NEL Commissioning Support Unit

Issue 110 October 2015

The Norfolk & Waveney Prescriber

In this issue:

Feedback and comments on this edition to fiona.marshall3@nhs.net / 01603 257035

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Main points from MHRA Drug Safety Updates August to October 2015

- **Simeprevir with sofosbuvir: *risk of severe bradycardia and heart block when taken with amiodarone –***
  Avoid concomitant use of amiodarone with simeprevir (Olysio▼) and sofosbuvir (Sovaldi▼) combination therapy, unless other anti-arrhythmics cannot be given.

- **Pseudoephedrine and ephedrine: *update on managing risk of misuse in the UK***
  Implementation of measures to regulate sales, together with the additional voluntary actions overseen by the pharmacy profession, has made an important contribution to managing the risk of misuse of pseudoephedrine and ephedrine in the UK.

- **Proton pump inhibitors: *very low risk of subacute cutaneous lupus erythematosus***
  Proton pump inhibitors (PPIs) are associated with very infrequent cases of subacute cutaneous lupus erythematosus (SCLE), a non-scarring dermatosis that can develop in sun-exposed areas.

- **Mirabegron (Betmiga▼): *risk of severe hypertension and associated cerebrovascular and cardiac events***
  Mirabegron is now contraindicated in patients with severe uncontrolled hypertension; advice about regular monitoring is being introduced because of cases of severe hypertension.

You can subscribe to MHRA updates via
https://service.govdelivery.com/accounts/UKMHRA/subscriber/new?topic_id=UKMHRA_0044

Yellow Card scheme extended

The following can now be reported on a **Yellow Card**:

- suspected adverse drug reactions
- medical device incidents
- defective medicines
- suspected counterfeit medicines

Yellow Card app for reporting suspected side effects

A smartphone app for reporting side effects to the Yellow Card Scheme and receiving up to date information on your medicines of interest has been launched.

Reminder - Reports of diabetic ketoacidosis (DKA) with SGLT2 inhibitors

Sodium glucose co-transporter 2 (SGLT2) inhibitors are licensed for use in adults with *type 2 diabetes* to improve glycaemic control. Serious and life-threatening cases of DKA have been reported in patients taking SGLT2 inhibitors (*canagliflozin, dapagliflozin or empagliflozin*). https://www.gov.uk/drug-safety-update/sglt2-inhibitors-canagliflozin-dapagliflozin-empagliflozin-risk-of-diabetic-ketoacidosis

In several cases blood glucose levels were only moderately elevated (e.g. <14 mmol/L or 250 mg/dL), which is **atypical for DKA** and could delay diagnosis and treatment. Therefore inform patients of the signs and symptoms of DKA (e.g. nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness) and test for raised ketones in patients with these signs and symptoms.

Half of the cases occurred during the first 2 months of treatment. Some cases occurred shortly after stopping the SGLT2 inhibitor. One third of the cases involved off-label use in patients with type 1 diabetes. NB this drug class is **not licensed** for the treatment of type 1 diabetes.

The underlying mechanism for SGLT2 inhibitor-associated DKA has not been established. The MHRA is investigating this concern along with other EU medicines regulators and will communicate further advice as appropriate once the investigation is complete.

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Therapeutic Advisory Group (TAG) and D&TCG Clinical and Commissioning Recommendations – *Sept to Oct 2015*

The **TAG** and the **D**rugs **& T**herapeutics **C**ommissioning **G**roup **(D&TCG)**'s most recent recommendations on prescribing responsibility and funding decisions for medicines ***include:***

Treatments for Adults with ADHD:

Classified as Amber (Option for GP prescribing under an approved Shared Care Agreement) - the revised Shared Care document is available for use in Great Yarmouth & Waveney CCG only ***here***

Riluzole for treatment of the amyotrophic lateral sclerosis form of Motor Neurone Disease:

Classified as Amber (Option for GP prescribing under an approved Shared Care Agreement) - the revised Shared Care document is available ***here***.

The following Secondary Care-led treatments and indications were considered by the TAG and the D&TCG and classified as Red (Hospital/Specialist only):

- **Nintedanib (*Ofev*®)** for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer – as per **NICE TA 347 (July 2015)**

The following Secondary Care-led treatments and indications with NICE Guidance were considered by the TAG and the D&TCG and classified as Double Red (Not recommended for routine use):

- **Naloxegol (*Moventig*®)** for treatment of opioid-induced constipation pending the production of a local treatment pathway – as per **NICE TA 345 (July 2015)**
- **Aflibercept (*Eylea*®)** for treating diabetic macular oedema pending the provision of an application and patient pathway – as per **NICE TA 346 (July 2015)**.
- **Everolimus (*Certican*®)** for treatment for preventing organ rejection in liver transplantation – as per **NICE TA 348 (July 2015)** (review of TA 85).
- **Dexamethasone intravitreal implant (*Ozurdex*®)** for treatment of diabetic macular oedema pending the agreement on a revised local treatment pathway – as per **NICE TA 349 (July 2015)**
- **Secukinumab (*Cosentyx*®)** for treatment of moderate to severe plaque psoriasis pending the production and agreement of a Trust business case and treatment pathway – as per **NICE TA 350 (July 2015)**.
- **Cangrelor (*Kengrexal*®)** for 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 (July 2015)**
- **Vedolizumab (*Entyvio*®)** for treatment for moderately to severely active Crohn's disease after prior therapy pending the submission of a business case and treatment pathway – as per **NICE TA 352 (August 2015)**
- **Bevacizumab (*Avastin*®)** for treatment for relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer – as per **NICE TA 353 (August 2015)**
- **Edoxaban (*Lixiana*®)** for treatment and prevention of deep vein thrombosis and pulmonary embolism pending local commissioning arrangements being finalised, and agreement on a treatment pathway – as per **NICE TA 354 (August 2015)**

View the complete list for September / October 2015 here.

All **TAG recommendations**, **Shared Care Prescribing Agreements** and **GP Prescribing Guidance**, *plus* a table listing the commissioning status of drug treatments in Norfolk and Waveney, can be accessed via the TAG's webpage.

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Drugs – Price Hikes, Shortages & Discontinuations

Significant Price Increases in the Last 12 months

Prescribers may be interested to note that there have been ***significant price increases*** in certain products over the past 12 months. It would appear hard to justify such large hikes in cost. The list below includes several examples:

Product	Oct14 price	Oct 15 price	Rate of increase
Chloramphenicol 5% ear drops	£40.92 (10ml)	£57.90 (10ml)	x 1.4
Demeclocyline 150mg caps	£81.49 (28)	£160.89 (28)	x 2
Dicycloverine 10mg tabs	£67.46 (100)	£146.61	x 2
Dicycloverine 20mg tabs	£71.14 (84)	£155.09	x 2
Doxepin 50mg capsules	£48.00 (28)	**£84.00 (28)**	x 1.75
Fucithalmic eye drops 1%	£2.09 (5g)	£29.06 (now Fucidic acid eye drops 1%)	**x 14**
Gentisone HC drops	£4.76 (10ml)	£23.92 (now Genticin/hydrocortisone)	x 5
Liothyronine 20mcg	£52.46 (28)	**£198.62 (28)**	**x 3.8**
Metronidazole 200mg tabs	£1.27 (21)	£14.07 (21)	**x 11**
Nitrofurantoin 25mg/5ml susp	£195.83 (300ml)	**£260.46 (300ml)**	x 1.3
Phenindione tabs 25mg	£99.89 (28)	**£519.98 (28)**	**x 5**
Prednisolone soluble tabs 5mg	£20.44 (30)	£53.48 (30)	x 2.6

Most of these price increases are for drugs owned by AmCo Ltd.

Recently Discontinued Products – "*RIP*"*!*

Advantage Plus test strips	Suprax Paed. Susp (cefixime)
Camcolit (lithium carbonate) 250mg	Voltarol Dispersible (diclofenac)
Milupa PKU 3 Advanta	Voltarol Retard (diclofenac)
Novopen 4	Zeasorb
De-Noltab – *Astellas plans to discontinue De-Noltab from the UK market at the end of December 2015 for commercial reasons* – *link to more info*	

Department of Health Price Concessions – *October 2015*:

Contractors who have problems obtaining a Part VIII product or problems obtaining the product at the set Drug Tariff price can report the issue via the PSNC website using their online feedback form.

Generic Shortages - DoH Price Concessions for October 2015:

Drug name	Pack size	Price concession
Celiprolol 200mg tablets	28	£19.83
Cimetidine 400mg tablets	60	£6.55
Clindamycin 150mg capsules	24	£13.25
Diclofenac Sodium 50mg gastro-resistant tablets	28	£2.73
Disulfiram 200mg tablets	50	£91.73
Lamotrigine 5mg dispersible tablets sugar free	28	£8.50
Mefenamic acid 500mg tablets	28	£12.15

The price concession only applies to the month that it is granted. No additional endorsements are required for price concessions.

Cont'd

PSNC endorsing guide for NCSO/ price concessions

NCSO Endorsement Guidance and FAQs **Key things to consider:**

- The NCSO concession is granted at different times during the month - have staff considered whether the concession needs to be claimed for all products on the NCSO list?
- Does the endorsement to claim the NCSO concession include all of the necessary information? The most common omission is the dispenser's initial - any authorised staff member can add the initial, it doesn't need to be the pharmacist. The initials can be computer generated.
- If the Pricing Authority does not have a price on their system for the endorsed brand or supplier, the endorsement must also include the price paid (before discount and ex VAT). An indication of which suppliers are listed on the NHS RxS system for a particular product is available through the Dictionary of Medicines and Devices.
- The Pricing Authority will only reimburse based on an NCSO endorsement where a prescription has been **submitted in the month that the concession has been granted**. Care should be taken to ensure that prescriptions dispensed in a particular month are submitted with that month's prescription bundle.

Product shortages of significant concern reported as at October 2015:

Product (Supplier)	**Comment**
Haloperidol Injection 5mg/ml (AmCo Ltd)	Due Nov 2015 – AmCo report a delay in delivery and predict intermittent supply for next couple of months. See UKMi memo regarding managing any shortages.
Indapamide tablets 2.5mg (28) (Zentiva)	56s due end of October 2015
Lacri-lube eye ointment 3.5g (Allergan)	5g due Nov 2015; use Xailin-Night ointment
Lansoprazole 30mg capsules (28) (Teva)	Manufacturer unable to confirm
Simvastatin 20mg tablets (28) (Teva)	Due December 2015

NB: This is only a small selection. Talk to your pharmacist or Prescribing Adviser about alternatives for other products.

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Cost-effective Prescribing

Respiratory Update

Flutiform® (fluticasone propionate/ formoterol) price reduction

The NHS list price of the low and medium strengths of Flutiform® was reduced on the 1st of August 2015.

The new pricing structure for Flutiform® is as follows:

Dose	Strength	Original Price	New Price
Low	50/5mcg	£18.00	**£14.40**
Medium	125/5mcg	£29.26	**£28.00**
High	250/10mcg	£45.56	**£45.56**

For locally recommended treatment choices please refer to the NEL CSU (Anglia) Respiratory – **Asthma Formulary** on Knowledge Anglia adopted by local CCGs.

See also our latest summary of **INHALER TYPES AND DEVICES** which provides a detailed overview of all inhaled treatment devices including the latest products to hit the UK market in recent months.

Prescribing Advice:
Recommendation to prescribe inhaled treatments by Brand Name

Given the increase in number and type of respiratory inhalers now available, the therapeutic equivalence of some and also variable licensed indication or use, we would recommend, at least for the time being, that you consider prescribing inhaled respiratory treatments by BRAND.
This will ensure that your patients receive both the *intended* medication and inhaler device.

Adrenaline auto- injectors

Emerade® is now the locally recommended adrenaline auto-injector (AAI) pen for emergency treatment of anaphylaxis.

Background

The accepted optimal route of administration of adrenaline for emergency treatment of anaphylaxis is by intramuscular injection into the anterolateral aspect of the mid-thigh. This is supported by limited pharmacokinetic data demonstrating that IM adrenaline is absorbed more quickly (shorter Tmax) with a higher maximum plasma concentration (Cmax) than by the subcutaneous route. This is important for a in anaphylaxis where swift treatment decreases the risk of a fatal outcome.

Emerade® pens are the now the locally recommended AAIs of choice for the following reasons:

- Although priced at a higher unit cost, Emerade® has an overall **reduced cost** due to having a **longer shelf life** than other AAI products: **30 months** verses 18 months.
- A **higher strength** suitable for people aged >12 years is available in the product range: 150mcg, 300mcg and **500mcg**.
- A **longer (25 mm) needle** is provided in the 300 and 500mcg strengths for effective IM injection **in more patients**.
- The product design is **intuitive and easy to use**. The cap is removed from the needle end, revealing an obvious needle exit. There is no hole at the other end to cause confusion since it is easy to see where the needle emerges.

Product strengths and needle lengths are in line with the recommendations of UK Resuscitation Council's Guidelines for Healthcare Providers.

Cont'd

Emerade® has therefore been added to the local **Allergies Formulary** as follows:

3.4.3 – Allergic Emergencies

Adrenaline (Epinephrine) – local cost effective choice now **Emerade ®** 150, 300 and 500 micrograms.

Dose *by intramuscular injection*

CHILD body-weight 15-30kg: 150micrograms (but on the basis of a dose of 10 micrograms/kg, 300 micrograms may be more appropriate for some children) repeated after 5–15 minutes as necessary;

ADULT and CHILD body-weight over 30 kg: 300 micrograms repeated after 5–15 minutes as necessary.

ADULT and CHILD over 12 years at risk of severe anaphylaxis: 500 micrograms repeated after 5–15 minutes as necessary.

Emerade® product information is available via:
http://www.emerade.com/hcp/adrenaline-auto-injector

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Guidance & Policy News – *National* (1)

"NICE Bites" Bulletins – *easily digestible* summaries of NICE guidance

Following publication of a recent key NICE Guideline

- **Anaemia management in people with CKD** **NICE NG8; 2015**
the UKM*i* has developed a companion **NICE Bites Bulletin (No. 78)**, which provides a two-page summary of the full guideline.

The bulletin is available via:
http://www.medicinesresources.nhs.uk/upload/documents/Health%20In%20Focus/August2015%20Anaemia%20CKDFinal.pdf

Also, following publication of the NICE Guideline

- **Diabetes in pregnancy - management of diabetes and its complications from preconception to the postnatal period** **NICE NG3; 2015**,
the UKM*i* has developed a companion **NICE Bites Bulletin (No. 77)**, which provides a four-page summary of the full guideline.

The bulletin is available via:
http://www.medicinesresources.nhs.uk/upload/documents/Health%20In%20Focus/NICEBitesJuly2015%20Diabetes%20in%20pregnancy.pdf

Other recent NICE guidance

In September 2015 the **Therapeutics Advisory Group (TAG)** also noted:

- **NG 14 (July 2015)**
Assessment and management of melanoma in children, young people and adults
- **NG 15 (August 2015)**
Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use
This guideline 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.
- **NG 17 (August 2015)** (*Updates and replaces the sections for adults in NICE CG15*)
Type 1 diabetes in adults: diagnosis and management
This guideline contains several new recommendations for 2015.
- **NG 18 (August 2015)**
Diabetes (type 1 and type 2) in children and young people: *diagnosis and management*
This guideline covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes.
- **NG 19 (August 2015)**
Diabetic foot problems: *prevention and management*

NICE "*Do not do*" Recommendations

During the process of developing NICE guidance, NICE's advisory bodies often identify NHS clinical practices that they recommend should be discontinued completely or should not be used routinely.

This may be due to evidence that, on balance, the practice is not beneficial, or due to a lack of evidence to support continued use of the practice in the NHS.

An on-line database is available of NICE's "Do not do" recommendations from 2007 onwards.

A selection of the key NICE Do Not Do recommendations have recently been collated in a 'do not do' recommendations booklet by Nottingham Healthcare NHS Trust.

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Guidance & Policy News – *National* (2)

Malaria Prevention Guidelines

Public Health England (PHE)'s Advisory Committee on Malaria Prevention (ACMP) has recently published its **2015 Malaria Prevention guidelines** for medical professionals and other travel medicine advisors based in the UK.

The ACMP 2015 guidelines are available via https://www.gov.uk/government/publications/malaria-prevention-guidelines-for-travellers-from-the-uk.

Key changes to the 2015 guidelines include:

- updated guidance on the use of insect repellent and sun protection
- clarification on the use of hydroxychloroquine
- updated guidance on the use of anticoagulants with antimalarials
- updated guidance on the use of doxycycline in epilepsy
- changes to the country recommendations for Vietnam and Malaysian Borneo, and clarifications on the recommendations for India
- additional notes added at the beginning of the country recommendations table including information on vulnerable travellers, and new malaria maps for India and South Africa
- clarification of advice for travellers moving through areas where different antimalarials are recommended

Undertaking a stringent individual risk assessment:
The guidelines state that recommendations for antimalarials should be appropriate for the destination and tailored to the individual, whilst taking into account possible risks and benefits to the traveller.
A **full clinical history** should be obtained, detailing current medication, significant health problems and any known drug allergies. A suggested **risk assessment template** is included in the guidelines.

ACMP position on the use of mefloquine:
The ACMP currently recommends mefloquine as one of a number of antimalarials for travellers to high risk areas, following an individual risk assessment. Following review of current evidence and consideration of recommendations made by other countries, the ACMP decided that there should be no changes to existing recommendations regarding mefloquine at this time.

Conclusion:
While the focus of these guidelines is on malaria prevention, the ACMP emphasises that malaria prevention is only one aspect of pre-travel advice. A comprehensive risk assessment-based package of travel health advice should be provided to travellers ideally 6-8 weeks before they travel. Travel health advice is available from the new National Travel Health Network and Centre (NaTHNaC) website at http://travelhealthpro.org.uk/ or via the NaTHNaC advice line for health professionals on 0845 602 6712.

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Guidance & Policy News – *National* (3)

Guidance on how to manage Dental Patients who are on Anticoagulants

Colleagues in the UKMi have recently shared their advice on the above issue as follows:

New guidance from the Scottish Dental Clinical Effectiveness Programme (SDCEP) addresses the management of dental patients taking anticoagulants (including NOACs) and antiplatelets - **Management of Dental Patients Taking Anticoagulants or Antiplatelet Drugs** (August 2015).

The guidance is aimed primarily at dentists, hygienists and therapists in primary care dental practice but will also be useful for secondary care dental services, those involved in dental education, and general healthcare practitioners who manage and prescribe for these patients in primary care.

The guidance provides comprehensive background information, recommendations and practical advice.

The full guidance and supporting tools are free to download from the SDCEP website:

- **Full Guidance** – provides comprehensive background information, recommendations and practical advice
- **Quick Reference Guide** – summarises the main recommendations from the full guidance in a treatment planning **flow-chart**

Supporting tools:

A number of supporting tools are included with the full guidance to assist the dental team to implement the guidance recommendations.

- **Patient Information Leaflets:** explain to the patient the importance of advising their dental practitioner of their medication and how their dental treatment may be affected by the drugs:
  - **Warfarin and Your Dental Treatment**. Also available as a double-sided A5 leaflet
  - **Antiplatelet Drugs & Your Dental Treatment**. Also available as a double-sided A5 leaflet
  - **NOACs and Your Dental Treatment**. Also available as a double-sided A5 leaflet
- **Post-Treatment Advice Sheets for Patients:** advice sheets to which local emergency contact details can be added:
  - Post-Treatment Advice for Patients Taking Warfarin
  - Post-Treatment Advice for Patients Taking Antiplatelet Drug(s)
  - Post-Treatment Advice for Patients Taking a Novel Oral Anticoagulant (NOAC)

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Guidance & Policy News – *Local*

The following updates have recently been added to the Prescribing and Medicines Management page on Knowledge Anglia -

Update – TAG Shared Care Agreements & GP Prescribing Guidance:

- **Shared Care Agreement:** **Riluzole for treatment of the amyotrophic lateral sclerosis form of Motor Neurone Disease** **(*Review*)**
- **Shared Care Agreement:** **ADHD - treatments for adults** **(*Review*)** - GYW only

All TAG-approved prescribing guidance and Shared Care Agreements are available on Knowledge Anglia.

NHS PrescQIPP Bulletin:

Reducing medicines waste in care homes: *Information for prescribers*

The research report *"Evaluation of the Scale, Causes and Costs of Waste Medicines"*

http://discovery.ucl.ac.uk/1350234/1/Evaluation_of_NHS_Medicines_Waste__web_publication_version.pdf

highlighted the residential and care home sector as a significant contributor to medicines waste in the NHS in England, suggesting the systems and processes used in the sector account for around £50m of the estimated £300m annual total medicines waste.

Many factors can contribute to medicines waste in care homes and a ***joint effort*** involving the care homes, GPs, community pharmacies and GP practices is required. There needs to be effective systems of communication and ***appropriate training*** for staff involved in the repeat prescribing process.

The **NHS PrescQIPP Bulletin 93 | April 2015 |** - recently published on the PrescQIPP website via http://www.prescqipp.info/ - contains *Top Tips* to reduce unnecessary waste of medicines prescribed for care home residents.

The bulletin can be downloaded from http://www.prescqipp.info/resources/finish/333-care-homes-waste-reduction/1907-bulletin-93-care-homes-reducing-waste-information-for-prescribers

Prescribing Advice: Respiratory *update*

Recommendation to prescribe inhaled treatments by Brand Name

Given the increase in number and type of respiratory inhalers now available, the therapeutic equivalence of some and also variable licensed indication or use, we would recommend, at least for the time being, that you consider prescribing inhaled respiratory treatments by BRAND.
This will ensure that your patients receive both the *intended* medication and inhaler device.

Methotrexate Tablets and Blood Forms for monitoring DMARDs

Reminder to prescribe only the 2.5mg strength tablets

The Rheumatology Department at the Norfolk & Norwich Hospital has recently reported a small number of cases of patients attending clinic who have been issued with **10mg strength methotrexate tablets** in primary care rather than **2.5mg tablets** which are recommended to be used locally in order **to avoid confusion and potential overdose**.

ICE forms generated by Hospital to facilitate initial monitoring by Specialists

GPs are requested to ***use the ICE forms generated by hospital*** for patients being initiated on DMARDs, and not to raise their own forms during this period.
There have been recent clinical governance issues where hospital specialists have been unable to monitor blood results when prescribing and monitoring responsibility has still been under their care. This is especially important when DMARD medication is first started and supervised by the specialist.

Please refer also to the Norfolk & Waveney Shared Care prescribing Agreement for use of methotrexate.

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Formulary News

NEL CSU Anglia Prescribing & Medicines Management Team has been continuing the work of revising and updating local formularies, supported by NICE good practice guidance – *Developing and updating local formularies*.

Cardiovascular Formulary: *update*

BNF 2.2.3 Potassium sparing diuretics

- **Epleronone** has been included as second choice for heart failure for those patients who are intolerant to spironolactone due to hormonal side-effects.

BNF 2.3.2 Drugs for arrhythmias

- **Amiodarone** a reminder has been added from the NICE do not do recommendations – **Do not offer amiodarone for long-term rate control.**

BNF 2.4 Beta-adrenoceptor blocking drugs

- **Metoprolol,** an additional first choice. This is now included in the QEH angina pathway.

BNF 2.6.3 Other anti-anginal drugs

- **Ivabradine,** added in accordance with NICE TA 267 – an option for mild to severe stable chronic heart failure in combination with standard therapy.

BNF 2.8.2 Oral anticoagulants

- **Warfarin –** please note the 5mg tablets have been removed as a formulary choice but remain available and MAY be suitable for those patients who require a higher dose.
- **New Oral Anticoagulants (NOACs)** are now listed as preferred choice
    - **First choice – Dabigatran –** please note the additional safety information that bioavailability may be increased by 75% after a single dose when the pellets are taken without the capsule shell. Patients should be advised not to open the capsules. See Summary of Product Characteristics for full information.
    - **Second choice – Rivaroxaban**
    - **Third Choice - Apixaban** also note the addition of NICE TA 341 for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism.

Please continue to use the Therapeutics Advisory Group (TAG)-recommended pathway for Oral Anticoagulant Therapy in Atrial Fibrillation (updated Sept 2014) and the NICE New Oral Anticoagulants (NOACs): GP / Patient Decision Support Aid, Prescriber checklist before making the final decision with the patient. Patient Information links have also been added to the formularies information resources.

BNF 2.12 Lipid-regulating drugs

- **Atorvastatin** – this has been moved to first line in accordance with NICE CG 181.

Allergies Formulary: *update*

BNF 3.4.3 – Allergic Emergencies

Adrenaline (Epinephrine) – cost-effective choice is **Emerade ®** 150, 300 & 500 mcg
(*see also Report on page 6)*.

Dose *by intramuscular injection*:

CHILD body-weight 15–30 kg: 150 micrograms (however a 10 micrograms/kg dose, means that 300 micrograms may be more appropriate for some children) repeated after 5–15 minutes as necessary.

ADULT and CHILD body-weight over 30 kg: 300 micrograms repeated after 5–15 minutes as necessary.

ADULT and CHILD over 12 years at risk of severe anaphylaxis: 500 micrograms repeated after 5–15 minutes as necessary.

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Prescribing Advice – Oral treatment options for Hypomagnesaemia

What oral magnesium preparations are available in the UK and which preparation is preferred for the treatment and prevention of hypomagnesaemia?

The **UKMi** recently updated its **Q&A guidance 111.5** which aims to address the issues raised in the above question, and offers the following points of advice:

Summary

- **Magnesium-L-aspartate (*Magnaspartate*®) is the preferred choice** for the treatment and prevention of magnesium deficiency when clinically appropriate as it is the only UK **licensed** oral magnesium preparation.
- If magnesium-L-aspartate (Magnaspartate®) is not effective in raising magnesium levels or if it is poorly tolerated it is reasonable to try an alternative oral magnesium preparation, if the patient's condition allows.
- Robust evidence of the superiority of one oral magnesium preparation over another does not exist; therefore it is not possible to recommend one particular preparation over another on the basis of efficacy and safety.
- Large scale clinical outcome studies are needed to compare the different oral magnesium preparations in patients with hypomagnesaemia.
- Information from the small studies available suggests there are differences in the bioavailability of some magnesium salts.
- Factors affecting the choice of a second line preparation may include local availability, patient tolerability, and price. Examples of oral magnesium preparations which are available in the UK are given in **Table 1**.
- Caution should be exercised when switching between magnesium preparations. **Swapping on a mmol for mmol basis may not result in an equivalent therapeutic effect as magnesium preparations have differing bioavailability**. The new preparation needs to be titrated to the maximum tolerated dose with monitoring of magnesium serum levels. Tolerability of a particular preparation may limit the dosage.
- The use of sustained-release preparations (e.g. Mag-Tab SR® containing Magnesium L-lactate dihydrate) may allow the use of lower doses, which minimises the risk of diarrhoea.

Table 1

Magnesium (Mg^{2+}) salt and form	Supplier (Brand)	Licensed status in UK	Form and strength of salt (where available)	Mg^{2+} content in dosage form	
				mg	mmol
Magnesium-L-aspartate	KoRa Healthcare Ltd (Magnaspartate®)	Prescription only medicine	6.5g oral powder	243	10
	IDIS World Medicines (Magnesiocard ®)	Unlicensed medicine	Granules	121.5	5
	IDIS World Medicines (Magnesiocard®)	Unlicensed medicine	615mg tablets	60.8	2.5
Magnesium carbonate	Martindale Pharma	Unlicensed medicine	100mg capsules	25.06	1.03
			500mg capsules	125.31	5.15
	IDIS World Medicines	Unlicensed medicine	500mg capsules	144.58	5.93
Magnesium citrate	IDIS World Medicines (Magnesium Diasporal 300®)	Unlicensed medicine	1830mg granules	295.7	12
Magnesium chloride	Martindale Pharma	Unlicensed medicine	100mg/ml solution	12mg/ml	0.5 mmol/ml

Magnesium (Mg^{2+}) salt and form	Supplier (Brand)	Licensed status in UK	Form and strength of salt (where available)	Mg^{2+} content in dosage form	
				mg	mmol
Magnesium chloride	Martindale Pharma	Unlicensed medicine	200mg/ml solution	23.9mg/ml	1 mmol/ml
Magnesium Hydroxide	Omega Pharma Ltd (Phillips' Milk of Magnesia®)	Not licensed for hypomagnesaemia. Licensed as an antacid and a laxative.	83mg/ml liquid	34.59 mg/ml	1.424 mmol/ml
	Thornton and Ross Ltd	Not licensed for hypomagnesaemia. Licensed as an antacid and a laxative.	265mg/ml mixture	34.6 mg/ml	1.4 mmol/ml
Magnesium glycerophosphate *Note different strengths are available. Care must be taken to ensure the correct product is prescribed and supplied.	Special Products Limited (Maglyphos®) OR Altovida (Glysmag®) OR IDIS World Medicines	Unlicensed medicine	1g tablets or capsules*	97	4
	Special Products Limited OR Altovida (Glysmag®) OR IDIS World Medicines	Unlicensed medicine	Liquid - varying quantity of salt to give the required quantity of Mg^{2+}	24.3 mg/ ml	1 mmol/ml
	Martindale Pharma	Unlicensed medicine	Various concentrations of liquid available		
	Arjun Products Ltd (Magnaphate®)	Borderline substance	1g tablets*	97.2	4
	IDIS World Medicines	Unlicensed medicine	97.2mg capsules*	9.4	0.4
Magnesium L-lactate dehydrate	Durbin (Mag-Tab SR®)	Unlicensed medicine	Sustained release tablet	84	3.5
Magnesium oxide	Martindale Pharma	Unlicensed medicine	Made to order in strength required (e.g. Magnesium oxide 100mg capsules containing approximately 60mg magnesium (2.5mmol))		
	IDIS World Medicines	Unlicensed medicine	140mg capsules	84	3.5
			160mg capsules	96	4
Magnesium sulphate	Martindale Pharma	Unlicensed medicine	98.6mg/ml solution	9.7mg/ml	0.4 mmol/ml
			400mg/ml mixture	53.6 mg/ml	2.2 mmol/ml
			250mg/ml	39 mg/ml	1.6 mmol/ml

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Prescribing Interface – When can dentists supply medicines?

When can dentists supply medicines?

The **UKMi** recently published its **Q&A guidance 193.4** which aims to explain the legal status of medicines in the UK and when and how they may be supplied by dentists to patients.

Background:
Lack of awareness of the laws and regulations that apply to the sale and supply of medicines by dentists was highlighted following the introduction of Duraphat® toothpaste which, as a Prescription only Medicine (PoM), cannot be sold in the same way as ordinary toothpastes.

Confusion arises because dentists are bound by two sets of rules **depending on whether they are providing private or NHS services to an individual patient**. Dentists are allowed to mix private and NHS work and can provide and charge for private treatment to patients for whom they also provide NHS treatment.

This situation is different to general medical practice where medical practitioners cannot* provide private medical services to their registered NHS patients. Exemptions include travel vaccinations, malaria prophylaxis and blacklisted medicines.
**except where specifically permitted in their individual contract or laid down in their terms of service*.

Summary

- The **Human Medicines Regulations (2012)** allow dentists to supply any medicine (PoM or P) directly to a patient but only if patients are receiving **private treatment**.
- The current **NHS terms of service** do ***not*** allow dentists to supply any medicines, other than those for immediate use before the issue of a prescription, directly to a patient.
- The NHS regulations as set out in the **NHS Act 2006** do ***not*** allow dentists providing an NHS service to provide any form of pharmaceutical service.
- Prescription only Medicines issued by a dentist directly to a patient must be labelled as directed by the Human Medicines Regulations 2012.
- The Human Medicines Regulations 2012 enable dental therapists and dental hygienists to sell, supply and administer specified medicines under a **Patient Group Direction (PGD)**.
- The supply and administration of **General Sales List (GSL) medicines** is not regulated by the Human Medicines Regulations 2012 but for clinical governance purposes simple protocols are recommended.

The table below helps to put the legal framework into a practical context:

What are the legal classifications of medicines commonly used in dentistry?		
PoMs	All oral antibiotics Aciclovir tablets and suspension Betamethasone soluble tablets Duraphat toothpaste (both strengths)	Duraphat Varnish (N.B. other fluoride varnish brands may be medical devices) All dental local anaesthetics injections Diclofenac tablets (25mg, 50mg & 75mg)
P medicines	Aciclovir cream (2g, some brands GSL) Chlorhexidine dental gel (e.g. Corsodyl dental gel) Difflam mouthwash/spray Fluoride drops / Fluoride tablets	Hydrocortisone muco-adhesive buccal tablets Ibuprofen (>16 tab/cap packs) Miconazole oral gel Paracetamol (up to 32 tab/cap packs)
GSL medicines	Aciclovir cream (2g, not all brands) Chlorhexidine mouthwash (e.g. Corsodyl) Chlorhexidine oral spray	Fluoride mouthwash 0.05% (e.g. Colgate FluoriGuard, En-De-Kay Mouthrinse) Ibuprofen (up to 16 tab/cap packs) Paracetamol (up to16 tab/cap packs) Peroxyl mouthwash
Can Duraphat toothpaste be sold or supplied directly to:		
NHS patients?	**No.** Duraphat toothpaste is a prescription only medicine (POM) and a prescription must be issued except when supplied under a PGD	
Private patients?	**Yes.** Duraphat toothpaste may be supplied directly to private patients BUT only after a documented recommendation from a dentist. It must be labelled with the following ♦ the name of the person to whom the medicine is to be administered ♦ the name and address of the supplying dentist	

	♦ the date of dispensing
Patients PGD?	**Yes.** In both NHS and private dental practice Duraphat toothpaste may be issued by a hygienist or therapist (not dentists) if a valid PGD has been set up.
Can Corsodyl gel be sold or supplied directly to:	
NHS patients?	**No.** Corsodyl gel is a pharmacy medicine (P) and a prescription must be issued.
Private patients?	**Yes.** Corsodyl gel may be supplied directly to private patients BUT only after recommendation from the dentist. No additional labelling is required.
Patients under a PGD?	**Yes.** In both NHS and private dental practice Corsodyl gel may be issued by a hygienist or therapist (not dentists) if a valid PGD has been set up.
Can chlorhexidine mouthwash be sold directly to	
NHS patients?	**Yes.** Chlorhexidine mouthwash is licensed as either a General Sales List (GSL) medicine or Medical Device and can be sold to any patient without first seeing the dentist and without the requirement for further labelling.
Private patients?	
Can dentists prescribe any item in the BNF to:	
NHS patients?	**No.** On an NHS prescription form (FP10D, WP10D, GP14) dentists are restricted to prescribing items from the list approved by the Secretaries of State (Dental Practitioners' Formulary (DPF) – see the current BNF). BUT if a medicine not on the list is required, the dentist is allowed to prescribe it on a private prescription (the medicine must NOT be supplied directly to the patient).
Private patients?	**Yes.** Legally dentists can prescribe any medicine on a private prescription however, ethically dentists should restrict prescribing to areas in which they are competent (i.e. medicines that are used in dentistry).
Can NHS prescription forms be issued to private patients?	
No. If a patient is being treated as a private patient they must always be given a private prescription even if the medicine required is on the DPF list.	
Can dentists use medicines within the surgery that are not on the DPF list?	
Dentists can use any medicine within the surgery as long as they are competent in its use in dentistry, e.g. any analgesic may be given to a patient perioperatively. N.B. all local anaesthetic cartridges are PoMs but are not on the DPF list.	
If an emergency supply of analgesics or antibiotics is required, how should they be supplied?	
NHS patients	In an emergency out of hours it may be impossible for the patient to obtain the required prescribed medicine from a pharmacy as an emergency supply may be issued. The medicines must be supplied as a dispensed medicine and suitably packaged in a child resistant container, include a patient information leaflet and be labelled with the following: ♦ the name of the person to whom the medicine is to be administered ♦ the name and address of the supplying dentist ♦ the date of dispensing Plus the following, if not included on the pack issued: ♦ the name of the product ♦ the directions for use ♦ precautions relating to the use of the medicine.
Private patients	Private patients may be issued with a private prescription or supplied with the whole course of the required medicine. The medicine must be supplied as a dispensed medicine and must be suitably packaged in a child resistant container, be accompanied by a patient information leaflet and be labelled with the following: ♦ the name of the person to whom the medicine is to be administered ♦ the name and address of the supplying dentist ♦ the date of dispensing Plus the following if not included on the pack issued (manufacturers' original packs may include some (PoMs) or all (P) of these): ♦ the name of the product ♦ the directions for use ♦ precautions relating to the use of the medicine.

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Quality & Governance Issues – CQC ambitions for end of life care

The CQC's new set of principles for ensuring consistent end of life care in hospitals, care homes and in hospices

Ambitions for Palliative and End of Life Care gives details of the work that *several organisations*, including the Care Quality Commission (CQC), have agreed to do to improve local services so that people have fair access to care, based on individual needs.
http://endoflifecareambitions.org.uk/

The CQC assesses end of life care in acute hospitals to determine if the care provided is either: Outstanding, Good, Requires Improvement or Inadequate.

They also inspect and assess end of life care in community hospitals, specialist palliative care community services and community health teams.

Care Homes are not given a rating for the quality of end of life care, but as part of each inspection, CQC inspectors always ask a specific question about care in the *last days of life*.

Six ambitions for palliative and end of life care:

- Each person is seen as an individual
- Each person gets fair access to care
- Maximising comfort and wellbeing
- Care is coordinated
- All staff are prepared to care
- Each community is prepared to help

The CQC's aim is to make sure services adopt these principles, and to make sure there is continuous improvement.

Priority patient groups:

Certain groups of people are known to experience end of life care which is of poorer quality and does not always meet their needs. The CQC is therefore focusing on the following priority groups:

- People with a diagnosis other than cancer
- People aged over 75
- People with dementia
- People from Black, Asian and Minority Ethnic (BAME)
- Other groups of people who may have specific needs -
  e.g. people with mental health needs, people with learning disabilities, people who identify as LGBT, people who are homeless, prisoners, travellers and gypsies

The CQC's aim is to understand the barriers which prevent people from receiving good quality and joined-up end of life care and to identify good local practice that can be shared. They will also identify actions that need to happen nationally to address inequalities in end of life care services.

The CQC's findings are due to be published spring 2016.

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CPD – Diabetes Care – Insulin Safety Training

Joint British Diabetes Societies (JBDS) / Trend UK - free insulin safety e learning

A *free* insulin safety module is now live on the CPD Centre of the **diabetes on the net** website at http://www.diabetesonthenet.com/ .

The "**Six Steps to Insulin Safety**" module is for all Healthcare Professionals in the community and hospital setting who manage patients on insulin, with the overall aim of reducing insulin errors in clinical practice. An assessment at the end and the pass mark is set at 75% correct answers.

How does the module work?

Users access the module in the online diabetes "CPD centre" at www.cpd.diabetesonthenet.com

A log-in is required, with free registration on the site available by completing an on-line form.

The module takes approximately 60 minutes to complete.

On successful completion of a short assessment, users receive a downloadable certificate that can form an essential part of their CPD log.

Benefits of completing the module

Healthcare professionals are able to undertake essential training that could form part of their continuing professional development.
CCGs and ***Trusts*** are able to track the progress of healthcare professionals working in their area, to monitor who have accessed training in the management of patients on insulin, to a standard recognised by the **PCDS** and **TREND-UK.**

The module has been endorsed by all the JBDS, NHS England and also Diabetes UK and has been reviewed by local diabetes specialists.

Dispensing Practice

NHSBSA Info resource - Electronic Prescribing

Special edition NHS Prescription Services Hints and Tips for dispensing contractors

A special edition of NHS Prescription Services 'Hints and Tips' for dispensing contractors is now available to read on the NHS BSA website here. This issue focuses on helping dispensers to make the most of EPS, and so will be of particular interest to pharmacy contractors and dispensing appliance contractors.

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Seasonal Snippets – e-learning and resources

An interactive flu immunisation e-learning programme -

- written by Public Health England and produced by Health Education England's eLearning for Healthcare (e-LfH), is available on the **eLearning for Healthcare website** at http://www.e-lfh.org.uk/programmes/flu-immunisation/.

The programme consists of a core knowledge and accompanying assessment session, followed by knowledge and assessment sessions on the live and inactivated flu vaccines.

After completing the core knowledge session, practitioners can choose to complete one or both of the vaccine specific sessions depending on which session(s) is relevant to their role.

This programme has been made 'Open access' for everyone so that those not employed by the NHS, or eligible to register for e-LfH learning programmes, will also be able to undertake the programme if they wish to.

Training slide sets:

- for the **National Flu Programme** and for the **Childhood Flu Programme** are available at https://www.gov.uk/government/collections/annual-flu-programme along with updated **childhood flu programme Q&As** (entitled '***Information for healthcare practitioners'***).

Internet updates:

Guidance: Which flu vaccine should children have?
Updated: Poster for GPs and clinics, showing which flu vaccines children should have.
A quick reference guide to the childhood flu vaccines for winter 2015 to 2016.

Guidance: Influenza vaccine (Fluenz Tetra®): patient group direction (PGD) template
PGD template to support the national influenza (Fluenz Tetra®) vaccination programme: September 2015 to August 2016.

Guidance: Intramuscular inactivated influenza vaccine: patient group direction (PGD) template
PGD template to support the administration of intramuscular inactivated influenza vaccine in accordance with the national immunisation programme.

Guidance: Influenza: the green book, chapter 19
Updated: Clarification regarding asthma and egg allergy; updated background on the decision to extend vaccination to children, the choice of the LAIV vaccine and the benefit of quadrivalent vaccines.

This article was adapted from information shared by the East Anglia Medicines Information Service (EAMIS).

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Seasonal Snippets – Community Pharmacy Flu vaccination service

Flu vaccination via Community Pharmacies

NHS England has commissioned a flu vaccination service for patients in at risk groups through community pharmacies for the 2015-16 flu season. This service is an ***Advanced Service*** within the Community Pharmacy Contractual Framework (like MURs and NMS) which commenced from 16th September 2015.

The service is complimentary to the GP service and aims to nationally increase the uptake of flu vaccination amongst the under 65s in the at risk groups. The national target is 75% which to date has not been achieved.

The service can be provided by any community pharmacy in England that fully meets the requirements for provision of the service and has notified NHS England of their intention to begin providing the service by completing a notification form on the NHS BSA website.

Details of the nationally commissioned service can be found at:

http://psnc.org.uk/services-commissioning/advanced-services/flu-vaccination-service/
which provides links to the service requirements and associated briefing and support materials.

The PSNC has also produced a briefing in response to feedback from some Local Medical Committees.

At risk groups for influenza vaccination:

An additional at risk group has been added to the existing risk groups for 2015-16:

Morbid obesity (class III obesity)* - Adults with a Body Mass Index ≥40 kg/m²
** Many of this patient group will already be eligible due to complications of obesity that place them in another risk category*

Chapter 19 of the Green Book:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427809/Green_Book_Chapter_19_v9_0_May_2015_.PDF

Patient Group Direction (PGD):

NHS England have also reviewed and updated the Influenza PGD.
This is available via http://www.england.nhs.uk/south/wp-content/uploads/sites/6/2015/06/PGD-Flu-Adults-Multiple-Brands-v1.0-31.08.2015-BGSW.pdf .

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Antibiotic awareness resources 2015: treating your infection leaflets

Public Health England have recently published two additional leaflets for patients to support the “no antibiotic” messages.

The standard leaflet for use by GPs which mentions delayed prescriptions, is now accompanied by a version for Community Pharmacists and for Out of Hours providers.

The new leaflets are designed to be shared with patients by out of hours prescribers and community pharmacies during consultation, advising on infection self-care. The aim is to improve the patient’s confidence to self-care and the healthcare professional’s communication with the parents.

Links to the leaflets are available via the hyperlinks in the test above or via the PHE webpage: https://www.gov.uk/government/publications/antibiotic-awareness-resources-treating-your-infection-leaflets

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Hot Topic – Nutrition Resources

The **NEL CSU North Norfolk Prescribing and Medicines Management Team** recently hosted a meeting for practice Medicine Champions which included an educational session from the Community Dietetic Team.

The dieticians presented guidance to support practices when prescribing nutritional supplements for their patients. This included nutritional guidelines, and the process for referral, review and choice used when the team consider appropriate action for patients, including food supplementation.

The main message from the meeting was that **Food First** and **Food Fortification** are the preferred options rather than routinely prescribing oral nutritional supplements (ONS).

The main learning points from the session were:

- Ensure all patients receiving food supplementation have had a referral to the dietician team (ideally stagger any newly identified referrals to avoid overwhelming the service).
- Add **review criteria** to the dose or as admin note on the prescription record for when the need for food supplements may end. This information should be available within the dietician's letter, where a time frame or anticipated outcome be specified, e.g. expected increase in weight or BMI.
- The nutrition guidelines state that patients should be reviewed monthly, and that ongoing supply of ONS may not necessarily be required.
- Check that the quantity of ONS product prescribed on repeat is appropriate.
- Ensure quantity prescribed *before referral* is a maximum of 7 to 14 days and up to twice daily only (*being taken in between meals rather than instead of meals*) to avoid waste through non-compliance and palatability issues.
- Promote the use of 'Food First', 'Food Fortification' and consider OTC supplements before providing ONS on prescription as per the nutrition guidelines.
- The need for ONS in Care Homes should be minimal. There is a training budget available to assist practices - contact the dietetic team for further information via: dietitians.office@nnuh.nhs.uk)

Direct Links to Nutrition & Dietetic Resources:
Malnutrition Universal Screening Tool (MUST)

NNUH Nutrition and Dietetic Information Leaflets

NNUH Nutrition & Dietetic Resources, including information on referral, are available on Knowledge Anglia via http://nww.knowledgeanglia.nhs.uk/nutrition.htm

Local NHS Guidelines for Food Fortification and Use of Oral Nutritional Supplements in Adults:
http://nww.knowledgeanglia.nhs.uk/prescribing_nhsn/oral_nutritional_supplements.pdf

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Medicines Management News

Launch of the Journal of Medicines Optimisation (JoMO)

Pharmacy Management have just launched the first issue of a new publication
The Journal of Medicines Optimisation (JoMO)

The publication is universally available to NHS colleagues in eBook format in an easily readable style.

If you would like to have access to this publication, please first register on the JoMO website which can be found at www.jmedopt.com

Medicines Information News – UK National Poisons Information Service Number *update*

From the **5th October 2015** the *prefix code* of the telephone number for the UK National Poisons Information Service (NPIS) changed from **0844 to 0344**.

Therefore the new telephone number for the service is **0344 892 0111**.

For a transitional period callers using the previous number will be reminded of the change and their enquiries will be automatically transferred to the new number free of charge.

This forwarding service will cease on **11th January 2016**.

Users are reminded that the National Poisons Information Service is ***not*** a public access service and **this telephone number should *not* be issued to members of the public**.

TOXBASE, the online database of the NPIS, will continue to be available at www.toxbase.org for registered users.

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Health Promotion

NHS England Self Care Week's message for healthy living:

NHS staff, patients and carers are being urged to support and help raise awareness of Self Care Week next month.

The theme for the week, running from **16 to 22 November**, is **'Self Care for Life**' and aims to help people understand what they can do to better look after their own health and that of their family, as well as living as healthily as possible.

The aim for the week is for people-facing organisations such as GP surgeries, CCGs, pharmacies, dentists, local authorities and the voluntary and community sector, to use it as a focus to increase people's ability to self care and improve their levels of health literacy.

The national awareness campaign is run by the Self Care Forum. The Self Care Forum has been running its annual awareness campaign since 2011, with the ethos being to further the reach of self care and have it embedded into everybody's everyday life.

The "Self Care for Life" campaign looks at health across the spectrum, from coughs, colds and flu, to self care for long term conditions like Type 2 diabetes, heart disease and lung conditions.

The aim is to support people to help themselves, to improve quality of life for individuals but also use NHS services even more effectively. This is particularly relevant with winter approaching when A&E services and GPs face increased demands.

"Self Care for Life" aims to help raise people's awareness on how they can safely treat minor ailments such as colds or fever, and also live healthily to prevent avoidable but more serious problems with long terms conditions such as Type 2 diabetes or heart disease.

Helping people to help themselves is a two-way partnership between individuals and the NHS to provide information, tools, support and care to allow people to stay well and use health services appropriately.

http://www.england.nhs.uk/2015/09/09/self-care-week/

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New Medicines & Indications News

New Medicines and Licensed Indications in the UK August to September 2015

Items relevant to Primary Care and Secondary Care:

Capsaicin patch (*Qutenza*®)
Licence extension/variation for use in peripheral neuropathic pain in adults with diabetes

Empagliflozin + metformin (*Synjardy*®)
Type 2 diabetes mellitus in adults – second-line [new formulation]

Ethinylestradiol + drospirenone (low-dose) (*Eloine*®)
Contraception [new formulation]

Insulin glargine biosimilar (*Abasaglar*®)
Type 1 and 2 diabetes mellitus in adults and children aged two years and older

Insulin glargine U300 (*Toujeo*®)
Type 1 and 2 diabetes mellitus in adults [new formulation]

Vortioxetine (*Brintellix*®)
Major depressive disorder in adults

New items relevant to Secondary / Specialist care:

Cangrelor (*Kengrexal*®)
An IV $P2Y_{12}$ inhibitor licensed to reduce the risk of thrombotic events in patients with coronary artery disease undergoing percutaneous coronary intervention (PCI) who have not received an oral $P2Y_{12}$ inhibitor where such treatment is not feasible or desirable.

Ceritinib (*Zykadia*®)
Non-small cell lung cancer, advanced ALK-positive in adults – second-line after crizotinib

Ciclosporin (*Ikervis*®)
Severe keratitis in adults with dry eye disease, which has not improved despite treatment with tear substitutes [new formulation].

Netupitant + palonosetron (*Akynzeo*®)
Prevention of chemotherapy-induced nausea and vomiting [new formulation]

Nivolumab (*Nivolumab BMS*®)
Advanced squamous non-small cell lung cancer in adults who have previously received chemotherapy

Pembrolizumab (*Keytruda*®)
Advanced malignant melanoma in adults – monotherapy

Changes to licensed indications regarding specialist drugs:

Adalimumab (*Humira*®)
Licence extension/variation for use in active moderate-to-severe hidradenitis suppurativa

Dabrafenib (*Tafinlar*®)
Licence extension/variation for use in unresectable or metastatic melanoma in adults with a BRAF V600 mutation – in combination with trametinib.

Daclatasvir (*Daklinza*®)
Licence extension/variation for use in Hepatitis C infection, genotype 3 – shorter 12-week course in combination with sofosbuvir.

Eltrombopag (*Revolade*®)
Licence extension/variation for use in acquired severe aplastic anaemia, in adults refractory to immunosuppressants or heavily pre-treated and unsuitable for haematopoietic stem cell transplantation

Factor VIII + von Willebrand factor (*Voncento*®)
Licence extension/variation for use in prophylaxis of haemorrhage in adults with von Willebrand disease, when desmopressin alone is ineffective or contraindicated, and prophylaxis and treatments of paediatric patients

Pertuzumab (*Perjeta*®)
Licence extension/variation for use in breast cancer, HER2-positive, locally advanced, inflammatory or early stage – neoadjuvant therapy in combination with trastuzumab and chemotherapy for adults at high risk of recurrence

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