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

# Meeting of the Devon Formulary Interface Group

## Minutes

## Wednesday 25 January 2023

## Via Microsoft Teams

### Present:

| Name | Job Title | Organisation |
|---|---|---|
| Tawfique Daneshmend (Chair) | Consultant Gastroenterologist | RDUH NHS FT |
| Glen Allaway | GP | NHS Devon ICB |
| Ailene Barclay | Pharmacist | UHP NHS Trust |
| Heidi Campbell | Pharmacist | NHS Kernow ICB |
| Andy Craig | GP | NHS Devon ICB |
| Matt Howard | Clinical Evidence Manager | NHS Devon ICB |
| Nick Keysell | GP | NHS Devon ICB |
| Carole Knight | Medicines Information Pharmacist | RDUH NHS FT |
| James Leavy | Medicines Information Pharmacist | RDUH NHS FT |
| Rebecca Lowe | Joint Formulary Technician | NHS Devon ICB |
| Sarah Marner | Senior MO Pharmacist | NHS Devon ICB |
| Jess Parker | GP | NHS Devon ICB |
| Hilary Pearce | Clinical Effectiveness Pharmacist | NHS Devon ICB |
| Graham Simpole | Medicines Optimisation Pharmacist | NHS Devon ICB |
| Larissa Sullivan | Pharmacist | T&SD NHS FT |
| Darren Wright | Joint Formulary Specialist Pharmacy Technician | NHS Devon ICB |

### Guests:

| | | |
|---|---|---|
| Amy Rice | Clinical Effectiveness Pharmacist (Commissioning Projects Lead) | NHS Devon ICB |
| Deborah Reeves | Senior Clinical Pharmacist | DPT NHS Trust |

### Observers:

| | | |
|---|---|---|
| Sarah Barrett | Senior MO Pharmacist | NHS Devon ICB |
| Selina Lourgouilloux | MO Pharmacist | NHS Devon ICB |
| Sharon Stone | Pharmacy Governance and Formulary Technician | UHP NHS Trust |

### In attendance:

| | | |
|---|---|---|
| Fiona Dyroff | Clinical Effectiveness Governance Support Officer | NHS Devon ICB |

## 1. Welcome and announcements

### Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

### Chairman's welcome

Tawfique Daneshmend 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 |
| Chris Sullivan | Deputy Chief Pharmacist | Devon Partnership NHS Trust |

Subsequent to the start of the meeting apologies were received from:

| | | |
|---|---|---|
| Nicola Diffey | Pharmacist | Livewell Southwest |

Tawfique Daneshmend announced that he was stepping down as Chair of the Devon Formulary Group.

The group thanked Dr Daneshmend for all his hard work, help and support in developing the Devon Formulary over the last 25 years. Dr Daneshmend's contribution included being instrumental in the development of the first Exeter, East and Mid Devon Formulary, chairing both the North and East Devon Formulary Interface Group, and subsequently the Devon Formulary Group which brought together the two predecessor groups (namely the North & East and South & West Devon Formulary Interface Groups).

### 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 |
|---|---|
| **Guanfacine** (Intuniv) **for the management of ADHD in children and adolescents** | Takeda UK Ltd |
| Alternative treatments: | |
| Dexamfetamine | Various manufacturers |
| Lisdexamfetamine (Elvanse, Elvanse Adult) | Takeda UK Ltd |
| Methylphenidate, Atomoxetine | Various manufacturers |

| DRUG TO BE CONSIDERED | PHARMACEUTICAL COMPANY/ MANUFACTURER |
|---|---|
| **Hyperhidrosis management and the use of systemic oral anticholinergic drugs**<br>(propantheline bromide and oxybutynin) | |
| Propantheline bromide | Kyowa Kirin Ltd |
| Oxybutynin | Various manufacturers |
| Glycopyrronium bromide | Various manufacturers |
| Aluminium chloride hexahydrate | Dermal laboratories Ltd/GlaxoSmithKline Consumer Healthcare |
| Botulinum toxin A (Botox, Dysport, Xeomin) | AbbeVie Ltd, Ipsen Ltd, Merz Pharma UK Ltd |
| **Osteoporosis** | |
| Various medicines including oral and intravenous bisphosphonates and biosimilar teriparatide | Various manufacturers |
| Denosumab (Prolia) | Amgen Ltd |
| Romosuzumab (Evenity) | UCB Pharma Ltd |
| **4.10.2 Nicotine Dependence**<br>**Smoking cessation and nicotine replacement therapy (NRT)** | |
| **Long-acting nicotine replacement therapy:**<br>24-hour transdermal patches, 16-hour transdermal patches | Various manufacturers |
| **Short-acting nicotine replacement therapy:**<br>Medicated chewing gum, lozenges, sublingual tablets, inhalators, nasal sprays, oromucosal sprays | Various manufacturers |
| **Nicotinic receptor agonists:**<br>Varenicline tablets (Champix) | Pfizer (discontinued) |
| **Serotonin and noradrenaline re-uptake inhibitors:**<br>Bupropion hydrochloride modified-release tablets (Zyban) | GlaxoSmithKline UK |
| **Nicotine-containing e-cigarettes:**<br>Various e-cigarettes | Various manufacturers |
| **Luforbec 200/6 pMDI** | Lupin Healthcare (UK) Ltd |

| DRUG TO BE CONSIDERED | PHARMACEUTICAL COMPANY/ MANUFACTURER |
|---|---|
| **Alternative treatments:**<br>AirFluSal / AirFluSal Forspiro<br>DuoResp Spiromax<br>Fobumix Easyhaler, Fusacomb Easyhaler<br>Fostair / Fostair NEXThaler<br>Relvar Ellipta<br>Symbicort Turbohaler | <br>Sandoz Limited<br>Teva Pharma B.V.<br>Orion Pharma (UK) Limited<br>Chiesi Limited<br>GlaxoSmithKline UK<br>AstraZeneca UK Limited |

| | |
|---|---|
| **Immediate release melatonin tablets**<br>Adaflex tablets<br><br>**Alternative treatments:**<br>Licensed melatonin tablets / oral solution / modified-release tablets<br>Unlicensed melatonin products | <br>AGB-Pharma AB<br><br>Various manufacturers<br><br>Various manufacturers |
| **Sodium zirconium cyclosilicate (Lokelma)**<br><br>**Treatment modification:**<br>Renin-angiotensin-aldosterone system (RAAS) inhibitors**:**<br><br>ACE inhibitors (e.g. enalapril, lisinopril, ramipril etc.)<br>ARBs (e.g. candesartan, losartan, irbesartan, valsartan etc. and sacubitril / valsartan (Entresto))<br>Aldosterone antagonists / mineralocorticoid receptor antagonists (e.g. eplerenone and spironolactone)<br><br>**Alternative treatments**:<br>Patiromer calcium (Veltassa)<br><br>Calcium resonium | AstraZeneca UK Limited<br><br>Various manufacturers<br><br>Various manufacturers (including Novartis Pharmaceuticals UK Ltd for Entresto)<br><br>Various manufacturers<br><br>Vifor Fresenius Medical Care Renal Pharma UK Ltd<br><br>Sanofi |

| Name | Job Title | Declaration |
|---|---|---|
| Becki Lowe | Joint Formulary Technician | I have a second job at HMP Channings Wood. |

## 2. Minutes of the meeting held on 7th December 2022 and Actions list update

### Minutes of the meeting held on 7th December 2022

The minutes of the meeting held on 7th December 2022 were approved.

| Summary of actions | | | |
|---|---|---|---|
| | **Action** | **Lead** | **Status** |
| 21/23 | Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists. | Formulary Team | Ongoing |
| 21/24 | Thyroid disorders: Update – circulate the final draft via e-FIG for agreement. | Formulary Team | Ongoing |
| 21/54 | Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement.<br><br>*Post meeting note: RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*<br><br>25th January 2023<br><br>This will be picked up by the SMS Pharmacist as two pieces of work. | Formulary Team<br><br>SMS Pharmacist | Ongoing<br><br>Ongoing |
| 22/25 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) – Feedback to specialists on the discussion to understand the frequency of potassium monitoring required. | Formulary Team | On agenda |
| 22/26 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) look at TA599 evaluations to determine if potassium threshold of 5.5mmol/L has been considered for patients with heart failure. | Formulary Team | On agenda |
| 22/27 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) - update the proposed formulary entry and bring back to a future FIG meeting. | Formulary Team | On agenda |

| | | | |
|---|---|---|---|
| 22/48 | NICE guidance NG196 – Atrial fibrillation: consult with specialists on the anticoagulation guidance. | Formulary Team | Complete |
| 22/51 | Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – discuss the impact of the amber classification on prescribing in primary care with the Head of Medicines Optimisation. | Formulary Team | Ongoing |
| 22/52 | Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – Update Devon formulary as agreed by the Devon FIG. | Formulary Team | Ongoing |
| 22/61 | Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin. | Formulary team | Ongoing |
| 22/62 | Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group. | Formulary team | Ongoing |
| 22/64 | MHRA Drug Safety Update: July 2022 – update the formulary section on migraine, epilepsy and the topiramate entry. | Formulary Team | Complete |
| 22/65 | Asymptomatic bacteriuria screening in pregnancy – liaise with local specialists/Local Maternity Network and bring views and formulary guidance back to the FIG either via the e-FIG process or to a meeting. | Formulary Team | Ongoing |
| 22/68 | Solriamfetol for the treatment of excessive daytime sleepiness – bring SMS prescribing guideline back to the FIG via the appropriate route. | SMS pharmacist | Complete |
| 22/70 | Following further consultation with specialists bring formulary guidance for osteoporosis and drug entries back to the FIG via the appropriate route. | Formulary Team | On agenda |
| 22/74 | Potassium permanganate – notify LPC (via MOCC LPC representative) of new formulary entry for potassium permanganate when published. | Formulary Team | Complete |
| 22/75 | Schedule the formulary entry for potassium permanganate for review by the FIG at an appropriate time in the future. | Formulary Team | Complete |
| 22/76 | Remove potassium permanganate from the South & West Devon guidance for infected eczema and review formulary guidance for infected eczema and bring to FIG for discussion following specialist consultation.<br><br>***Post meeting note**: Potassium permanganate removed from South & West guidance for infected eczema (3rd Nov 2022).*<br><br>*Review NICE guidance for infected eczema and update formulary if required.* | <br><br><br><br><br><br>Formulary Team | <br><br><br><br><br>Complete<br><br>Ongoing |
| 22/77 | Liaise with Wound Management Group over alternatives to potassium permanganate for highlighting in the formulary. | Formulary Team | Complete |

| | | | |
|---|---|---|---|
| 22/80 | Pharmacological treatment for type 2 diabetes (NICE NG28): bring the formulary guidance for the pharmacological treatment of Type 2 diabetes to a future meeting. | Formulary Team | Ongoing |
| 22/82 | Stoma care: guidance and product recommendations review: bring review to a future meeting. | Formulary Team | Complete |
| 22/85 | Consideration of SyreniRing 0.120mg/0.015mg per 24 hours, vaginal delivery system: progress through a future meeting or via the e-FIG process. | Formulary Team | Complete |
| 22/87 | Formulary entries for salbutamol and terbutaline and formulary nebulisation guidance to be updated to include a link to the Drug Safety Update. | Formulary Team | Complete |
| 22/88 | Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to difference in formulations: Formulary entry for methylphenidate MR to be updated to include a weblink to the Drug Safety Update. | Formulary Team | Complete |
| 22/89 | SMS Guidelines: Methylphenidate, lisdexamfetamine and atomoxetine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Update the guidelines in line with discussion. | Formulary Team | Ongoing |
| 22/90 | Report of COVID-19 related changes to the formulary (October 2022 to December 2022 – Formulary section 16.17: End of life symptom control for patients dying of COVID-19 infections. Liaise with palliative care consultants. | Formulary Team | Complete |
| 22/91 | Report of COVID-19 related changes to the formulary (October 2022 to December 2022 – Formulary section 16.17: End of life symptom control for patients dying of COVID-19 infections. Formulary team to take down section 16.17 and relevant information from the Covid-19 update page pending consultation with palliative care consultants. | Formulary Team | Ongoing |
| 22/92 | Report of e-FIG decisions: November 2022: Treatment of vaginal candidiasis - seek the views of specialists on the use of vaginal creams which require insertion using an applicator during pregnancy and bring revised guidance back to the FIG via the appropriate route. | Formulary Team | Ongoing |
| 22/93 | Stoma Care: to feedback to Trust Stoma Teams to raise the environmental impact of stoma products with manufacturers. | Formulary Team | Complete |
| 22/94 | Stoma Care: Update the Formulary stoma care guidance and formulary entries. | Formulary Team | Complete |
| 22/95 | Just in case bags: Update the Formulary section. | Formulary Team | Complete |
| 22/96 | Continuous Glucose Monitoring: highlight the updated isCGM criteria in the formulary entry and Formulary Update communications to stakeholders. | Formulary Team | Complete |
| 22/97 | Continuous Glucose Monitoring: update the formulary entry with the accepted entry. | Formulary Team | Complete |

| | | | |
|---|---|---|---|
| 22/98 | Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients. | Formulary team | Ongoing |
| 22/99 | Add the accepted formulary entry for NICE TA832: Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroid to the Formulary. | Formulary Team | Complete |
| 22/100 | Immediate Release melatonin tablets: update the Devon Formulary with the accepted entry for Immediate Release Melatonin Tablets. | Formulary Team | On agenda |
| 22/101 | SyreniRing 0.120mg/0.015mg per 24hours, vaginal delivery system: update the formulary with the accepted formulary entry 7.3.1 Combined hormonal contraceptive (CHC) without amendment and associated sections on the contraception page. | Formulary Team | Complete |
| 22/102 | Opiodur transdermal patch: update the 4.7.2 Opioid analgesics with the accepted formulary entry. | Formulary Team | Complete |
| 22/103 | Solriamfetol for the treatment of excessive daytime sleepiness in adults: seek clarity from specialists regarding repeat blood pressure and heart rate measurements. | Formulary Team | Ongoing |
| 22/104 | Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Clarity to be sought from specialists regarding repeat blood pressure measurements. | Formulary Team | Ongoing |
| 22/105 | Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Add updated shared care agreement letters to the recently updated methylphenidate, atomoxetine and lisdexamfetamine paediatric SMS guidelines. | Formulary Team | Ongoing |
| 22/106 | Dexamfetamine 10mg and 20mg tablets to be added to the formulary. | Formulary Team | Ongoing |
| 22/107 | Dexamfetamine 5mg/5ml sugar free oral solution to be added to the formulary with supporting note. | Formulary Team | Ongoing |

## 3. Matters Arising

### New boardpack software

NHS Devon ICB has transitioned to a new board meeting software. The Formulary Team reassured FIG members that they will still receive meeting documents through the usual method and presented in a familiar format and design.

### Report of COVID-19 related changes to the formulary – Dec 2022

Since the last Devon FIG meeting (7th December 2022) the Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

A verbal update was given summarising the key changes to the UK interim commissioning policies for treatments for COVID-19. The updates to the policies were published at the end of November 2022 after meeting papers were finalised for the December FIG meeting. Updated formulary entries incorporating the changes to the UK commissioning policies will be included in the Board Pack for the meeting due to take place in March 2023. The FIG was informed that NICE is undertaking a multiple technology appraisal of therapeutics for COVID-19 which is due to be published on 29th March 2023.

### Recent Drug Decisions – Dec 2022

The FIG received a report of the recent drug decisions.

## 4. Guanfacine for the management of attention deficit hyperactivity disorder (ADHD) in children and adolescents

On the 16th November 2022, the Clinical Policy Recommendation Committee considered an application for the use of guanfacine in children and adolescents with ADHD.

Previously, the use of guanfacine for this indication was not routinely commissioned in NHS Devon. However, following consideration of more recently published evidence for efficacy, safety and cost-effectiveness, in addition to updated national guidance from NICE, the Clinical Policy Recommendation Committee recommended that the routine commissioning of guanfacine is accepted in Devon for the management of ADHD, in children and adolescents aged 6 to 17 years, where previous treatment with stimulants and previous treatment with atomoxetine, is ineffective, or not tolerated, or these treatments are not suitable.

NICE guidance for ADHD states that following titration and dose stabilisation, prescribing and monitoring of ADHD medication should be carried out under Shared Care Protocol arrangements within primary care, however there are no existing protocols in place within Devon for this drug. It is therefore proposed that guanfacine is initially added to the Devon formulary as a red drug, with all prescribing and monitoring to be completed by the relevant specialist. Once appropriate shared care arrangements are in place, this formulary position can be reviewed with potential for the drug to be listed as an amber, specialist initiated, option.

The proposal of inclusion of guanfacine as a red drug in the formulary has been discussed with local specialists. Responses received from lead representatives at each of the provider organisations indicated support for this approach.

The FIG was asked to consider whether they accept the classification of guanfacine in the Devon formulary as a red (hospital only) option to be prescribed in line with the local commissioning policy and whether they accept the proposed formulary entry.

The FIG considered and accepted the red (hospital only) classification and the proposed Formulary entry without amendment.

**ACTION: Formulary Team to add the accepted formulary entry for guanfacine for the management of ADHD in children and adolescents to the Devon Formulary.**

## 5. Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin)

The Devon Formulary Team received a request from dermatologists at all three acute providers to review the formulary content for the management of hyperhidrosis including the formulary position of two drugs, oxybutynin and propantheline bromide.

The FIG received a proposed update to the formulary content relating to the management of hyperhidrosis. This included a change in the formulary classification of oxybutynin (when used to manage hyperhidrosis) and propantheline bromide from amber (specialist initiated) to blue (second line) and for their use to be extended to cover both focal (primary) and generalised (secondary) hyperhidrosis. Specialist support for the management of hyperhidrosis, including guidance on the use of these drugs, will continue to be available through the Advice & Guidance request service. In addition, it was proposed that glycopyrronium bromide topical solution 0.05% is removed from the formulary. This product is currently included as a red (hospital) option for iontophoretic treatment of hyperhidrosis, however iontophoresis is no longer available at any of the acute providers in Devon.

Whilst oxybutynin is not licensed for the management of hyperhidrosis, efficacy has been demonstrated in small placebo controlled randomised controlled trials (RCTs) in addition to several uncontrolled observational studies. Its use is supported by guidance from NICE Clinical Knowledge Summaries (CKS), the British Association of Dermatologists, the Primary Care Dermatology Society and the BNF. Local specialists currently advise the use of oxybutynin ahead of propantheline owing to greater evidence of efficacy and lower cost.

Currently, both oxybutynin and propantheline are prescribed by GPs in Devon following advice from a dermatologist (following an Advice and Guidance request). Specialists have stated that they do not provide prescriptions in secondary care. As such this proposed change in formulary position is not expected to have a significant effect on primary care prescribing activity.

Local specialists support this change in formulary position and the proposed changes to the relevant entries in the formulary.

The FIG considered and accepted the proposed update to the formulary content for hyperhidrosis management subject to minor amendment and the reclassification and extended indication for systemic oral anticholinergic drugs (propantheline bromide and oxybutynin). It was agreed that:

- A note be included to highlight that 20% aluminium chloride hexahydrate roll on applicator is available for patients to buy over the counter.
- The Clinical Effectiveness Pharmacist will feedback to specialists that whilst higher strength (50%) aluminium hexahydrate topical products are included as an option in British Association of Dermatologists (BAD) guidance raised, no products are available in the UK.

It was agreed that the updated formulary entries will not be published until related updates to referral criteria are made to the hyperhidrosis Clinical Referral Guideline. The Clinical Effectiveness Pharmacist will liaise with Devon Referral Support Service (DRSS) regarding this. The FIG will be advised when the formulary entry had been published.

**ACTION: Proposed Formulary update to be amended in line with the discussion and published in the Formulary when CRG has been updated.**

## 6. 4.10.2 Nicotine dependence

The Devon Formulary team received a request from an Advanced Public Health practitioner (Public Health Devon) and a Senior Clinical Pharmacist from Devon Partnership NHS Trust (DPT) for a revised list of Formulary recommended nicotine replacement products.

Local Authorities (via Public Health teams) are the responsible commissioners for Smoking cessation services. In Devon, the responsibility for commissioning and funding these services lies with Devon County Council, Torbay Council, and Plymouth City Council.

A review, led by a Senior Clinical Pharmacist (DPT) in liaison with service commissioners and representatives from community smoking advisory teams has been undertaken. A draft proposed update to section 4.10.2 Nicotine dependence was presented to the FIG for initial discussion pending further consultation with the specialist providers and responsible commissioners to ensure that they support the proposals from a financial perspective.

The draft seeks to provide concise Devon-wide guidance in respect of providing or prescribing nicotine replacement therapy (NRT) or oral therapies to treat nicotine dependence. Currently all NRT products in the N&E Devon presentation of the Devon formulary are ‘green’ (first line) and in the South and West Devon presentation of the Devon Formulary all NRT products are ‘blue’ (Second line).

A Senior Clinical Pharmacist from DPT attended the meeting for discussion of this item.

The FIG considered the proposed formulary update in principle.

The discussion noted that:

- Clarity is required on whether patients should be referred to a Stop Smoking service in the first instance and what services are available.
- A CRG is in existence for Torbay and Plymouth, and information on accessing Stop Smoking services is provided for patients on the MyHealth Devon website, which is maintained by DRSS.
- Further information on the likely duration of treatment and the adverse effects of long-term use of Nicotine replacement, time scales for prescribing (including managing patient expectations), and how to assist relapsing patients would be helpful.
- Contact with patients by primary care provides opportunities to talk to patients about stopping smoking.
- a Medicines Shortage Notification for bupropion was issued in December 2022. Key points were included in the formulary entry for bupropion including that as a result of the shortage of bupropion, new patients should not be prescribed bupropion.

It was agreed that:

- Harmonisation of formulary content across Devon was accepted in principle
- Any flavour of agreed products may be included in the formulary.
- Varenicline be declassified as it has been withdrawn and it is not known when it will be available again. The entry will remain listed while the mandatory NICE Technology Appraisal (TA123) continues to positively recommend varenicline.
- Bupropion will remain 'Blue' in the formulary.

**ACTION: Formulary team to update the proposed formulary entry in line with the discussion.**

It was agreed that the Formulary team undertake additional work to clarify the availability of specialist / enhanced services and various routes of referral.

The FIG accepted the proposals subject to resolution of referral issues. Following further consultation, the proposed formulary entry will be brought back to the FIG via an appropriate route.

**ACTION: Formulary team to undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.**

## 7. Management of osteoporosis: Update

The FIG discussed a draft update to the formulary guidance for the management of osteoporosis on 17th August 2022. A consultant rheumatologist from RDUH NHS FT was present for the discussion. The draft was based on NICE guidance (CG146) 'Assessing the risk of fragility fracture' and a new clinical guideline for the prevention and treatment of osteoporosis developed by the National Osteoporosis Guideline Group (NOGG). The FIG accepted the draft proposed update to the formulary guidance in principle, subject to amendment in line with the discussion, and a further consultation with specialists.

Following further consultation, the Formulary Team amended the draft guidance in line with the discussion. The FIG considered and accepted the proposed update to the formulary guidance subject to a minor clarification. The FIG also agreed that the Formulary team seek clarity on the frequency of fracture risk reassessment for patients who do not meet the NOGG fracture risk chart threshold for pharmacological treatment.

**ACTION: Formulary team to seek clarity on the frequency of fracture risk reassessment.**

The FIG agreed that the Formulary team publish the accepted formulary guidance once the frequency of fracture risk reassessment is clarified and the CRG is in place.

**ACTION: Formulary team to publish the accepted formulary guidance once clarification on the frequency of reassessment has been received and the CRG is in place.**

## 8. Luforbec 200/6

Luforbec 200/6 is a pressurised metered dose inhaler (pMDI) containing extrafine beclomethasone dipropionate 200 micrograms and formoterol 6 micrograms. It is licensed for use in adults for regular treatment of asthma where use of a combination product (ICS/LABA) is appropriate.

The recommended dose is two inhalations twice daily. The maximum daily dose is 4 inhalations. Luforbec 200/6 should be used as maintenance therapy only. A lower strength (Luforbec 100/6) is available for maintenance and reliever therapy.

A request was received from a Senior Medicines Optimisation Pharmacist, NHS Devon ICB for inclusion of Luforbec 200/6 in the Devon Formulary for use in the management of asthma in line with its licenced indications. The request was made on the basis that it would provide consistency for patients prescribed Luforbec 100/6 who subsequently require a higher dose, and to provide a lower cost alternative to Fostair 200/6 pMDI.

It was also proposed that Fostair 200/6 pMDI is removed from the Devon Formulary, with an interim statement to recognise continued prescribing of Fostair 200/6 for existing patients, until such time as they can be reviewed and considered for a switch to Fostair NEXThaler (dry powder inhaler) or Luforbec pMDI, if clinically appropriate. This is in line with an existing statement in respect of Fostair 100/6 pMDI.

Feedback from specialists indicated that the removal of Fostair 200/6 pMDI from the Devon Formulary was acceptable. However, some concerns were raised regarding patients for whom Luforbec 200/6 may not be appropriate and those who may not use their inhalers optimally due to product changes.

The FIG considered and accepted in principle the proposed formulary entry for Luforbec 200/6 for asthma. A discussion took place, points raised included that:

- the FIG accepted, in principle, the addition of Luforbec 200/6 as an option in the Devon Formulary.
- the FIG was minded to accept the removal of Fostair 200/6 pMDI and the interim position subject to further consultation with specialists. Patients currently receiving Fostair 200/6 pMDI will be able to remain on it as a non-formulary option if they do not get on with Luforbec 200/6 pMDI.
- the cost of Fostair may change in future, however it was noted that Luforbec 100/6 pMDI has been available for over 18 months with no change in the cost of Fostair 100/6 pMDI
- If there are no objections from the second consultation with specialists, the accepted formulary entry for Luforbec 200/6 can be published without coming back to the FIG.

**ACTION: Formulary team to undertake further consultation with specialists**

**ACTION: Subject to feedback from specialists Formulary Team to publish the accepted formulary entry for Luforbec 200/6.**

## 9. Revised Formulary Entry: Melatonin

An application for the inclusion of melatonin immediate release tablets in the Devon Formulary was considered and accepted at the December 2022 FIG meeting.

At that time, separate formulary drug entries were accepted for immediate release tablets and for prolonged release tablets. This was originally proposed in an effort to provide clarity in the supported indications for each presentation (including where this was off-label), and nuance in the supporting notes.

The FIG requested several changes to the proposed formulary entries at the December meeting. The proposed entries were subsequently redrafted to include these amendments. It was apparent that there was no clear benefit to maintaining two separate drug entries; therefore, to reduce duplication of information that is applicable to both the immediate release and modified release preparations, a single entry was proposed.

The single entry was circulated to specialists for comment; comments received were incorporated into the proposed formulary entry.

The FIG considered and accepted the proposed formulary entry without amendment.

**ACTION: Formulary Team to add the accepted formulary entry for Melatonin to the Devon Formulary.**

## 10. Sodium zirconium cyclosilicate for treating hyperkalaemia: consideration of reclassification

NICE issued technology appraisal TA599 for sodium zirconium cyclosilicate on 4th September 2019, and this was included in the Devon Formulary on 22nd November 2019; in line with the requirements of the TA, sodium zirconium silicate was classified as a red (hospital only) drug.

TA599 was amended on 24th January 2022 to remove the requirement for treatment of persistent hyperkalaemia to be limited to outpatient care. The company had removed the commercial arrangement which made sodium zirconium cyclosilicate available to NHS secondary care providers at a discounted price. The list price of the medicine had been lowered, making the same (lower) price available across both primary and secondary care.

The Devon Formulary entry for sodium zirconium cyclosilicate was updated to reflect this amendment to the TA recommendations; sodium zirconium cyclosilicate remained a red formulary option. NICE TA599 recommends it as an option for treating hyperkalaemia in adults, only if used:

a) in emergency care for acute life-threatening hyperkalaemia alongside standard care or,
b) for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they:

    i. have a confirmed serum potassium level of at least 6.0 mmol/litre, and
    ii. because of hyperkalaemia are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor, and

iii. are not on dialysis

c) Stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable

Following publication of the updated NICE TA, the Formulary team received a request for sodium zirconium cyclosilicate to be reclassified from red to amber (specialist input). This request was discussed at the FIG meeting in April 2022:

- Sodium zirconium cyclosilicate in chronic heart failure – the heart failure teams indicated that initiation of sodium zirconium cyclosilicate at a potassium threshold of 5.5mmol/L was more appropriate for patients with chronic heart failure. It was agreed that the Formulary team would review NICE TA599 evaluations to determine whether a potassium threshold of 5.5mmol/L has been considered for patients with chronic heart failure.
- Sodium zirconium cyclosilicate in chronic kidney disease – it was agreed that the Formulary team would feedback the FIG discussion to the renal consultants and request further information on frequency of serum potassium monitoring for patients receiving sodium zirconium silicate.

The Formulary team reviewed the background to NICE TA599 and reported to the FIG that the NICE TA599 Committee had considered the initiation of sodium zirconium cyclosilicate at a potassium threshold of 5.5mmol/L and 6.0mmol/L for chronic heart failure but the final TA recommendation is for initiation at a threshold of 6.0mmol/L.

The FIG was asked to consider the additional feedback received from the RDUH renal service on the frequency of monitoring of potassium levels and attendance at renal clinics for patients receiving sodium zirconium cyclosilicate, and to discuss whether sufficient information is provided to support reclassification from red (hospital) to amber (specialist input) for use in chronic kidney disease.

It was noted that, if considered clinically appropriate, a final decision on the reclassification of sodium zirconium silicate cannot be taken until the potential financial impact of prescribing in primary care is discussed with the Medicines Optimisation team.

A discussion took place:

- Heart Failure - The FIG agreed that a decision would not be taken locally on the initiation of sodium zirconium cyclosilicate at a potassium threshold of 5.5mmol/L. Initiation at this threshold was considered and not recommended by the NICE TA599 committee.
- Chronic kidney disease (CKD) - it was noted that:
  - GPs will not be familiar with this drug and there is expected to be a low number of patients, so GPs are unlikely to become experienced in its use.
  - There was concern over the long-term stability of potassium levels.
  - Information is required from the UHP renal service on monitoring of patients receiving sodium zirconium cyclosilicate and the number of patients considered suitable for long-term prescribing by primary care.
  - Sodium zirconium cyclosilicate is a red (hospital) formulary option in five of the six other formularies in South West England.

The FIG was minded not to support the request for reclassification of sodium zirconium cyclosilicate and would need to have a greater understanding of the reason for the request before taking a final decision. The FIG will reconsider the request for reclassification of sodium zirconium cyclosilicate when the Formulary team has received feedback from the specialists.

**ACTION:** **Formulary team will contact the renal specialists for further feedback on the reason for requesting reclassification of sodium zirconium cyclosilicate.**

**ACTION:** **Formulary Team to liaise with heart failure teams.**

## 11. MHRA Drug Safety Updates

The two MHRA Drug safety updates issued since the last meeting of the Devon FIG were noted:

**November 2022**

**Dupilumab (Dupizent): risk of ocular adverse reactions and need for prompt management**

Dupulimab is included as a red (hospital) drug in the Devon Formulary in line with NICE technology appraisals for the treatment of moderate to severe atopic dermatitis and severe asthma. The potential for adverse reactions affecting the eye with dupilumab was established in the initial clinical trials. UK expert consensus-based guidance on the management of people with dupilumab-related ocular surface disorders is currently being developed. It is important for the patient to receive timely advice and intervention with appropriate care and management of ocular reactions, and for patients and healthcare professionals to recognise red flags for serious reactions (e.g. eye pain, visual loss) and when ophthalmological referral is necessary.

The article is also alerting prescribers of tralokinumab, a more recently licensed medicine for moderate to severe atopic dermatitis, to discuss with patients the potential for side effects affecting the eye and to ensure any reactions are managed promptly.

The formulary entries for dupilumab and tralokinumab (also a red drug) have been updated with key points from the article and a weblink to the Drug Safety Update.

**National Patient Safety Alert for Prenoxad 1mg/ml Solution for Injection**

Prenoxad is naloxone solution provided in prefilled syringes licensed for emergency use in the home or other non-medical setting by appropriate individuals or in a health facility setting for the complete or partial reversal of respiratory depression induced by natural and synthetic opioids, including methadone, and certain other opioids.

The National Patient Safety Agency (NPSA) alert relates to some batches of Prenoxad packs with missing needles. Providers are asked to contact individuals supplied with Prenoxad kits, where possible, and support checks to ensure that each kits contains two needles. The alert includes a patient information leaflet.

Prenoxad 1mg/ml Solution for Injection is included in the Devon formulary as a red (hospital) drug in South & West Devon. A weblink to the alert is included in the Prenoxad entry in the Devon Formulary. The alert will be removed after a suitable time period.

## December 2022

**Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months.**

In view of data showing ongoing exposure to valproate in pregnancy, this article reminds healthcare professionals of the risks in pregnancy and the current Pregnancy Prevention Programme requirements. The formulary guidance for epilepsy has a section on women and girls which includes details from previous Drug Safety Updates on the risks of valproate in pregnancy and the Pregnancy Prevention Programme. Information on the risk of pregnancy with valproate is also included under relevant drug entries and other sections of the formulary. The update also provides information about the potential risks of valproate in other patients following a review of the latest safety data.

In 2022, the Commission on Human Medicines (CHM) considered a review of safety data relating to valproate. This review included prescribing data showing continued use of valproate in female patients and also some use during pregnancy, as well as evolving information about potential risks in male patients. The CHM also considered the views of patients and other stakeholders on the current use of valproate and on how the risks of valproate are currently managed.

Following advice from the CHM, new safety measures for valproate-containing medicines are to be put in place in the coming months. The CHM has established an implementation group with a cross-health sector membership to support the safe introduction of the new measures into clinical practice. This will be via a phased programme currently under development according to patient safety priorities, and developed in collaboration with the healthcare bodies, to ensure ongoing patient care is not disrupted. No action is needed at present except for women of childbearing potential not on the Pregnancy Prevention Programme. Repeat prescriptions should continue to be provided and patients should not stop taking valproate unless advised to do so by a specialist.

There was discussion of the CHM recommendations to be implemented in the future including:

- The CHM recommendation that for patients under 55 years (male or female) currently receiving valproate, two specialists should independently consider and document that there is no other effective or tolerated treatment or the risks do not apply. There was concern that due to the existing pressure on local neurology services that two specialists would not be able to review patients in a timely manner which would leave GPs holding the risk of continuing to prescribe valproate without the required specialist review.
- The measures are being extended to new patient groups (females up to 55 years and males under 55 years). Current measures apply only to females of child-bearing potential. There was discussion of whether any information had been provided on how these new patient groups would be identified for specialist review.
- It was considered that releasing information on new measures ahead of a clear plan for implementation was unhelpful and some prescribers may consider they have been put in a difficult position.

**Imbruvica (ibrutinib): New risk minimisation measures, including dose modification recommendations, due to the increased risk for serious cardiac events.**

Ibrutinib tablets are included in the Devon Formulary as a red (hospital) drug in line with a NICE TAs for leukaemia and lymphoma. The formulary entry for ibrutinib includes a weblink to a Drug Safety Update article issued in 2017 on the risk of ventricular tachyarrhythmia with ibrutinib. A Dear

Healthcare Professional communication has been issued highlighting further measures to reduce the risk of cardiotoxicity with ibrutinib. The formulary entry for ibrutinib has been updated with a weblink to the Dear Healthcare Professional letter.

| Summary of actions | | | |
|---|---|---|---|
| | **Action** | **Lead** | **Status** |
| 21/23 | Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists. | Formulary Team | Ongoing |
| 21/24 | Thyroid disorders: Update – circulate the final draft via e-FIG for agreement. | Formulary Team | Ongoing |
| 21/54 | Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement.<br><br>***Post meeting note:*** *RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*<br><br>***25th January 2023 update:*** *This will be picked up as a partial review by the SMS Pharmacist.*<br><br>*A Devon-wide review will be considered at a future date* | SMS Pharmacist<br><br>SMS Pharmacist | On agenda<br><br>Closed |
| 22/25 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) – Feedback to specialists on the discussion to understand the frequency of potassium monitoring required. | Formulary Team | Complete |
| 22/26 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) look at TA599 evaluations to determine if potassium threshold of 5.5mmol/L has been considered for patients with heart failure. | Formulary Team | Complete |
| 22/27 | NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) - update the proposed formulary entry and bring back to a future FIG meeting. | Formulary Team | Complete |
| 22/51 | Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – discuss the impact of the amber classification on prescribing in primary care with the Head of Medicines Optimisation. | Formulary Team | Ongoing |
| 22/52 | Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – Update Devon formulary as agreed by the Devon FIG. | Formulary Team | Ongoing |

| | | | |
|---|---|---|---|
| 22/61 | Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin. | Formulary team | Ongoing |
| 22/62 | Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group. | Formulary team | Ongoing |
| 22/65 | Asymptomatic bacteriuria screening in pregnancy – liaise with local specialists/Local Maternity Network and bring views and formulary guidance back to the FIG either via the e-FIG process or to a meeting.<br><br>***Post meeting note:*** *Updated national guidance is expected in 2023. Formulary guidance will be reviewed once this is published* | Formulary Team | Closed |
| 22/70 | Following further consultation with specialists bring formulary guidance for osteoporosis and drug entries back to the FIG via the appropriate route. | Formulary Team | Complete |
| 22/76 | Remove potassium permanganate from the South & West Devon guidance for infected eczema and review formulary guidance for infected eczema and bring to FIG for discussion following specialist consultation.<br><br>***Post meeting note****: Potassium permanganate removed from South & West guidance for infected eczema (3rd Nov 2022).*<br><br>*Review NICE guidance for infected eczema and update formulary if required.* | Formulary Team | Complete<br><br>Ongoing |
| 22/80 | Pharmacological treatment for type 2 diabetes (NICE NG28): bring the formulary guidance for the pharmacological treatment of Type 2 diabetes to a future meeting. | Formulary Team | Ongoing |
| 22/89 | SMS Guidelines: Methylphenidate, lisdexamfetamine and atomoxetine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Update the guidelines in line with discussion.<br><br>***Post meeting note****: These guidelines are affected by the outcome of discussions in respect of SMS guidelines for dexamfetamine for ADHD in children and young people aged 6 years and above (see action 22/104 & 22/105)* | Formulary Team | Ongoing |

| | | | |
|---|---|---|---|
| 22/91 | Report of COVID-19 related changes to the formulary (October 2022 to December 2022 – Formulary section 16.17: End of life symptom control for patients dying of COVID-19 infections. Formulary team to take down section 16.17 and relevant information from the Covid-19 update page pending consultation with palliative care consultants. | Formulary Team | Ongoing |
| 22/92 | Report of e-FIG decisions: November 2022: Treatment of vaginal candidiasis - seek the views of specialists on the use of vaginal creams which require insertion using an applicator during pregnancy and bring revised guidance back to the FIG via the appropriate route. | Formulary Team | Ongoing |
| 22/98 | Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients. | Formulary Team | Ongoing |
| 22/100 | Immediate Release melatonin tablets: update the Devon Formulary with the accepted entry for Immediate Release Melatonin Tablets. | Formulary Team | Complete |
| 22/103 | Solriamfetol for the treatment of excessive daytime sleepiness in adults: seek clarity from specialists regarding repeat blood pressure and heart rate measurements. | Formulary Team | On agenda |
| 22/104 | Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Clarity to be sought from specialists regarding repeat blood pressure measurements. | Formulary Team | On agenda |
| 22/105 | Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Add updated shared care agreement letters to the recently updated methylphenidate, atomoxetine and lisdexamfetamine paediatric SMS guidelines. | Formulary Team | Ongoing |
| 22/106 | Dexamfetamine 10mg and 20mg tablets to be added to the formulary. | Formulary Team | Complete |
| 22/107 | Dexamfetamine 5mg/5ml sugar free oral solution to be added to the formulary with supporting note. | Formulary Team | Complete |
| 23/01 | Add the accepted formulary entry for guanfacine for the management of ADHD in children and adolescents to the Devon Formulary. | Formulary Team | Complete |
| 23/02 | Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin – Proposed Formulary Entry to be amended in line with the discussion and added to the local formulary. | Formulary Team | Ongoing |
| 23/03 | 4.10.2 Nicotine dependence – update proposed formulary entry in line with the discussion. | Formulary Team | Complete |
| 23/04 | 4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route. | Formulary Team | Ongoing |

| | | | |
|---|---|---|---|
| 23/05 | Management of osteoporosis: Update – seek clarity on the frequency of fracture risk reassessment. | Formulary Team | Ongoing |
| 23/06 | Management of osteoporosis: publish accepted formulary guidance once clarification of the frequency of fracture risk reassessment has been received and the CRG is in place. | Formulary Team | Ongoing |
| 23/07 | Luforbec 200/6: undertake further consultation with specialists. | Formulary Team | Complete |
| 23/08 | Luforbec 200/6: subject to feedback from specialists publish the accepted formulary entry. | Formulary Team | Complete |
| 23/09 | Add accepted entry for Melatonin to the Devon Formulary. | Formulary Team | Complete |
| 23/10 | Sodium zirconium cyclosilicate for treating hyperkalaemia: consideration of reclassification: contact renal specialists for further information on reason for requesting reclassification. | Formulary Team | Ongoing |
| 23/11 | Sodium zirconium cyclosilicate for treating hyperkalaemia: liaise with heart failure team. | Formulary Team | Ongoing |