use in patients with rheumatoid arthritis (RA) or osteoarthritis (OA). They should be used, in preference to standard NSAIDs, when clearly indicated as part of the management of RA or OA only in patients who may be at 'high risk' of developing serious gastrointestinal adverse effects.
Patients at 'high risk' of developing serious gastrointestinal adverse events include those of 65 years of age and over, those using concomitant medications known to increase the likelihood of upper gastrointestinal adverse events, those with serious co-morbidity or those requiring the prolonged use of maximum recommended doses of standard NSAIDs. The risk of NSAID-induced complications is particularly increased in patients with a previous clinical history of gastroduodenal ulcer, gastrointestinal bleeding or gastroduodenal perforation. The use of even a Cox II selective agent should therefore be considered especially carefully in this situation.
See full guidance for more criteria.

10.1.4 - Gout and cytotoxic-induced hyperuricaemia

Febuxostat *(Adenuric®)* TAG recommendation: Mar 2009

for use in: Management of chronic hyperuricaemia in patients with gout who are intolerant of allopurinol - as per NICE TA 164 (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: December 2008.

Specific points: March 2009: Febuxostat is not currently marketed in the UK and is therefore not yet available on NHS prescription.

NICE Technology Appraisal 164 states:
Febuxostat, within its marketing authorisation, is recommended as an option for the management of chronic hyperuricaemia in gout only for people who are intolerant of allopurinol (as defined below) or for whom allopurinol is contraindicated.
For the purposes of this guidance, intolerance of allopurinol is defined as adverse effects that are sufficiently severe to warrant its discontinuation, or to prevent full dose escalation for optimal effectiveness as appropriate within its marketing authorisation.

November 2010: Febuxostat available in the UK. The TAG considered a business case from the NNUH for use of febuxostat as per NICE TA 164. The TAG agreed to support the application which was referred to the PCTs' commissioning bodies for a final decision regarding funding.

December 2010: The NHS Norfolk Drugs & Therapeutics Commissioning Group supported the NNUH's business application provided that intolerance to allopurinol is defined.

12.3.5 - Treatment of dry mouth

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

12.3.5 - Treatment of dry mouth

Artificial saliva or salivary stimulants *(Xerotin Oral spray or other cost-effective product)* TAG recommendation: Sep 2017

for use in: Xerostomia from any cause where simple measures alone have been ineffective (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2013: The TAG noted the NNUH application for Xerotin® oral spray or other cost-effective product in the treatment of xerostomia from any cause. Treatment cheaper in hospital and better tolerated than other saliva substitute sprays. Primary Care prescribing is not restricted under Drug Tariff ACBS criteria and could therefore be used for a wider spectrum of indications. Cost in Primary Care are comparable with other products.

N&W CCGs Drugs and Therapeutics Commissioning Group (D&TCG) noted that in Primary Care where prices include VAT, costs are comparable to other products and supported the TAG recommendation. Treatment commissioned.

September 2017:
The TAG considered the Prescribing Reference Group's recommendations regarding impelementation of the East of England Priority Advisory Committee (PAC) Medical Devices DROP List regarding use of dry mouth products - artificial saliva or salivary stimulants - where simple measures have been ineffective.

Simple measures for managing dry mouth include:
Regular sips of water or an unsweetened drink
Sucking sugar-free sweets or chewing sugar-free gum
Sucking on ice cubes
Avoiding alcohol, caffeine and smoking; all make dry mouthsymptoms worse.
Good oral hygiene to avoid dental problems is essential.
Some dry mouth products are borderline substances (for those with dry mouth due to radiotherapy orsicca syndrome - endorse 'ACBS').
Products can be purchased from a pharmacy; most cost the same or less than a prescription charge.

September 2017:
The TAG's recommendation was noted and supported by the N&W D&TCG - commissioned.

13.4 - Topical corticosteroids

Corticosteroids (Topical) *(Various)* TAG recommendation: Jan 2005

for use in: Atopic eczema - as per NICE TA 81 (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: August 2004.

Specific points: January 2005: The TAG acknowledged NICE TAG No. 81 which relates to the frequency of application of topical corticosteroids in the treatment of atopic eczema and does not include the use of topical agents that combine corticosteroids with other active agents (for example, antimicrobials or salicylic acid).
1.1 It is recommended that topical corticosteroids for atopic eczema should be prescribed for application only once or twice daily.
1.2 It is recommended that where more than one alternative topical corticosteroid is considered clinically appropriate within a potency class, the drug with the lowest acquisition cost should be prescribed, taking into account pack size and frequency of application.

13.6.3 - Topical preparations for rosacea

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

13.6.3 - Topical preparations for rosacea

Ivermectin Cream 10mg/g (1%) *(Soolantra®)* TAG recommendation: Sep 2016

for use in: Papulopustular Rosacea (PPR) (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: September 2016: The TAG considered the QEH's application and accompanying evidence reviews and agreed to support use of Topical Ivermectin Cream 10mg/g (1%) (Soolantra®) as second-line option after topical metronidazole for Papulopustular Rosacea (PPR) as Double Green (Suitable for GPs to initiate and prescribe).

September 2016: The NHS Norfolk CCGs' D&TCG supported the TAG's recommendations and agreed that use of topical ivermectin cream 10mg/g (1%) (Soolantra®) as second-line option after topical metronidazole for Papulopustular Rosacea (PPR) is commissioned as Double Green (Suitable for GPs to initiate and prescribe).

13.8.1 - Photodamage

5-fluorouracil + salicyclic acid topical solution *(Actikerall®)* TAG recommendation: Nov 2016

for use in: Hyperkeratotic actinic keratosis (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG noted and supported (subject to agreed amendments) a pharmacological treatment pathway for actinic keratosis which specified the place of 5-fluorouracil + salicyclic acid topical solution as being suitable for GPs to initiate and prescribe.

January 2017: The published version of the treatment pathway was noted and supported by the TAG and the Norfolk & Waveney CCGs' D&TCG.

Available via: http://nww.knowledgeanglia.nhs.uk/tag/actinic_keratosis_pathway.pdf

5-fluorouracil 5% w/w cream *(Efudix®)* TAG recommendation: Nov 2016

for use in: Non-hypertrophic actinic keratosis (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: November 2016:
The TAG noted and supported (subject to agreed amendments) a pharmacological treatment pathway for actinic keratosis which specified the place of 5-fluorouracil 5% w/w cream as being suitable for GPs to initiate and prescribe.

January 2017: The published version of the treatment pathway was noted and supported by the TAG and the NHS Norfolk & Waveney CCGs' D&TCG.
Available via: http://nww.knowledgeanglia.nhs.uk/tag/actinic_keratosis_pathway.pdf

13.9 - Preparations for hair conditions

Double-Green - 'Suitable for GPs to initiate and prescribe'

Drugs for which it has been deemed reasonable for GPs to initiate and prescribe.

13.9 - Preparations for hair conditions

Eflornithine 11.5% cream *(Vaniqa®)* TAG recommendation: Sep 2016

for use in: Hirsutism in women, transgender and non-binary adults - restricted use where alternative therapy is ineffective, contraindicated or inappropriate as per local guidance (A licensed indication).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE has not issued any guidance.

Specific points: January 2011: The TAG considered available evidence for management of hirsutism and the place of elfornithine in the treatment pathway.
The TAG agreed to develop prescribing guidance for GPs based on the following recommendations:
Eflornithine cream should not be prescribed for purely cosmetic facial hirsutism. Eflornithine cream should only be used in patients with an associated raised free androgen index associated with an androgenic disease (e.g. polycystic ovary disease).
Eflornithine cream is restricted to use in women for whom alternative therapy is ineffective, contraindicated or considered inappropriate.
Eflornithine 11.5% cream, as a licensed topical treatment, may offer advantages over existing therapy for some women as it avoids the risks associated with licensed systemic therapies (such as DVT associated with co-cyprindiol [Dianette®] use).
Prescribers are reminded that eflornithine cream is only licensed for the treatment of facial hirsutism in women. Patients should be reviewed at 4 months, and if no effects are seen by this time, treatment should be discontinued. Patients should be advised on the dosage and administration instructions before consenting to use and that they may need to continue to use a hair removal method (e.g. shaving or plucking) in conjunction with Vaniqa®.

September 2016: The TAG agreed that following publication of NHS England Specialised Services Circular SSC 1620 (22 April 2016) Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Transgender and Non-Binary Adults, Vaniqa® may also be prescribed by GPs for transgender and non-binary adults on the recommendation of a Gender Identity Clinic specialist.

September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed that although this product will remain on the East of England DROP list, the policy supporting restricted use in Norfolk precedes its inclusion on the list.
The D&TCG therefore decided to support the TAG's recommendation to maintain the classification for restricted use of Vaniqa® as Double Green (suitable for GPs to initiate and prescribe) with the added text referring to use in Transgender and Non- Binary Adults in line with NHS England Specialised Services Circular SSC 1620 (22 April 2016).

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

- Poisoning,emergency treatment

Fomepizole *(Antizol®)* TAG recommendation: May 2018

for use in: Methanol and ethylene glycol poisoning (Poison Centre prescribing only) (x).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: May 2018:
Commissioned in line with National Poisons Centre Guidance - Local commissioner to be notified when used

Noted by the TAG and recommended to be added to the TAG's database in line with the Norfolk and Waveney CCGs' Combined Commissioned Drug Therapies List (March 2018) - http://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=QaUeiUvL_pI%3d&tabid=2668&portalid=1

2.5.1 - Vasodilator antihypertensive drugs

Ambrisentan *(Volibris® ▼)* TAG recommendation: Nov 2011

for use in: Pulmonary Arterial Hypertension - specialist centre only (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.
These are:
Hammersmith Hospital, Royal Brompton Hospital and the
Royal Free Hospital in London.
Papworth Hospital near Cambridge.
Royal Hallamshire Hospital , Sheffield.
Great Ormond Street Hospital provides PAH services for children.

The TAG noted and acknowledged the SCG policy and recommended that the above-mentioned treatments for Pulmonary Arterial Hypertension (PAH) are classified as Red (Not for use in Primary Care / Specialised funding only).

On 17th November 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided NOT to fund the above-mentioned treatments for pulmonary arterial hypertension for use in Primary Care due to Specialised Commissioning arrangements already being in place.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

2.5.1 - Vasodilator antihypertensive drugs

Bosentan *(Tracleer®)* TAG recommendation: Sep 2011

for use in: Pulmonary arterial hypertension - - as per NHS England policy - specialist centres only (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (July 2008) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.
These are:
Hammersmith Hospital, Royal Brompton Hospital and the
Royal Free Hospital in London.
Papworth Hospital near Cambridge.
Royal Hallamshire Hospital , Sheffield.
Great Ormond Street Hospital provides PAH services for children.

The TAG noted and acknowledged the SCG policy and recommended that the above-mentioned treatments for Pulmonary Arterial Hypertension (PAH) are classified as Red (Not for use in Primary Care / Specialised funding only).

On 15th September 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided NOT to fund the above-mentioned treatments for pulmonary arterial hypertension due to Specialised Commissioning arrangements already being in place.

Iloprost *(Ventavis®)* TAG recommendation: Sep 2011

for use in: Pulmonary arterial hypertension (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Sept 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (July 2008) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

2.5.1 - Vasodilator antihypertensive drugs

Tadalafil (Adcirca) *(Adcirca®)* TAG recommendation: Nov 2011

for use in: Pulmonary Arterial Hypertension (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (September 2011) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults and are able to initiate treatment.
These are:
Hammersmith Hospital, Royal Brompton Hospital and the
Royal Free Hospital in London.
Papworth Hospital near Cambridge.
Royal Hallamshire Hospital , Sheffield.
Great Ormond Street Hospital provides PAH services for children.

The TAG noted and acknowledged the SCG policy and recommended that the above-mentioned treatments for Pulmonary Arterial Hypertension (PAH) are classified as Red (Not for use in Primary Care / Specialised funding only).

On 17th November 2011 the NHS Norfolk Drugs & Therapeutics Commissioning Group considered the TAG's recommendation and decided NOT to fund the above-mentioned treatments for pulmonary arterial hypertension for use in Primary Care due to Specialised Commissioning arrangements already being in place.

2.8.1 - Parenteral anticoagulants

Epoprostenol (prostacyclin) ▼ *(Flolan®)* TAG recommendation: Sep 2011

for use in: Primary pulmonary hypertension - as per NHS England policy - specialist centre only (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: Sepetmber 2011:
The TAG noted the National Specialised Commissioning Group (NCG) Interim Commissioning Policy (July 2008) on Target therapies for the treatment of pulmonary arterial hypertension in adults.

Only centres designated by the NCG may provide pulmonary hypertension services for adults are able to initiate treatment.

April 2013: NHS England SCG took over commissioning responsibility for this treatment.

3.4.2 - Allergen immunotherapy

Bee and Wasp allergen extracts *(Pharmalgen®)* TAG recommendation: Mar 2012

for use in: Bee and wasp venom allergy - as per NICE TA 246 - specialist centre only (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: February 2012.

Specific points: NICE TA 246 states that: Pharmalgen is recommended as an option for the treatment of IgE-mediated bee and wasp venom allergy in people who have had a severe systemic reaction to bee or wasp venom, or a moderate reaction and other risk factors or anxiety about future stings. Treatment with Pharmalgen should be started and monitored in a specialist centre experienced in venom immunotherapy.

3.6 - Oxygen

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

3.6 - Oxygen

Oxygen therapy *()* TAG recommendation: Nov 2011

for use in: Approved indications outside of usual Long Term Oxygen Therapy (LTOT) (x).

Prescribing responsibility: GP can initiate and take responsibility for all scripts.

NICE issued Guidance in: September 2012.

Specific points: November 2012: Guidance (Sept 2011) amended in line with NICE CG 150 (http://guidance.nice.org.uk/CG150) - Diagnosis and management of headaches in young people and adults.

January 2017:
The TAG supported revised guidance for use of Home Oxygen which had been updated in line with updated BTS Guidelines for Home Oxygen Use in Adults - Thorax June 2015 Volume 70 Supplement 1.

The revised supported indications for use of Home Oxygen are:
* Patients with proven hypoxia, either resting or on exercise, in line with BTS guidance (see as above) - patients should receive formal assessment via HOS-AR services
* Nocturnal hypoxaemia/desaturation - The assessment for this will have to be made by services specialising in the identification and treatment of diseases leading to this condition.
* Patients with distressing dyspnoea / breathlessness intractable to or with inadequate response to other forms of therapy - Supply should not be initiated until need is identified.
* Cluster headache - There should be a positive diagnosis of the condition. Oxygen is not a preventative therapy and is only effective in aborting attacks. Ideally preventative therapy should also be considered.
* Other uses are not supported. Any requests for proposed use outside of those agreed should be discussed initially with the HOS Lead.

The guidance is available on Knowledge Management via http://nww.knowledgeanglia.nhs.uk/tag/home_oxygen_guidance.pdf

All other guidance on Home Oxygen can be accessed via:
http://nww.knowledgeanglia.nhs.uk/respiratory/home_oxygen.htm

5.1.2.3 - Other beta-lactam antibiotics

Aztreonam (nebulised) *(Cayston®)* TAG recommendation: Nov 2012

for use in: Gram negative infections in cystic fibrosis - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: November 2012:
The TAG also noted that national Specialised Commissioning Group guidance on nebulised treatments in CF (Oct 2012) recommends use of nebulised aztreonam.
Refn: http://www.england.nhs.uk/wp-content/uploads/2013/04/a01-ps-a.pdf

The NHS England SCG took over funding responsibility for CF treatment from April 2013.

September 2015: The TAG noted NG 15 (August 2015) Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use which covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.

November 2017:
The TAG acknowledged NICE NG 78 (October 2017) - Cystic fibrosis: diagnosis and management

5.2 - Antifungal drugs

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

5.2 - Antifungal drugs

Amphotericin B, itraconazole & voriconazole *(Various)* TAG recommendation: Mar 2011

for use in: Chronic Pulmonary Aspergillosis (CPA) - specialist centre only (A licensed indication).
Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE has not issued any guidance.

Specific points: The Chronic pulmonary Aspergillosis Service was designated and nationally commissioned from April 2009. It is a single centre service provided at the University Hospital of South Manchester NHS Foundation Trust.
All anti-fungal therapies for the treatment of CPA are to be commissioned nationally.
There should be no local prescribing of anti-fungal therapies for the treatment of CPA.

Following a review of the evidence, in conjunction with the service provider, the following treatments are recommended:
* Short course IV amphotericin B for in-patient treatment to induce disease control in severely ill patients before transfer to oral itraconazole.
* Antifungal therapy limited to oral itraconazole (1st line) with oral voriconazole available only for those who are intolerant or resistant to itraconazole.
* Patients intolerant or resistant to voriconazole will receive either (i) supportive care or non-pharmaceutical intervention (subject to further presentation of evidence) or (ii) additional anti-fungal therapy offered only as part of a robust clinical trial commissioned and funded outside the NCG contract. Therefore, the use of posaconazole, long-term IV amphotericin B, IV micafungin or IV gamma interferon (the latter solely as a treatment for chronic pulmonary aspergillosis) should not be routinely commissioned because of the lack of evidence to support their use.
* Individual funding requests for patients considered to be exceptional to this policy will be submitted (subject to clarification of this process) and, where appropriate, funded by NCG.

9.3 - Intravenous nutrition

Total parenteral nutrition *(Various)*

for use in: Various (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

9.8.1 - Drugs used in metabolic disorders

Imiglucerase *(Cerezyme®)* TAG recommendation: Mar 1998

for use in: Gaucher's disease (A licensed indication).
Prescribing responsibility: Consultant responsible for all scripts N/A.

NICE has not issued any guidance.

Specific points: April 2013: Commissioning responsibility for this treatment transferred to NHS England SCG.

Highly specialised use only.

10.2.2 - Skeletal muscle relaxants

Special - 'Special contract - not for GP prescribing'

Drugs purchased and supplied under special contracts

10.2.2 - Skeletal muscle relaxants

Baclofen (via intrathecal pump) *(Lioresal®)* TAG recommendation: Nov 2012

for use in: Muscle spasm in neurological conditions as per NICE guidance (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: July 2012.

Specific points: The TAG supported the East of England Priorities Advisory Committee's (PAC) policy statement (Sept 2012) as follows:

The PAC supports the use of intrathecal baclofen in line with:
NICE CG 8; management of multiple sclerosis in primary and secondary care, issued November 2003
NICE CG 145; spasticity in children and young people, issued July 2012
and for no other indications.
Prior approval is recommended.

The D&TCG commissioned use of intrathecal baclofen pump as per the PAC policy, under prior approval.

14.5 - Immunoglobulins

Immunoglobulin ▼ *(Various)*

for use in: Congenital agammaglobulinaemia (A licensed indication).

Prescribing responsibility: Consultant responsible for all scripts.

NICE has not issued any guidance.

Specific points: July 2008: Demand Management Plan for Immunoglobulin Use - 2nd edition May 2008
The Department of Health has published this document in response to global supply shortages and supply problems specific to the UK.
The plan states that "GPs should not prescribe immunoglobulin; prescribing should be restricted to the specialist responsible for the patient's treatment."
The TAG therefore recommends that use of immunoglobulin is restricted to prescribing in Hospital only i.e. Red.

April 2013: Commissioning responsibility transferred to NHS England SCG.

In progress - 'Prescribing responsibility yet to be confirmed'

Local commissioning arrangements are in progress and have yet to be finalised

2.8.2 - Oral anticoagulants

Apixaban *(Eliquis®)* TAG recommendation: Jul 2015

for use in: Anticoagulation in DC Cardioversion of Atrial Fibrillation / Atrial Flutter (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE has not issued any guidance.

Specific points: July 2015: The TAG supported the JPUH's application subject to recommended changes to supporting documents. The TAG recommended a classification of Red (Hospital / Specialist use only) since this is time-limited treatment under specialist control. Final details of the proposed service to be forwarded to the commissioners for consideration.

July 2015: The D&TCG noted the TAG's support for this proposal pending recommended amendments to the supporting documents. The D&TCG agreed to support the proposal if it was confirmed that the complete course of treatment with a NOAC will be provided In-Tariff by the Trust and that patients who require continued anticoagulation post DC cardioversion will have no expectation of remaining on a NOAC and will be transferred to warfarin as a matter of routine. The D&TCG deferred its final commissioning decision on this application until the amended documents had been provided by the Trust.

Dabigatran *(Pradaxa®)* TAG recommendation: Jul 2015

for use in: Anticoagulation in DC Cardioversion of Atrial Fibrillation / Atrial Flutter (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE has not issued any guidance.

Specific points: July 2015: The TAG supported the JPUH's application subject to recommended changes to supporting documents. The TAG recommended a classification of Red (Hospital / Specialist use only) since this is time-limited treatment under specialist control. Final details of the proposed service to be forwarded to the commissioners for consideration.

July 2015: The D&TCG noted the TAG's support for this proposal pending recommended amendments to the supporting documents. The D&TCG agreed to support the proposal if it was confirmed that the complete course of treatment with a NOAC will be provided In-Tariff by the Trust and that patients who require continued anticoagulation post DC cardioversion will have no expectation of remaining on a NOAC and will be transferred to warfarin as a matter of routine. The D&TCG deferred its final commissioning decision on this application until the amended documents had been provided by the Trust.

April 2016: The Norfolk and Waveney Drugs & Therapeutics Commissioning Group (D&TCG) agreed to maintain the commissioning position for use of dabigatran as stated above.

Rivaroxaban *(Xarelto®)* TAG recommendation: Jul 2015

for use in: Anticoagulation in DC Cardioversion of Atrial Fibrillation / Atrial Flutter (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE has not issued any guidance.

Specific points: July 2015: The TAG supported the JPUH's application subject to recommended changes to supporting documents. The TAG recommended a classification of Red (Hospital / Specialist use only) since this is time-limited treatment under specialist control. Final details of the proposed service to be forwarded to the commissioners for consideration.

July 2015: The D&TCG noted the TAG's support for this proposal pending recommended amendments to the supporting documents. The D&TCG agreed to support the proposal if it was confirmed that the complete course of treatment with a NOAC will be provided In-Tariff by the Trust and that patients who require continued anticoagulation post DC cardioversion will have no expectation of remaining on a NOAC and will be transferred to warfarin as a matter of routine. The D&TCG deferred its final commissioning decision on this application until the amended documents had been provided by the Trust.

September 2016: September 2016: The NHS Norfolk & Waveney CCGs' D&TCG agreed with the TAG recommendation that a revised commissioning statement be produced for the use of oral anticoagulants across all NICE-recommended indications. The revised commissioning statement to read:
"Where there is no clinical reason to do otherwise, the anticoagulant drug with the lowest acquisition cost should be used."

4.10 - Drugs used in substance dependence

In progress - 'Prescribing responsibility yet to be confirmed'

Local commissioning arrangements are in progress and have yet to be finalised

4.10 - Drugs used in substance dependence

Nicotine Replacement Therapy (NRT) *(Various)* TAG recommendation: Jul 2013

for use in: Harm reduction in smoking (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE issued Guidance in: June 2013.

Specific points: July 2013: The TAG noted NICE Public Health Guidance 45 (June 2013) Tobacco: harm-reduction in smoking. Commissioning arrangements for this use of NRTyet to be finalised. Public Health are the lead commissioners of this guidance.

May 2018: The TAG noted NICE NG 92 (March 2018) - Stop smoking interventions and services , which updates and replaces NICE guidelines PH1 (March 2006) and PH10 (February 2008).

8.1.5 - Other antineoplastic drugs

Erlotinib *(Tarceva®)* TAG recommendation: Jan 2016

for use in: Treatment of non-small-cell lung cancer (NSCLC) as per NICE TA 374 - as per NHS England policy (A licensed indication).

Prescribing responsibility: Consultant/Specialist responsible for all scripts.

NICE issued Guidance in: December 2015.

Specific points: January 2009:
ther TAG noted that NICE Technology Appraisal Guidance No.162 - erlotinib for the treatment of non-small-cell lung cancer states that:

"Erlotinib is recommended as an alternative to docetaxel for patients with non-small-cell lung cancer (NSCLC) who have already tried one chemotherapy regimen but it has not worked. Erlotinib should be used only when the manufacturer provides the drug at the same overall treatment cost as docetaxel. This cost includes the cost of giving the drug, treatments for any side effects and the cost of monitoring patients to check that treatment is working.

If the overall treatment cost is equal, specialists should discuss with patients the potential benefits and risks of erlotinib and docetaxel before deciding which treatment to use.

Erlotinib is not recommended for people with locally advanced or metastatic NSCLC who cannot take docetaxel and have already tried one chemotherapy regimen but it has not worked.

Erlotinib is not recommended for people who have already tried two chemotherapy regimens, including docetaxel, but they haven't worked.

January 2013: Stated as commissioned by NHS Norfolk & Waveney in line with Cancer Network regimens. Non-tariff treatment.

April 2013: NHS England SCG took over commissioning responsibility.

November 2013: NICE treatment pathway for NSCLC: http://pathways.nice.org.uk/pathways/lung-cancer

November 2013: Commissioning responsibility of NHS England SCG from April 2013.

Not included in the Cancer Drugs Fund List Sept 2013 - http://www.england.nhs.uk/wp-content/uploads/2013/09/ncdf-list-sept.pdf

January 2016:
The TAG noted NICE TA 374 (which supersedes NICE TA 162) which recommends use of Erlotinib (Tarceva®) and gefitinib (Iressa®) as options for treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) that has progressed after prior non-targeted chemotherapy because of delayed confirmation of epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation status, if
* the cancer tests positive for the EGFR TK mutation or
* it is not known if the cancer is EGFR TK mutation positive because of problems with the test, and
  the cancer is very likely to be EGFR TK mutation positive
  it responds to the first 2 cycles of treatment with erlotinib

January 2016:
The Norfolk & Waveney CCGs' D&TCG noted NICE TA 374 for these SCG-commissioning responsibility treatments and the TAG's recommendations.

In progress - 'Prescribing responsibility yet to be confirmed'

Local commissioning arrangements are in progress and have yet to be finalised

9.1.3 - Drugs in hypoplastic, haemolytic & renal anaemias

Erythropoietin / Epoetin *(Eprex)* TAG recommendation: Jul 2015

for use in: Treatment of transfusion-dependent anaemia in myelodysplasia (A licensed indication).

Prescribing responsibility: No prescribing recommended until local commissioning arrangements are finalised.

NICE has not issued any guidance.

Specific points: July 2015: The TAG supported the QEH's application for use of this treatment in a niche group of patients and recommended a classification of Red (Hospital only) pending further applications from the other local Trusts, and details of costings regarding blood transfusions being forwarded to the commissioners.

The D&TCG had been advised that use of erythropoietin was SCG-commissioning responsibility and that such use should be considered as In-Tariff.
The D&TCG noted the potential savings for the local health economy related to reduced numbers of blood transfusions and recommended that the West Norfolk CCG considers commissioning this treatment on this basis.

General guidance and good practice

Whilst GPs are encouraged to assume responsibility for the management of patients when appropriate, there is a group of drugs around which there is little or no debate over who holds clinical responsibility for the management of the associated disease or condition. In this situation prescribing responsibility would be expected to lie with the hospital consultant or specialist. These are listed in **"Red (Hospital only)"**.

Certain drugs are purchased and supplied under special contracts. These are listed in **"Special contracts"**. Trusts will provide the purchaser with information on individual cases requiring treatment under these contracts as soon as possible prior to discharge of the patient to home. Trusts will not agree contracts with any other provider for the home care of patients covered by EL(95)5 without the prior approval of the purchaser.

There is a group of drugs which, although usually initiated, modified and terminated by specialists, offer some potential for a shared clinical responsibility with a GP. In these circumstances prescribing by a GP would be appropriate. However, such a shared care arrangement needs to be individually agreed with the GP before clinical and prescribing responsibility is transferred from the secondary sector. In the absence of such agreed arrangements, GPs will not be expected to prescribe. A list of drugs for which it has **already** been deemed reasonable to approach GPs to solicit their involvement in a shared-care arrangement, and for which a written shared care document has been approved by the TAG, is listed in **"Amber – Option for shared care"**. Drugs which are prescribable by GPs outside a shared-care arrangement are listed in **"Green – GP prescribable at the request of a Consultant / Specialist"** and in **"Double Green – GP prescribable"**.

In the transfer of clinical and prescribing responsibilities to the GP, consideration will be given to the "requirements for GPs to accept hospital-transferred prescribing" agreed at the Therapeutic Advisory Group as far back as in January 1996. A GP requires to have:

- a sound knowledge of the patient and his/her condition;
- an understanding of the effects of the drug;
- a clear clinical role in the continuing management of the patient, while he/she is on the drug;
- clear information and guidance on monitoring arrangements;
- a clear, workable, direct channel of communication to the consultant;
- an understanding with the patient of the GP's role in managing his/her condition;
- a process for sharing information and responsibility (consultant, GP & patient) informed agreement;

Good practice is:

- to ensure prior agreement has been reached between the GP and consultant;
- to provide a clear statement of responsibilities, with the particular activities, for which the GP will take clinical responsibility under a shared care arrangement, clearly identified and agreed;
- to ensure that the patient's condition has been stabilised;
- to provide education to GPs and nurses;
- to ensure prior dissemination of sufficient information to the patient's GP and other carers.

Where there is doubt or dispute about where clinical and prescribing responsibility rests, it will be considered to lie in secondary care if the patient is still under the care of the consultant (see EL(91)127). The consultant should initiate treatment until the situation is resolved. Patients should not be left without necessary treatment as a result of these disputes.

The Therapeutic Advisory Group (TAG) advises on issues of clinical and prescribing responsibility across the Primary-Secondary care interface. Doubts or disputes should be referred to TAG which will communicate decisions to GPs and the relevant consultants. It should be remembered that TAG recommendations are advisory and it has no executive authority over General Practitioners.