NHS Anglia
Commissioning Support Unit

A Policy and Procedure for introducing New Medicines and indications across Clinical Commissioning Groups (CCGs) in Norfolk and Great Yarmouth & Waveney

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NHS
Anglia
Commissioning Support Unit

A Policy and Procedure for Introducing New Medicines and Indications across Clinical Commissioning Groups (CCGs) In Norfolk and Great Yarmouth & Waveney

Providing commissioning support services for
South Norfolk CCG, North Norfolk CCG, West Norfolk CCG, Great Yarmouth and Waveney CCG and Norwich CCG

NHS Anglia
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March 2014

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1. Introduction

A new medicine, or a new indication for an existing medicine, can be a welcome addition to the formulary, providing a significant advance over current treatment in terms of its increased effectiveness or an improved side-effect profile. However, many new medicines or formulations offer little of clinical advantage over existing treatments. Furthermore, new medicines are often more expensive than existing treatments - sometimes spectacularly so.

Having made provision for the cost of medicines within fixed budgets, the unexpected introduction of an expensive new medicine or indication upsets carefully laid plans. Budgets become overspent and resources may be diverted from other areas of patient care to fund the new medicine - perhaps to the detriment of the overall well-being of patients.

We need to know whether the additional benefit brought about by the new medicine or indication is worth the hardship imposed on other patients when resources are diverted from their care.

We need to incorporate guidance from the National Institute for Health and Care Excellence (NICE) and consider how best to implement it within local circumstances. We need to estimate the financial and human resources necessary for implementation and secure appropriate funding, workforce and service development.

With these ethical, legal and financial implications, the introduction of new medicines must be undertaken in a considered fashion. This document describes the method used for the introduction of new medicines across the Norfolk and Waveney area.

2. Key features of the policy

- The introduction of new medicines or indications should take into account the cost pressures in all healthcare sectors. Affordability and cost-effectiveness are important wherever the medicine is prescribed.

- The default position for new medicines and indications is that they are not routinely available until they have been assessed, prioritised and commissioned. Thus, as the financial year progresses, there will be a growing list of new medicines and indications awaiting prioritisation and possible commissioning in the next financial year.

- The assessment of medicines will be an **on-going continuous process** throughout the financial year, but prioritisation for additional funding will only take place on an **annual basis** as part of the commissioning cycle. Medicines will be considered alongside all other proposals for development.

- The assessment of new medicines should prompt a comparison of existing medicines or treatments for the same or other conditions in order to determine their relative cost-effectiveness and, where appropriate, their place in the treatment pathway. Some introductions will only take place if resources are transferred from other, less valuable, activities.

- NICE Technology Appraisals will be funded within three months of the date of publication.

- The Therapeutics Advisory Group (TAG) will act as the professional advisory group for the Norfolk and Great Yarmouth & Waveney health economies. It will consider medicines or indications for which extra funding or guidance is sought that the Clinical Commissioning Groups (CCGs) will want to ensure equity of provision across the Norfolk and Waveney area. It will consider all guidance on medicines from the National Institute for Health and Care Excellence (NICE), NHS England and other national guidance (e.g. QIPP (Quality, Innovation, Productivity and Prevention)).

- The recommendation on the suitability of prescribing a medicine in primary care, as opposed to secondary care, should be made on grounds of clinical appropriateness and patient safety and will take account of guidance from NICE and other national bodies. It should not be influenced by the likely source of funding for the medicine.

- Provider Trust-based Drug and Therapeutics Committees (DTCs) will play a gatekeeper role for the introduction of new medicines or indications within the Trust. This includes medicines for clinical trials, which should be introduced in conjunction with R&D Governance Committees.

- In the case of medicines which are excluded from the tariffs of “Payment by Results”, Providers may shortlist new medicines and indications identified through the annual Horizon Scanning process for consideration for commissioning by CCGs. This includes estimates of the likely impact of expected guidance from the National Institute for Health and Care Excellence.

- CCGs will consider the more immediate use and funding of a medicine in individual patients on grounds of exceptionality – or, more widely, if there is national guidance or direction about a new medicine.

- The budget-setting process for prescribing will take account of the likely impact of expected new drugs and recommendations from NICE.

3. A series of decisions

When making decisions regarding whether or not a new medicine should be recommended for commissioning, a series of questions are asked in order to determine the treatment's worth against other medicines. The questions are posed as follows and are considered in line with the Ethical Framework attached at Appendix xx

- *Safety of the proposed treatment*……..Patient Safety
- *Does it work and what does it achieve?*..... Effectiveness
- *What are the characteristics of the medicine?.....*Criteria
- *What is the proposed use of the medicine?*..... Guideline for use
- *Where is the prescribing responsibility?* ..... Clinical responsibility
- *What is its cost and where does it fall?*..... Financial impact
- *Is it worth the (extra) cost?* ..... Economic appraisal
- *How does it compare with our other priorities?*..... Priority status
- *Can we afford it - or how do we afford it?* ..... Financial ability
- *Should we use it?*..... The final decision
- *What is the Prescriber Rating?*

In the light of the above, where available, we refer to the evaluations produced by the National Institute for Health and Care Excellence (NICE) and its guidance for the NHS.

4. Funding aims

CCGs are committed to ensuring that medicines recommended for use by NICE are properly implemented and appropriately funded – including considering the funding of any consequential service developments.

Where there is no guidance from NICE, CCGs **aim to ensure** that medicines or indications which are funded meet the following criteria. (These are adapted from those developed by the US National Institute for Health Care Management[1]).
These medicines will **still have to be assessed alongside other priorities** in the CCGs' commissioning plans before a decision is made on a medicine's priority and affordability.

4.1 Criteria

1. The medicine is used for a medical condition.

2. There is sufficient evidence to draw conclusions about the medicine's effects on health outcomes.

3. The evidence demonstrates that the medicine can be expected to produce its intended effects on health outcomes.

4. The medicine's expected beneficial effects on health outcomes outweigh its expected harmful effects.

5. The medicine is a cost-effective method to address the medical condition and that we have clarified the financial impact of its introduction.

4.2 Definitions

- **Medical condition:** a medical condition is a disease, an illness, or an injury. A biological or psychological condition that lies within the range of normal human variation is not considered a disease, illness or injury.

- **Health outcomes:** health outcomes are outcomes of medical conditions that directly affect the length or quality of a person's life. (for example: evidence of lowered mortality, not just lowered cholesterol.)

- **Sufficient evidence:** evidence is considered to be sufficient to draw conclusions if it is peer reviewed, is well controlled, directly or indirectly relates the intervention to health outcomes, and is reproducible both within and outside of research settings. (For example: for a medicine to be used in primary care:- a randomised controlled trial of a medicine used in a typical primary care setting of sufficient duration to measure a number of health as opposed to intermediate outcomes.)

- **Cost-effective:** a medicine is considered cost-effective if there is no other available intervention that offers a clinically appropriate benefit at a lower cost.

- **Indication:** the condition which is treated by the medicine.

1 Eddy DM. Benefit language: Criteria that will improve quality while reducing costs. JAMA Feb 1996. 275(8):650-657.

5. The introductory sequence

5.1 Effectiveness

The starting point for the introduction of a medicine or indication is to consider the research-based evidence of its effectiveness. We will take into consideration the quality and "maturity" of the evidence, the choice of outcome measures evaluated and the setting in which the trial took place.

5.2 Guideline for use

Drawing on the evidence of effectiveness, clinicians should collaborate to develop treatment pathway and guideline for the proposed use of a medicine. The guideline will be considered alongside the evidence. Where a medicine is likely to be started, modified, monitored and stopped by specialists, prescribing responsibility for the patient rests with the specialist. However, if it is considered that patient care would be improved through sharing clinical and prescribing responsibility with GPs, a shared-care protocol should be developed for consideration by the Therapeutics Advisory Group. Shared care guidelines should follow the recommendations made by the GMC[2]

5.3 Clinical responsibility

A key decision when introducing medicines within Norfolk and Waveney is the assessment of whether a medicine is **appropriate for prescribing in primary care.** This is formally determined by the Therapeutics Advisory Group (TAG) through the use of decision grids.. Furthermore, hospital clinicians should only ask GPs to prescribe those medicines which have been approved for use by their Trust.

5.4 Financial impact

The total cost of the proposed introduction of the treatment is estimated for the population of the local health economy . This cost can then be apportioned to the primary and secondary sectors depending on where clinical responsibility rests. This allows for an assessment of the medicine's financial impact on existing agreements and prescribing budgets.

5.5 Economic appraisal

An assessment of the cost-effectiveness of the proposed medicine or indication will be made which should take into account the additional costs needed for the introduction of the medicine in the setting in which it is proposed to be used - that is, to take into account any extra staff, equipment, activity or monitoring needed.

5.6 Prioritising medicines for commissioning

The CCGs are legally required to fund the medicines and indications recommended by the technology appraisals from NICE. The Therapeutics Advisory Group (TAG) will estimate the financial impact of upcoming appraisals to inform the commissioning process.

Otherwise, the TAG will identify those medicines which are of highest priority for introduction. These are likely to be the medicines or indications with the greatest cost-effectiveness. TAG

2 [2] http://www.gmc-uk.org/mobile/14321

will take into account - and may need to review - previous decisions to ensure consistency and to ensure that medicines and indications of greatest value are used.

Technical factors which will influence the priority status of a medicine or indication include the quantity, quality and strength of evidence of effectiveness and cost-effectiveness, the availability of alternative treatments, safety, etc.

In prioritising medicines for commissioning recommendations, the TAG takes into account the Department of Health publications 'Innovation, Health & Wealth: Accelerating Adoption and Diffusion in the NHS' and 'Good Practice Guidance on developing and updating local formularies' .

In order to meet the requirements for NICE TAs to be funded and in formularies within 90 days, the TAG will make recommendations to the CCG Drugs and Therapeutics Commissioning Group based on the NICE Final Appraisal Document (FAD), facilitating the timely adoption of a NICE TA. The TAG will consider NICE FADs where the drug is supported as an "option" in treatment. The TAG will provide clinical input as to where the drug sits in a treatment pathway and the views of local Trust clinicians will be sought.

5.7 Commissioning process

The Therapeutics Advisory Group recommendations are submitted to the CCGs, via the Drugs and Therapeutics Commissioning Group (D&TCG) for a commissioning recommendation to be made to the CCG Boards.

5.8 The final decision

If commissioned the treatment (and any related service developments) will be made available.

6. Introducing medicines in Primary Care

With few exceptions, all medicines licensed in the UK can be prescribed by GPs. Even unlicensed medicines can be prescribed, although GPs are discouraged to do this.

CCGs consider both clinical appropriateness and affordability when using a medicine. The introduction of medicines within Norfolk and Waveney should take into account cost-pressures in the primary care sector as well as the secondary sector. Cost-effectiveness is important whoever prescribes the medicine.

The process for assessing medicines which are licensed and likely to be prescribed by GPs is as follows:

- Medicines are proposed for assessment by the Therapeutics Advisory Group (TAG) by the CCGs, acting via the locally commissioned Prescribing and Medicines Management services where appropriate.

- Recommendations made by the TAG are returned to the CCGs for commissioning consideration via the Norfolk & Waveney CCG Drugs and Therapeutics Commissioning Group (D&TCG)

- Commissioning decisions regarding medicines and indications are formally communicated to NHS provider Trusts by the CCGs and are also disseminated to all prescribers and pharmacists through the Norfolk & Waveney Prescriber Newsletter and **updates on the Knowledge Anglia website**

- The TAG will make recommendations on whether the medicine is suitable for prescribing by GPs, by specialists or whether a shared-care arrangement is appropriate.

- Drugs less suitable for prescribing are listed on the Drugs of Low Priority List.

CCG prescribing leads, the CSU's Prescribing and Medicines Management team and Trust-based Drug and Therapeutics Committees are working together to harmonise formularies for medicines which are widely used in primary care. This activity is conducted through working groups such as the Prescribing Reference Group.

7. Introducing medicines within NHS Provider Trusts

Most new medicines or formulations have modest cost-impact and/or will join medicines of comparable clinical impact. Most decisions on the introduction of new medicines are appropriately made within an NHS Provider Trust. This will allow the Trust to take account of its specialty mix, clinical experience and expertise, work settings and financial status.

Trusts have developed suitable mechanisms for the assessment of new medicines and indications. Such mechanisms build upon the functions of existing Drug and Therapeutics Committees.

A typical mechanism involves Clinical Directors who make submissions to their D&T Committee or equivalent professional advisory body. Submissions address the issue of the medicine's clinical effectiveness and its cost-effectiveness when compared to other treatments for the same condition.

D&T Committees validate these submissions according to their organisation's Ethical Framework.

7.1 Responsibilities of NHS Provider Trust D&T Committees[3]

In respect to the introduction of new medicines or indications, this policy endorses the following responsibilities:

- the sole gateway advising on the introduction of new medicines or indications within the Trust;

[3] Or equivalent professional advisory body.

- evaluating the effectiveness and assessing the cost implications of new medicines or indications;
- horizon scanning for new medicines or new indications;
- consideration of guidance developed by the Therapeutics Advisory Group;
- collection and preparation of business cases for consideration by the Therapeutics Advisory Group;
- where a NICE technology appraisal is awaited for a new medicine or indication, a business case should be prepared sufficiently in advance so that, if such a medicine or indication is recommended for use by NICE, funding can be made available no later than three months after publication of the guidance. The CCGs will facilitate the development of business cases to improve NICE implementation across all Trusts;
- agreeing protocols for the use of a medicine or indication within the Trust;
- monitoring medicine use within the Trust;
- considering and endorsing requests for exceptional funding in individual patients.

8. Therapeutics Advisory Group (TAG)

Whilst it is expected that most decisions on the introduction of new medicines, formulations or new indications will be made by Trust D&TC, where a D&TC decision might affect other organisations there is an important role for submission to the TAG for guidance across the local health economy. It should be noted that submissions from a Trust should be made and have been considered by the Trust D&T Committee.

8.1 Tasks

The role of the Therapeutics Advisory Group is to provide informed professional advice across Norfolk and Waveney on the clinical use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc **that are commissioned by CCGs.** This includes:

- advice on the managed introduction and implementation of new medicines and indications into practice – including on the most appropriate method of introducing medicines recommended by NICE;
- advice on the prescribing responsibility across the Primary / Secondary care interface;
- advice on non-medical prescribing issues and PGDs where appropriate;
- to take note of commissioning decisions made by other commissioners e.g. NHS England, neighbouring CCGs.

8.2 Terms of Reference

These are appended as an annex.

8.3 What medicines are considered by TAG?

1. All medicines for which NICE has published Technology Appraisals where the medicine is an option for treatment.

2. Medicines for which guidance is needed on ***use in the primary care setting***, including the approval of ***shared-care guidelines***.

3. Medicines for which there is uncertainty over ***clinical and prescribing responsibility*** across the primary secondary care interface.

4. Medicines which are ***excluded from the tariffs*** of "Payment by Results" or are used in Healthcare Resource Groups which are ***excluded from tariff***.

5. Medicines or new indications for which a Trust is seeking ***additional funding*** e.g. as a "pass-through" payment - or ***guidance*** e.g. because of impact in primary care.

6. Medicines for which we need an assessment of their ***therapeutic value*** or ***cost-effectiveness***, including:

    - Medicines which open up ***new therapeutic avenues***, e.g. the "first medicine for a condition".

    - Medicines which operate through ***new mechanisms***, e.g. the first of a new class of medicine.

    - Medicines with a ***high*** impact on patient benefit or cost across primary and secondary care

7. Medicines which are subject to investigation in trials and which may require significant investment in excess treatment costs where the CCGs require additional clinical guidance in addition to information considered by the D&TCG.

Other points

- It is important not to overburden the process, so ***medicines with a high cost impact will be evaluated preferentially***.

- Submissions from a Trust should be made and have been considered by the Trust D&T Committee.

- Submissions should justify the requirement for ***additional*** expenditure on the treatment.

8.4 Taking forward TAG Recommendations

The Therapeutics Advisory Group is a professional advisory group. It gives advice and makes recommendations.

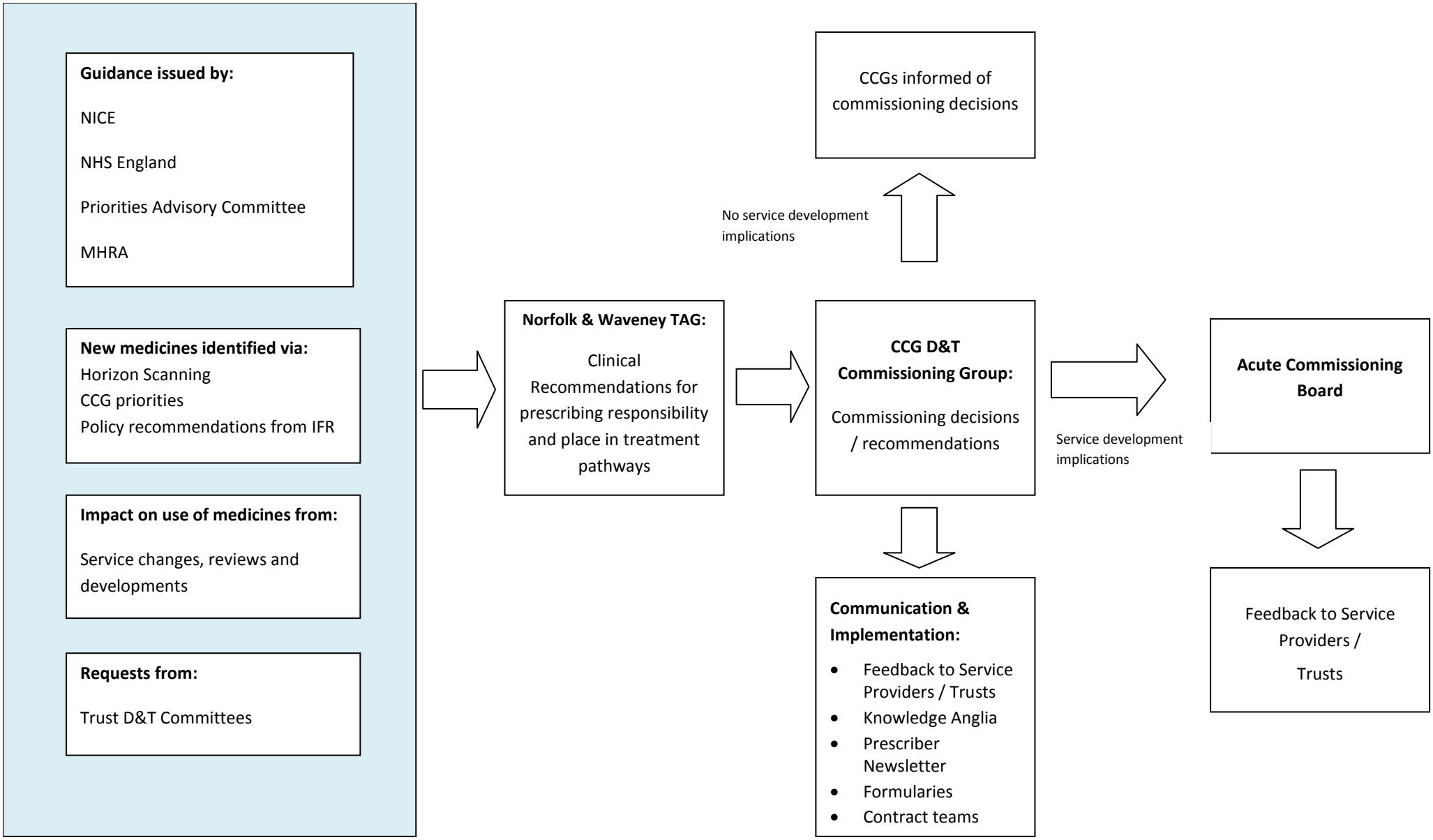
Most recommendations made through the Therapeutics Advisory Group can be implemented through small changes in clinical and administrative practice.

Recommendations for GPs are disseminated and supported by the commissioned Prescribing & Medicines Management service. Clinical recommendations affecting hospital Trust staff can usually be taken forward by Trust-based Drug and Therapeutics Committees and considered by usual internal mechanisms.

However, some recommendations will need to be handled through more complex commissioning arrangements - particularly those medicines which are excluded from Tariff where service developments are required. It is possible that some recommendations may not be implemented due to competing priorities.

The final outcome of TAG recommendations is determined by commissioning decisions ultimately made by the CCG Boards, via the Drugs and Therapeutics Commissioning Group (DTCG).

The TAG will receive reports on the implementation and prescribing outcomes of its recommendations for consideration, and report to DTCG where practice continues to differ from recommendations.


Guidance issued by:
NICE
NHS England
Priorities Advisory Committee
MHRA
New medicines identified via:
Horizon Scanning
CCG priorities
Policy recommendations from IFR
Impact on use of medicines from:
Service changes, reviews and developments
Requests from:
Trust D&T Committees
Norfolk & Waveney TAG:
Clinical Recommendations for prescribing responsibility and place in treatment pathways
CCGs informed of commissioning decisions
No service development implications
CCG D&T Commissioning Group:
Commissioning decisions / recommendations
Service development implications
Acute Commissioning Board
Communication & Implementation:
Feedback to Service Providers / Trusts
Knowledge Anglia
Prescriber Newsletter
Formularies
Contract teams
Feedback to Service Providers / Trusts

9. Commissioning new medicines

9.1 The annual commissioning cycle

As part of the annual commissioning cycle of the Horizon Scanning list of new medicines and indications for the coming financial year will be produced in collaboration with all Trusts and CCGs.

Trusts will need to facilitate in the preparation of business cases to support the introduction of a new medicine or indication and where this involves a medicine under appraisal by NICE, the business case will be developed before NICE publication to expedite timely service development where needed.

The TAG will review the medicines highlighted in Horizon Scanning alongside other sources of evidence and will attempt a prioritisation based largely on the ***technical aspects*** of a medicine – such as effectiveness and cost-effectiveness and will also estimate funding requirements and where a NICE TA is expected, the likely financial impact for the Commissioners and Providers.

The CCGs' commissioning process undertakes a further level of prioritisation to take account of the affordability of the recommendations when set alongside competing proposals for development in accordance with the CCG Ethical Framework.

Additional funding for new medicines or indications may only become available for the following April - a period of up to 14 months. Medicines will not ordinarily be funded "out-of-cycle".

The Therapeutics Advisory Group and NHS Provider Trust D&T committees will continue to evaluate medicines throughout the year. This will result in a prioritised list of medicines which are deemed of value, but are not yet funded. The Therapeutics Advisory Group will periodically review the list to take account of:

- new guidance prepared for the NHS by NICE;
- newly introduced medicines or indications;
- new research information on existing or new medicines;
- new information on pricing or licensed indications;
- new information on medicine safety.

9.2 Non-tariff medicines commissioned by CCGs

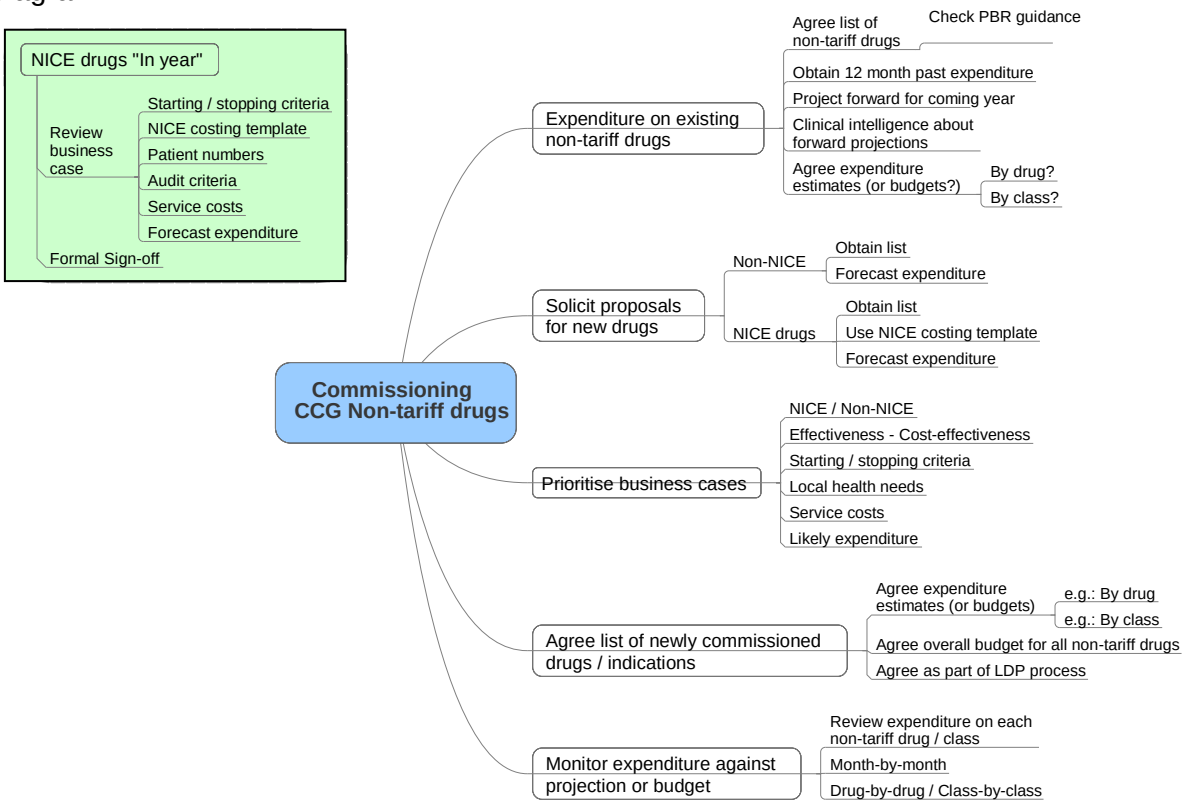
The list of “non-tariff medicines” may vary from year to year. Expenditure on this list of medicines and devices is subject to the local commissioning process.

The CCGs must agree clear implementation plans with the provider (as contained in a business case) for non-tariff medicines and in particular, they will need to be certain about the starting and stopping criteria before they commit resources. Alternative, extended or supplementary indications will not be funded without prior agreement.

The CCGs will also need to agree the appropriate associated service costs and HRGs. The CCGs may need assurance about the control mechanisms that NHS Provider Trusts establish to oversee the use of high cost medicines or devices and they will periodically expect to review audits of their use, as for example, using those audits recommended by NICE.

Where CCGs and NHS Provider Trusts have agreed an expenditure estimate for the financial year for a medicine or device, the CCGs expect NHS Provider Trusts to review the forecast expenditure with them if there is a significant variance. The CCGs may need to establish different eligibility criteria before further expenditure is committed.

The commissioning process for CCG non-tariff medicines is summarised in the following diagram:



9.3 National Institute of Care Excellence

The National Institute for Health and Care Excellence (NICE) is an independent organisation producing guidance on drugs and treatments. 'Recommended for use by NICE Technology Appraisal Guidance' refers to a type of recommendation set out in legislation. The relevant health body is obliged to fund specified NICE Technology Appraisal Guidance recommendations from a date no longer than three months from the publication of the recommendation unless, in certain limited circumstances, a longer period is specified.

Making "informed decisions" in the absence of NICE guidance

Department of Health guidance expects PCTs, and henceforward CCGs, to take informed views about new technologies in the absence of NICE guidance:

> *"If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced."*[4]

> *"**Reiterating the Message of HSC 1999/176**: It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established. … NICE does not exist to "kite mark" all the interventions which are introduced for use in the NHS. … Not all new interventions will be referred to NICE for appraisal and for those interventions that are referred to NICE there may be a time lag. … Therefore, the NHS will have to continue to make informed decisions about the use of these interventions under either circumstance."*[5]

4 HSC 1999/176

5 Good practice guidance on managing the introduction of new healthcare interventions and links to NICE technology appraisal guidance. 14 Dec 2006. Gateway Ref: 7521

10. Possible decisions on introduction

The final outcome of many TAG recommendations is determined by CCG commissioning decisions.

10.1 Double Red: Not recommended for routine use

- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their CCG if they chose to prescribe the medicine.
- NHS Provider Trust-based clinicians would not ordinarily be expected to use the medicine.
- Exceptional cases would still be considered initially via the chair of the Trust's DTC.

10.2 Red: Secondary care / Specialist use only

- Agreed criteria to determine which patients are treated and guideline for use.
- Need to agree funding arrangements: e.g. within tariff, excluded from tariff, pass-through payment.
- Could act, as a probationary period for new medicines for which there is immature or emerging data on effectiveness or cost-effectiveness. Also, for medicines for which the proven effective outcome is of uncertain or limited relevance.
- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their CCG if they chose to prescribe the medicine.

10.3 Amber: Option for Prescribing under an approved Shared Care Agreement

- Assessment and initiation by a specialist.
- Typically requires a specialist to modify or terminate treatment.
- Clinical and prescribing responsibilities are detailed in an agreed shared-care protocol.
- Suitable for a GP to prescribe ongoing treatment following an initial period of supply by the specialist as detailed in the shared-care protocol.

10.4 Green: GP prescribable at the request of Consultant/Specialist

- GPs may prescribe following recommendation by a specialist.
- Shared care protocol not required as with Amber classification.
- Hospital to supply when immediately necessary as an outpatient and on discharge, otherwise supplied by GP.

10.5 Double Green: Medicines considered to be suitable for GPs to initiate and prescribe

- GPs may take full responsibility for prescribing these medicines.

Summarised as:

Double-Red:	Not recommended for routine use
Red:	Hospital only – Drugs for which the NHS Provider Trust is responsible for prescribing. GPs should not be expected or approached to prescribe.
Amber:	Shared care following hospital initiation under agreed shared-care protocol.
Green:	Specialist recommendation, GP prescribing.
Double Green:	GP prescribing appropriate

Terms of reference

Therapeutics Advisory Group (TAG)

Accountability

- The TAG is established jointly by NHS CCGs in Norfolk and Waveney and is accountable to them.
- The TAG will report to NHS CCGs in Norfolk and Waveney on its recommendations on new medicines and indications.
- The TAG reports recommendations to relevant service development groups to assist those groups' commissioning roles.

Probity

- TAG members are expected to follow the guidance contained in "NHS England Standards of *Business Conduct (Oct 2012)"* and local policy on sponsorship http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf
- TAG members are expected abide by *"The Seven Principles of Public Life"* (Nolan Committee recommendations) attached.
- TAG members should take account of the principles described in the document *"Social Values Judgement: Principles for the development of NICE guidance"*.
- The TAG recommendations and related CCG commissioning decisions will be made publicly available through local NHS websites.
- An annual report on TAG recommendations and activities will be provided for CCG Boards.

Role

- The TAG will work within the NHS CCGs in Norfolk and Waveney 'Ethical & Commissioning Principles' Framework[6].
- The role of the TAG is to provide informed professional advice, after consideration of critically appraised evidence, to NHS CCGs in Norfolk and Waveney on the clinical and cost-effective use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc. This includes:
  - advice on the managed introduction of new medicines and indications into practice – including the most appropriate method of implementing guidance produced for the NHS by NICE;
  - advice on the transfer of prescribing responsibility across the Primary / Secondary care interface.

[6] See Appendix but also included in Individual Funding Request policy document

- The professional advice will apply to the area covered by NHS CCGs in Norfolk and Waveney.

- The TAG does not make recommendations on individual cases nor consider the application of TAG advice in individual circumstances.

- Priority will be given to issues which are of relevance to more than one NHS Provider Trust or CCG.

- The TAG has no executive authority.

- NHS CCGs in Norfolk and Waveney look to the TAG for advice to underpin their joint process for the introduction of new medicines and indications.

Process

- The TAG will consult with relevant parties when developing policies and advice.

- The TAG can solicit advice from external experts and local networks e.g. Cardiac network.

- The work of the TAG may be supported by *ad hoc* working groups.

- Advice and recommendations are agreed by a quorate TAG.

- TAG recommendations will be agreed by the development of a consensus. A small number of objections may be accepted and these should be recorded in the meeting notes.

- TAG members should be mindful to represent a body of opinion, not merely their own opinion

Membership[7]

Members are nominated by their organisations to provide informed professional advice.

NHS provider organisations are represented by a pharmacist and a senior clinician with responsibilities in medicines management – typically the Chair of a Trust's Drug and Therapeutics Committee. These organisations are encouraged to nominate deputies to attend in their absence to ensure appropriate input and balance.

[7] National Prescribing Centre Local decision-making Area Prescribing Committee (APC) Guide November 2009 http://www.npc.nhs.uk/local_decision_making/apc_guide.php

- Senior medical representative from each member organisation (local CCGs and NHS Provider Trusts)
- Consultant/Specialist in Public Health Medicine
- TAG Lead Pharmacist
- Senior pharmacist representative from each member organisation (local CCGs and NHS Provider Trusts)
- Non-Medical Prescriber representative
- Mental Health Care Trust representatives
- Local Medical Committee representative.
- Local Pharmaceutical Committee representative.
- Lay representation from Patients' Fora.
- Clinical Pharmacologist (Academic representative).

Quorum

- Seven members, or their deputies, to include the chair (or nominated deputy) and three from primary care organisations and three from secondary care organisations.

Responsibilities of TAG members

- Accept ownership of TAG recommendations.
- Undertake work as necessary between meetings.
- Promote two-way communication between the TAG and relevant NHS colleagues / organisations.
- Take specific views from the TAG back to the member organisations for comment, and then to feed back the responses to the TAG, as appropriate.
- Commit to regular attendance of TAG meetings to ensure continuity and balance of input into decision-making.
- Be an enthusiastic, motivated and active participant in the committee.
- Declare prior to each meeting any outside interests, which might have a bearing on their actions, views and involvement in discussions within the committee.

Remit

New medicines and new indications for existing medicines

1. To consider the clinical and cost-effectiveness of new medicines and indications and other matters relating to prescribing responsibility (see below).
2. To consider guidance on medicines prepared for the NHS by NICE and other national and regional advisory bodies which may impact on patients within the Norfolk and Waveney area.
3. To consider the resource implications (staff, services and financial) of new medicines and indications to the NHS Norfolk and Waveney CCGs health economies.

4. To receive and consider proposals for the use of new medicines and indications as endorsed by NHS Provider Trust-based Drug and Therapeutics Committees (focused on secondary care medicines) or as proposed through Norfolk & Waveney CCGs (focused on primary care medicines).

5. To agree an estimate of the clinical and cost-effectiveness of a new medicine or indication and the extent to which this is supported by research-based evidence.

6. To agree advice on the place of a medicine in relation to the other methods of managing the proposed indication.

7. In relation to other medicines considered by the TAG and taking into account the prevailing circumstances, including financial circumstances and national recommendations and expectations:

    - to issue advice on the appropriate use of the medicine in Norfolk and Waveney and the reasons for this view;

    - to indicate those medicines which are considered to be of highest priority for introduction in the current commissioning cycle and the reasons for this view;

    - to indicate those medicines which are not considered of sufficient priority to recommend their use in Norfolk and Waveney and the reasons for this view.

8. To review policies in the light of changed circumstances, including new research evidence and guidance from the National Institute for Health and Care Excellence and/or the Department of Health, the MHRA/CHM.

Primary–Secondary care interface

1. To consider matters which affect the clinical and prescribing responsibility of medicines by GPs and consultants/specialists, e.g. licensed and proposed indications, evidence to support use, alternatives, side-effects, monitoring requirements, follow-up by consultants/specialists, use in a clinical trial, etc.

2. To develop and update general guidance on clinical and prescribing responsibilities across the primary–secondary care interface.

3. To advise on the initial and subsequent prescribing responsibility for specific medicines and the clinical role of GPs and consultants/specialists in the supervision and monitoring of the patient.

4. To receive and consider shared-care protocols (which document the above) for adoption in Norfolk and Waveney.

5. To advocate the preferred funding mechanism to support the implementation of TAG advice.

6. To review policies in the light of experience, changed circumstances, including new research evidence and guidance from the National Institute for Health and Care Excellence and/or the Department of Health, the MHRA/CHM.

Clinical trials

1. To consider and issue advice on the clinical and prescribing responsibility of GPs who are approached to prescribe a medicine which is being used as part of a clinical trial

which may require significant investment in excess treatment costs and where the CCGs require additional clinical guidance in addition to the information considered by the D&TCG.

2. To develop general principles, but also provide advice on specific trials when not covered by the general principles.

Sponsorship

- To develop and advise the local health economy on the probity of relationships between the pharmaceutical industry and the workings of the local health economy with a particular focus on ensuring that the choice of medicines used is not adversely influenced by such relationships[8] [9].

Other issues

- In relation to the issues described above, to receive and comment on guidelines which contain therapeutic advice.

Complaints and other feedback

- Feedback on TAG recommendations should be made to the Chairman who will refer to the CSU's Prescribing & Medicines Management Team for guidance on further handling.

- The TAG will reconsider its recommendations in the light of new information, new proposals for use, alternative interpretations or changed circumstances brought to its attention by informants or complainants.

- In the absence of such changed circumstances, TAG members will have their attention drawn to feedback or complaints by the Chairman.

Dissemination of advice

1. Through the meeting notes to members of the TAG and local stakeholders.

2. Through letters stating commissioning decisions to local NHS Provider Trusts from the CCGs' Boards.

3. Through the "Norfolk & Waveney Prescriber" newsletter.

4. Through the "Traffic-light / TAG recommendations" document which is updated at least annually and usually between TAG meetings.

5. Through CCG and NHS Provider Trust intranets.

6. Through *ad hoc* communications where necessary.

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[8] DH Gateway 8926 February 2008 - "Best Practice Guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations" - http://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/dh_082569.pdf

[9] NHS England Standards of Business Conduct October 2012 (page 10 covers commercial sponsorship) - http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf

7. Through reports to relevant groups involved in service development.

8. Through contributions to guidelines produced by others.

9. In CCG strategic delivery plans when appropriate.

10. In response to queries made to CCGs.

Implementation of advice

1. Through the commissioning processes of CCGs.

2. Through processes internal to CCGs and NHS Provider Trusts (e.g., Trust-based Drug and Therapeutics Committees, CCG/CSU-facilitated prescribing committees, clinical governance processes, audits etc).

3. Through the work of NHS Anglia Commissioning Support Unit (CSU) Prescribing and Medicines Management Teams.

NICE: Social Value Judgements[10]

Summary of fundamental principles of evidence-based decision-making
The full document describes the principles NICE should follow when applying social value judgements to the processes it uses to develop guidance as well as during the development of individual forms of guidance. It is particularly concerned with the social value judgements that NICE should adopt when making decisions about effectiveness and cost effectiveness.

Principle 1
NICE should not recommend an intervention (that is, a treatment, procedure, action or programme) if there is no evidence, or not enough evidence, on which to make a clear decision. But NICE's advisory bodies may recommend the use of the intervention within a research programme if this will provide more information about its effectiveness, safety or cost.

Principle 2
Those developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them.

Principle 3
Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole.

Principle 4
NICE usually expresses the cost effectiveness of an intervention as the 'cost (in £) per quality-adjusted life year (QALY) gained.' This is based on an assessment of how much the intervention costs and how much health benefit it produces compared to an alternative. NICE should explain its reasons when it decides that an intervention with an ICER below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective.

Principle 5
Although NICE accepts that individual NHS users will expect to receive treatments to which their condition will respond, this should not impose a requirement on NICE's advisory bodies to recommend interventions that are not effective, or are not cost effective enough to provide the best value to users of the NHS as a whole.

Principle 6
NICE should consider and respond to comments it receives about its draft guidance, and make changes where appropriate. But NICE and its advisory bodies must use their own judgement to ensure that what it recommends is cost effective and takes account of the need to distribute health resources in the fairest way within society as a whole.

[10] Social Value Judgements: Principles for the development of NICE guidance, Second edition 2008 http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp

Principle 7

NICE can recommend that use of an intervention is restricted to a particular group of people within the population (for example, people under or over a certain age, or women only), but only in certain circumstances. There must be clear evidence about the increased effectiveness of the intervention in this subgroup, or other reasons relating to fairness for society as a whole, or a legal requirement to act in this way.

Principle 8

When choosing guidance topics, developing guidance and supporting those who put its guidance into practice, the Institute should actively consider reducing health inequalities including those associated with sex, age, race, disability and socioeconomic status.

The Seven Principles of Public Life

From the: *"First Report of the Committee on Standards in Public Life (Nolan Committee) CM2850-1"*

Selflessness
Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity
Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity
In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability
Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness
Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty
Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership
Holders of public office should promote and support these principles by leadership and example.

These principles apply to all aspects of public life. The Committee has set them out here for the benefit of all who serve the public in any way.