http://www.devonformularyguidance.nhs.uk/

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 27th March 2024

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Susie Harris (Chair)	Consultant Physician/Geriatrician	RDUH NHS FT
Glen Allaway	GP	NHS Devon ICB
Heidi Campbell	Pharmacist	NHS Kernow ICB
Andy Craig	GP	NHS Devon ICB
Stuart Crowe	GP	NHS Devon ICB
Jess Danielson	GP	NHS Devon ICB
Nicola Diffey	Pharmacist	Livewell Southwest
Lucy Harris	GP	NHS Devon ICB
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Alisha Kaliciak	GP	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Rebecca Lowe	Joint Formulary Technician	NHS Devon ICB
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Name	Job Title	Organisation
Dr Lucy Craven	GP Partner and BMS Menopause Specialist	Budleigh Medical Centre
Emma Gitsham	Clinical Effectiveness Pharmacist – Specialised Medicines Service (SMS) Guidelines Lead	NHS Devon
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon
Kirsty Gillies	GP extended role in women's health	Rolle Medical Centre
Stephanie Lamb	Consultant in Obstetrics and Gynaecology	UHP

Observers:

Name	Job Title	Organisation
Hui QI Tong	Trainee Pharmacist	Torbay and South Devon NHS Foundation Trust

In attendance:

Name	Job Title	Organisation
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Susie Harris explained the meeting etiquette.

Chairman's welcome

Susie Harris welcomed attendees to the meeting of the Devon Formulary Interface Group.

Apologies

NAME	JOB TITLE	ORGANISATION
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
Jess Parker	GP	NHS Devon ICB

Declarations of Interest

The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item.

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
HRT review **Transdermal oestrogens:** • Estradot patch • Oestrogel pump • Lenzetto transdermal spray **Alternative treatments:** • Sandrena gel • Various estradiol transdermal patches (including Evorel) • Femseven Conti patch **Alternative treatment:** • Evorel Conti patch **Progestogens:** • Oral micronised progesterone capsules (Gepretix; Utrogestan) • Medroxyprogesterone tablets (Provera)	 Sandoz Ltd Besins Healthcare UK Ltd Gedeon Richter UK Ltd Orion Pharma (UK) Ltd Various manufacturers; Theramex UK Ltd Theramex UK Ltd Theramex UK Ltd Exeltis UK Ltd, Besins Healthcare UK Ltd Pfizer Ltd

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Alternative treatments: • Various oestrogen/progestogen oral and transdermal HRT • Mirena	Various manufacturers Bayer PLC
Fluoroquinolone antibiotics: MHRA Drug Safety Update: • Ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin (various formulations) **Alternative treatments:** • Various antibiotics including trimethoprim, cefalexin, co-amoxiclav, doxycycline, azithromycin, ceftriaxone, cefixime, amoxicillin, metronidazole (various formulations)	Various manufacturers Various manufacturers
Deprescribing guidance for hypnotic drugs: • Benzodiazepines and Z-drugs (zopiclone, zolpidem) (various formulations) • Melatonin (various formulations)	Various manufacturers Various manufacturers
Diverticulitis update and harmonisation: • Co-amoxiclav, cefalexin, metronidazole, trimethoprim (various formulations) **Alternative treatments:** • Various antibiotics (various formulations)	Various manufacturers Various manufacturers
Epimax Oatmeal Cream: • Epimax Oatmeal Cream **Alternatives:** • AproDerm Colloidal Oat • Aveeno • Cetraben Natural Oatmeal • Cuderm • Miclaro Oat cream • Zeroveen • Other emollients	Aspire Pharma Fontus Health Johnson & Johnson Thornton & Ross Ltd Synergy Biologics Limited Penlan Healthcare Ltd Zeroderma Various manufacturers
Once-weekly oral methotrexate for patients within adult dermatology services (Devon wide): • Methotrexate tablets	Various manufacturers
Drug Safety Update: • Isotretinoin • Roaccutane **Alternative treatments:** • Various topical products and antibiotics	Various manufacturers Roche Products Ltd Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Drug Safety Update: • Valproate containing medicines **Alternative treatments:** • Various anti-epileptics, various antipsychotics	Various manufacturers Various manufacturers

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Direct-acting oral anticoagulants (DOACs): 2024 update to NHS England commissioning recommendations: • Edoxaban (Lixiana) • Rivaroxaban (Xarelto) • Apixaban (Eliquis) • Apixaban generic • Dabigatran (Pradaxa)	 Daiichi Sankyo UK Limited Bayer plc Bristol-Myers Squibb-Pfizer Various manufacturers Boehringer Ingelheim Limited

Name	Job Title	Declaration
Dr Jess Danielson	GP	I am a BMS menopause specialist and proposed addition of micronised progesterone and a greater range of transdermal oestrogens to the FIG in writing in 2022. I am working with the ICB commissioning team in the design of a NHS menopause service. I received placebo Lenzetto devices from Gedeon Richter and Oestrogel devices from Besins in February 2024 at my request, for use in patient and clinician education. I have received no funding or training from these firms.
Rebecca Lowe	Joint Formulary Pharmacy Technician	I have secondary employment at Channings Wood.
Kirsty Gillies	GP Partner	Work as menopause specialist.
Stephanie Lamb	Consultant in Obstetrics and	Declaration – the same a previously sent: I chair the Peninsula early pregnancy and emergency gynaecology meetings. James Harrison, key account manager for Gedeon Richter UK, sponsored the Peninsula EPU/EGU meeting November 2023. He discussed Ryeqo for the treatment of fibroids. April Rosson, National Key Account Manager for Besins Healthcare, sponsored the Peninsula EPU/EGU meeting November 2022. She discussed Dimetrum for the treatment of endometriosis.

2. Minutes of the meeting held on Wednesday 7th February 2024 and Actions/Matters Arising

Minutes of the meeting held on Wednesday 7th February 2024

The minutes of the meeting held on Wednesday 7th February 2024 were approved.

Action Log

The Action Log was reviewed and updated.

3. Recent Drug Decisions

The FIG received a report of the recent drug decisions.

4. Report of e-FIG decisions

February 2024

In February 2024 the FIG was asked to consider one item via the e-FIG process:

- Direct-acting oral anticoagulation (DOACs): 2024 update to NHS England commissioning recommendations.

The proposal was accepted, and the relevant information has been published on the Devon Formulary.

5. Terms of Reference

An updated ToR was received by the group.

Updates had been made to the membership and quoracy of the group as follows:

- The number of GP members on the group has increased from six to eight.
- The number of GPs required for quoracy of a meeting has increased from three to four.

It was noted that the new GP member may have previously arranged commitments which may prevent attendance at the next few meetings. It was agreed that in order to avoid quoracy issues the updated Terms of Reference will be introduced once it has been confirmed that enough GP members can attend the meeting on a regular basis.

ACTION 24/14: Formulary Team to introduce the updated Terms of Reference once GP members' attendance over the next few months has been confirmed.

6. Membership update

Four additional GP members have been appointed to the FIG:

- Dr Stuart Crowe, Mayfield Medical Centre, Paignton
- Dr Jess Danielson, Wooda Surgery, Bideford
- Dr Lucy Harris, Buckland Surgery, Newton Abbot
- Dr Alisha Kaliciak, formerly Castle Gardens Surgery, Torrington now locum in North Devon.

The FIG welcomed the new GP members.

7. Hormone Replacement Therapy (HRT) for menopausal symptoms

Applications for changes to the formulary recommended products for Hormone Replacement Therapy (HRT) for menopausal symptoms were discussed at the February FIG meeting. However due to the late circulation of the papers and the range of proposals, only limited decision making was possible.

A GP from Budleigh Medical Centre and a Consultant in Obstetrics and Gynaecology from UHP attended the meeting for this discussion. Additional comments received from Dr Jess Parker (FIG GP member who had given apologies) were presented to the FIG.

In February, the FIG agreed to the removal of conjugated equine oestrogens (CEE) and Premique modified release (CEE 300mcg/medroxyprogesterone 1.5mg) tablets from the formulary on the basis of their significantly increased cost in comparison to alternatives. Additional work has been undertaken with the specialists who were in attendance to further refine the remaining proposals. Proposed updates to section 6.4.1 of the formulary (specifically oral and transdermal oestrogens and progestogens) were presented to the FIG.

The output of FIG discussions will be circulated to specialists Devon-wide for consultation after the meeting. If responses from specialists suggest agreement, the formulary team will publish the updates and notify the FIG. If changes are requested the item will be brought back to the FIG via the most appropriate route.

Proposals included:

- Updated recommendations regarding the need for oestrogen plus progestogen to reflect guidance from the British Menopause Society (BMS) to consider progestogen for women who have had a subtotal hysterectomy (retaining the cervix).
- Updated recommendations regarding patients for whom the transdermal route is clinically indicated (to align with NICE CKS)
- Updated traffic light classification of some transdermal preparations as green, to reflect that they are first-line options when the transdermal route is clinically indicated.
- Addition of Estradot patches, Oestrogel pump-pack 0.06% gel, Lenzetto 1.53mg/dose spray, FemSeven Conti patches and micronised progesterone oral capsules.
- Harmonisation of formulary recommendations in respect of Evorel Sequi patches, tibolone and oral medroxyprogesterone acetate

The FIG paper considered the financial impact of the proposals, and the difficulty in providing credible estimates of the financial impact of some proposals as there is uncertainty regarding the required doses of transdermal oestrogen gel and spray. It was noted that the financial impact of

moving away from CEE as an option had the potential for significant savings, which may offset some cost increases. The FIG recognised that there was already significant non-formulary prescribing of some of the proposed options.

Estradot patches are more expensive than Evorel (current recommended estradiol patch) but may provide a useful alternative option. Local specialist opinion is that lower cost alternatives do not stick as well, are larger and crinklier, leading to poorer patient satisfaction. Estradot patches are proposed for use where the transdermal route is clinically indicated but Evorel patches are ineffective, not tolerated, or impractical.

Oestrogel is likely to be more expensive than Evorel patches but lower in cost than Estradot patches and alternative transdermal oestrogen gel / spray preparations. It is therefore proposed for use where the transdermal route is clinically indicated but Evorel patches are ineffective, not tolerated, or impractical.

Lenzetto spray is likely to cost more than Evorel or Oestrogel and as such was proposed as a third line option for use where the transdermal route is clinically indicated but patches and Oestrogel are ineffective, not tolerated, or impractical. Local specialists indicated it may be beneficial for women who do not tolerate estradiol patches or gel, and for those with skin disorders in areas that prevent them from using patches or gel (Lenzetto can be administered on the inner forearm).

FemSeven Conti patches are only marginally more expensive than Evorel Conti and are the only other licensed continuous combined HRT patch. They are applied once weekly, which may be preferable for some women (Evorel Conti, is applied twice weekly).

Micronised progesterone oral capsules are proposed for inclusion as the only licensed alternative to Mirena for use in combination with transdermal oestrogen-only HRT, in particular for women who are unable to use combination patches (due to lack of efficacy, intolerability etc.). Mirena is not suitable for all women and fitting services for Mirena may not be readily available for all women. Although more expensive per year than Mirena, oral micronised progesterone (in combination with transdermal estradiol) is likely to be cost saving compared to continuous combination HRT patches. Gepretix brand capsules were proposed as these are available at significantly lower cost compared with Utrogestan brand / generic prescribing.

The FIG accepted the proposals subject to some minor amendments pending final consultation with specialists. There was discussion about:

- Highlighting the place in therapy of the individual transdermal oestrogen products, including the possibility of producing a flow chart / visual summary.
- The comparative doses of various estradiol products, and the possibility of linking to the BMS resource “HRT - practical prescribing” which contains a helpful table.
- Linking to local 2WW CRGs for gynaecology.
- Recent shortages of Estradot; the patches can be added to the formulary once it has been confirmed that stock is readily available.
- Updated NICE guidance on the management of menopause is expected later in 2024.

ACTION 24/15 Formulary team to update section 6.4.1 (Oestrogens and Progestogens) in line with the discussion and consult with specialists.

ACTION 24/16 Formulary team to publish updates to section 6.4.1 (Oestrogens and Progestogens) if accepted by specialists, or bring back to FIG via appropriate route.

8. Fluoroquinolone antibiotics: MHRA Drug Safety Update (January 2024)

The MHRA has introduced new restrictions for systemic fluoroquinolones, in its third drug safety update on the antibiotics in the past six months. The MHRA has taken additional regulatory action to update the indications for all systemic fluoroquinolones to state they should only be used when other commonly recommended antibiotics are inappropriate, such as where:

- there is resistance to other first-line antibiotics recommended for the infection,
- other first-line antibiotics are contraindicated in an individual patient,
- other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped,
- treatment with other first-line antibiotics has failed.

Fluoroquinolones are used to treat a range of infections, including urinary tract, pyelonephritis, prostatitis, and respiratory infections. As of January 2024, the antibiotic class features in 13 NICE guidelines and 4 British Association for Sexual Health and HIV (BASHH) guidelines.

The evidence review on which the update was based has not been published, although the MHRA states that a public assessment report will be available later this year. The MHRA is working with other UK healthcare organisations to update clinical guidance to reflect the new regulatory position.

The formulary team has consulted with local specialists to understand the position of fluoroquinolones in Devon and to review the current formulary treatment guidelines in respect of fluoroquinolone use. The Devon Formulary recommends specific use of fluoroquinolones in six locally adapted management guidelines:

- First line in prostatitis (acute), pyelonephritis (acute), and catheter-associated UTI.
- Second line in chlamydia trachomatis and eradication of Helicobacter pylori.
- Specialist input in Neisseria gonorrhoea.

Early discussions with microbiology specialists suggest amendments could be made to provide alternative first line antibiotic recommendations, where appropriate, to reflect the updated restrictions from the MHRA. Where alternatives are not appropriate or fluoroquinolones are the most effective or only reliable option, a note to suggest this will also be included. In all instances where a fluoroquinolone is recommended in the Formulary, the associated MHRA Drug Safety Updates will also be included as a summary with a link to the drug pages for full detail.

Fluoroquinolones in prostatitis remain first line as many antibiotics penetrate the prostate poorly, but fluoroquinolones reach therapeutic levels in the prostate, a note to that effect is proposed.

It is proposed that fluoroquinolones are changed to second line in pyelonephritis and catheter-associated UTI, with cefalexin remaining the first line option for both indications.

Fluoroquinolones are proposed to remain second line in chlamydia and *H. pylori*, and specialist input in gonorrhoea.

NICE is assessing the impact of the regulatory restriction on guidance which includes recommendations for prescribing fluoroquinolones. The formulary team will review updates to NICE guidance and consult with specialists if required.

The FIG was asked to take a decision in principle on the proposed amendments while further feedback from microbiologists and other specialities is sought. If responses from specialists

suggest agreement the formulary team will publish the guidelines and notify the FIG. If changes are requested the paper may be brought back for further discussion via either FIG or eFIG. Additionally, when the MHRA public assessment report is published the formulary team will review the outcomes and update the FIG accordingly.

The FIG broadly accepted the proposed formulary guidelines in principle pending further consultation with specialists. This includes any changes from the MHRA public assessment report once published. There was discussion about:

- Acute verse chronic prostatitis and differentiating between them.
- It was suggested that guidance on Epididymo-orchitis would be helpful, and consideration could be given to developing formulary guidance based on BASHH guidance.
- It was requested that additional information be added about lowered seizure threshold in fluoroquinolone use.
- It was requested that reference to antibiotic use in penicillin allergy in gonorrhoea guidance be retained.

9. Deprescribing guidance for hypnotic drugs

In September 2023 the FIG accepted the inclusion of melatonin for the management of insomnia in adults over 55 years of age into the Devon formulary. To support this the FIG requested updated guidance for the management of insomnia, and deprescribing guidance for hypnotic drugs be developed.

Updated insomnia guidance was discussed by the FIG in December 2023. However, the meeting was not quorate, so the FIG was asked to take a decision via eFIG in January 2024. The guidance has been accepted for publication in the Devon formulary.

The proposed guidance for deprescribing hypnotic drugs was shared with local paediatric and adult specialists across a range of disciplines. Feedback was received from in-hospital, and community paediatric teams (including late feedback from C&FHD which was presented orally at the meeting). However, no feedback was received from any of the adult services.

The Formulary team made amendments to the proposed formulary guidance to address concerns raised by community paediatric teams regarding responsibility for ongoing review. The amended wording was presented to the FIG for consideration.

On the initial round of consultation, the Formulary team had raised a specific question to adult specialists regarding the duration of time that should pass between a first and second course of melatonin for the treatment of insomnia. However, at the time of the FIG meeting no feedback had been received from any adult services.

The FIG considered the proposed guidance. A discussion took place, the main points included:

- When considering the section of the guidance titled *"Reviewing prescriptions initiated in secondary care"* the committee highlighted the importance of clear guidance being provided by secondary care upon discharge regarding the need for drug continuation and review. Committee members highlighted that this does not always occur in practice. The FIG felt that the current guidance should be reworded to emphasise the responsibility of prescribers in secondary care to provide this information.

- The FIG accepted the remaining sections of guidance relating to the deprescribing of benzodiazepines and z-drugs in adults.
- It was agreed that the Formulary team will undertake further consultation with specialists regarding the optimal time between a first and second course of melatonin for insomnia in adults.
- The FIG discussed the mixed feedback which had been received from paediatric services. One in-hospital team had stated that the proposals were in line with current practice, however community outpatient teams stated that they did not have the capacity to provide ongoing review and deprescribing of melatonin in their patients. As such these teams felt that upon discharge responsibility for this aspect of care should transfer to the patients GP. The FIG agreed that this was not appropriate as prescribers in primary care should not be responsible for long term off-label prescribing of melatonin, alongside drug review, and deprescribing without sufficient secondary care input.
- The FIG reviewed the proposed new wording which had been developed by the formulary team relating to deprescribing melatonin in children and young people. The proposed new wording had been developed to address the concerns of the community paediatric teams. However, the FIG did not feel that this wording was acceptable as it did not address their concerns regarding the suitability of prescribers in primary care to take sole responsibility for review and deprescribing of melatonin in children and young people whose treatment had been initiated by specialist teams.
- The FIG also discussed that there can be difficulties with the transition from child to adult services. Problems may arise if GPs are asked to prescribe and then stop medication previously prescribed by specialists unless the initiating specialist has already had a conversation with the patient and/or carer regarding treatment breaks. It was noted that this is a system issue that is not within the capacity of the formulary to solve.
- The FIG asked that the issues of ongoing specialist clinical oversight and transition from paediatrics to adult services be escalated within the system. The section on deprescribing melatonin in children and young people will be removed from the guidance at this time.
- Following review of the deprescribing guidance the FIG agreed to publish the insomnia guidance and melatonin entry.

ACTION 24/17: Formulary team to publish the updated insomnia guidance and melatonin entry.

ACTION 24/18 Formulary team to update the deprescribing guidance in line with the discussion, consult with specialists and circulate via eFIG

ACTION 24/19: Formulary Team to the relevant commissioners the issue of specialist oversight / review of patients prescribed melatonin and transition from paediatric to adult services.

10. Diverticulitis update and harmonisation

Due to time constraints and specialist feedback being awaited, discussion of this item was deferred to a future meeting.

11. Epimax Oatmeal Cream

Epimax Oatmeal Cream has been proposed by the NHS Devon Medicines Optimisation team, as a lower cost blue (second line) option, for patients who may prefer an emollient cream containing colloidal oatmeal. It is proposed that Zeroveen oatmeal cream is removed in favour of Epimax Oatmeal Cream on the basis of acquisition cost. Epimax Oatmeal Cream is available at a lower cost per gram than Zeroveen oatmeal cream, and based on current prescribing in Devon, if all patients currently prescribed Zeroveen and non-formulary oatmeal cream options were switched to Epimax Oatmeal, annual savings would be in the region of £60,000.

Specialist consultation was in support of the proposal, though it was noted that only one respondent was a consultant dermatologist, with the majority of respondents from the Devon Wound Formulary Group (DWFG), including tissue viability and nurse specialists.

A discussion took place, the following points were noted:

- The level of potential savings.
- Likely availability of stock in community pharmacy.

The FIG considered and accepted:

- The inclusion of Epimax Oatmeal Cream as a blue, second line option in the Devon Formulary.
- The removal of Zeroveen oatmeal cream from the Devon Formulary.

ACTION 24/20: Formulary team to update the Devon Formulary in line with the discussion on Epimax Oatmeal.

12. LimbO Waterproof Protectors

A verbal report was submitted. LimbO Waterproof Limb Protectors have been proposed for inclusion in all sizes as green (first line) options, as they offer wider variety available for FP10 prescriptions, NHS Supply Chain, and patient self-purchasing than current options. It is proposed that SEAL-TIGHT Original Cast and Bandage Protectors [all sizes] are removed from the formulary (currently a green (first line) option listed in North & East Devon only).

ePACT2 data from January ’23 to December ’23 suggests around 1,400 wound protectors were dispensed in Devon at a cost of around £17,000. LimbO Waterproof Limb Protectors are nine pence more expensive per item than SEAL-TIGHT (£10.74 vs £10.63). However, primary care expenditure is unlikely to increase significantly as a result of the proposal, as most prescribing (~83%) is already for LimbO. If all wound protectors dispensed in primary care were to be for the proposed LimbO product, it would represent an increase in costs of less than £150 per annum.

The FIG was asked if it wished to see a summary paper for these products in line with the new proportional approach to wound product applications agreed in September 2023. A discussion took place, it was agreed that:

- A summary paper was not necessary.
- The proposed inclusion of LimbO Waterproof Limb Protectors in all sizes as green (first line) options was accepted.
- The proposal to remove all sizes of the SEAL-TIGHT Original Cast and Bandage Protectors from the North & East Devon presentation of the Devon Formulary was accepted.

ACTION 24/21: Formulary Team to update the Devon Formulary in line with the discussion on LimbO Waterproof Protectors.

13. Once-weekly oral methotrexate for patients within adult dermatology service (Devon wide)

There are three shared care guidelines in place in Devon, which support the continued prescribing of oral methotrexate in primary care for the management of dermatology conditions in adults. These have been reviewed and combined into a single Devon wide document.

The SMS guideline has been developed by the Clinical Effectiveness Team using recognised national reference resources and professional guidelines alongside consultation with local dermatology specialists. The guideline is intended for use in accordance with locally commissioned services.

The guidance has been developed with a focus on moving from monthly to three monthly blood monitoring in primary care for most patients in south and west Devon, as is already the case in north and east Devon. Guidance on the management of several adverse effects, signs and symptoms has been included and some updates have been made to align the format and general content with other recently agreed guidelines for consistency.

Local specialists and the Devon LMC had been consulted and had provided feedback.

The FIG was asked if the guidance was clear and easy to follow, whether the clinicians' responsibilities were acceptable and if it accepted the Devon wide implementation of the guidelines.

The FIG considered and accepted without amendment the SMS guideline supporting the continued prescribing of oral methotrexate in primary care for the management of dermatology conditions in adults. There was discussion about how GPs can access the relevant specialist for advice when needed.

ACTION 24/22: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to submit the oral methotrexate for adult dermatology guideline to LMC for negotiation of remuneration with the ICB primary care team.

ACTION 24/23: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to publish to updated oral methotrexate for adult dermatology guideline following negotiation of remuneration with LMC.

14. MHRA Drug Safety updates

February 2024

Drug Safety Update issued 20th February 2024

Codeine linctus (codeine oral solutions: reclassification to prescription-only medicine. Codeine linctus is not listed in the Devon Formulary.

Pseudoephedrine: very rare risk of posterior reversible encephalopathy syndrome (PRES) and reversible encephalopathy syndrome (RES) and reversible cerebral vasoconstriction (RCVS). A weblink to the article will be included in the formulary entry for pseudoephedrine.

ACTION 24/24: Formulary team to add a weblink to the MHRA Drug Safety Update article to the pseudoephedrine drug entry.

Letters sent to healthcare professionals and drug alerts in January 2024

Oral valproate-containing medicines: Restriction of indication for male and female patients aged under 55 years; use revised educational materials

This direct healthcare professional communication sent by Sanofi UK on behalf of the Marketing Authorisation Holders of the valproate-containing medicine has been reviewed. The new safety measures for valproate were addressed in an appendix to this paper.

Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000 mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors

The increased risk of atrial fibrillation in patients treated with omega-3-acid ethyl ester medicines was the subject of a Drug Safety Update article published in January 2024. This article was reviewed for the February 2024 FIG meeting.

Exkivity (mobocertinib) 40 mg hard capsules – Conditional Marketing Authorisation Withdrawal

Mobocertinib was included in the Devon Formulary as a red (hospital) option for the treatment of lung cancer in line with NICE TA855. The company has withdrawn the licence for mobocertinib. As a result, NICE has withdrawn TA855 and mobocertinib has been **removed** from the Devon Formulary.

ADAKVEO (crizanlizumab): revocation of UK marketing authorisation due to lack of therapeutic efficacy as determined by MHRA

Crizanlizumab was included in the Devon Formulary as a red (hospital) option for the treatment of sickle cell crises in line with NICE TA743. The MHRA has revoked the licence for crizanlizumab. As a result, NICE has withdrawn TA743 and crizanlizumab has been **removed** from the Devon Formulary.

Isotretinoin: Introduction of new safety measures (Drug Safety Update, October 2023)

Isotretinoin is a red (hospital-only) option in the Devon Formulary. The current formulary entry is in line with previous national recommendations and guidance from the British Association of Dermatologists (BAD) guidance which stated that isotretinoin may only be prescribed from the dermatology department under the supervision of a consultant dermatologist.

The new safety measures include additional oversight of the initiation of isotretinoin in patients under 18 years and strengthened assessment and monitoring of mental health and sexual function.

Guidance to support the safe implementation of the new regulatory position was developed by the CHM Isotretinoin Implementation Advisory Expert Working Group and published in the working group's report, which includes the treatment pathway.

At the February FIG 2024 meeting, the Formulary team highlighted the extensive package of additional supporting documents developed by the BAD and the British Dermatology Nursing Group (BDNG). The FIG discussed that nationally produced referral forms and guidance on steps to take pre-referral are not necessarily appropriate for GPs, as a GP will refer a patient for a specialist opinion on the management of acne and not specifically for the initiation of isotretinoin. Prescribing of isotretinoin will continue to be a specialist responsibility. It was agreed that the Formulary team would develop an extended formulary entry for isotretinoin. The 2023 safety measures supersede several previous Drug Safety Update articles with advice for healthcare professionals. Superseded Drug Safety Update articles will be removed from formulary guidance sections.

Discussions on the new safety measures for isotretinoin are ongoing at system level.

A draft update to the formulary entry for isotretinoin was presented to the FIG for review and the FIG asked if the proposed update is clear and acceptable.

The FIG considered and accepted the update to the formulary entry for isotretinoin without amendment.

ACTION 24/25: Formulary team to publish the accepted update to the formulary entry for isotretinoin.

Oral valproate-containing medicines: Introduction of new safety measures (NPSA November 2023, Drug Safety Update January 2024)

The MHRA issued a National Patient Safety Alert (NPSA) for oral valproate medicines on 23 November 2023. New safety materials for valproate medicines were included in the January 2024 Drug Safety Update. In addition, clinical guidance to support the new safety measures has been issued by professional societies.

NICE issued an update to CG185 guidance 'Bipolar disorder: assessment and management' on 21 December 2023 to amend recommendations in line with latest MHRA guidance on the use of valproate. The webpage for NICE guidance NG217 'Epilepsies in children, young people and adults' indicates the MHRA recommendations are being reviewed and an updated guidance will be available in early 2024.

An ICB/system group has been set up to implement the new safety measures for valproate in Devon, as recommended by the NPSA. A Formulary team member has joined the ICB/system group and attended the first meeting. Further information on the system-wide approach was provided by the Medicines Optimisation team formulary representative at the February 2024 meeting.

The Formulary team has developed a new formulary webpage on the safety measures for oral valproate-containing medicines. Superseded Drug Safety Update articles will be removed from formulary guidance sections. The draft new webpage will be shared with the specialist members of ICB/system group for review following the FIG discussion.

A draft new formulary page on the safety measures for oral valproate-containing medicines was presented to the FIG. The formulary entries for sodium valproate and valproic acid listing the formulary product options will remain.

The FIG was asked if the webpage is clear and acceptable and if there is any information which it would be helpful to include on the new webpage.

The FIG considered and accepted the proposed formulary page for valproate without amendment.

The consultation will be undertaken via the system Medicines Safety Officer (MSO) valproate group. Following the consultation, the formulary team will bring the valproate page back to the FIG via an appropriate route if required, or if the MSO group is in agreement, will publish the update.

ACTION 24/26: Formulary team to consult on the proposed formulary page on valproate safety measures with the MSO valproate group.

ACTION 24/27: Formulary team to publish the accepted formulary page on valproate safety measures, if the MSO valproate group is in agreement.

Actions Log

Outstanding and new actions have been moved to a separate action log.
