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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 22 March 2023

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Susie Harris (Chair)	Consultant Physician/Geriatrician	RDUH NHS FT
Glen Allaway	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Heidi Campbell	Pharmacist	NHS Kernow ICB
Matt Howard	Clinical Evidence Manager	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
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Graham Simpole	Medicines Optimisation 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:

Emma Gitsham	Clinical Effectiveness Pharmacist - Specialised Medicines Service (SMS) Guideline Lead	NHS Devon ICB

Observers:

Hazel Russell	MO Technician	NHS Devon ICB

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Subsequent to the retirement of Dr Daneshmend, Dr Susie Harris agreed to chair the FIG meeting. Dr 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
Andy Craig	GP	NHS Devon ICB
Nicola Diffey	Pharmacist	Livewell Southwest
Nick Keysell	GP	NHS Devon ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT

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
NICE Guidance NG196: Atrial fibrillation	
Beta-blockers	Various manufacturers
Calcium channel antagonists	Various manufacturers
Digoxin	Various manufacturers
Amiodarone	Various manufacturers
Dronedarone	Various manufacturers
Anticoagulants including warfarin and DOACs	Various manufacturers
Ketotifen preservative-free single dose unit eye drops Ketofall	Scope Ophthalmics
Alternatives treatments: Sodium cromoglicate eye drops multidose bottles	Various manufacturers
Sodium cromoglicate preservative-free single dose unit eye drops and multidose bottles	Various manufacturers

Bevespi Aerosphere **Alternative treatments**: Anoro Ellipta Duaklir Genuair Spiolto Respimat Ultibro Breezhaler	Astra Zeneca UK GlaxoSmithKline UK Astra Zeneca UK Boehringer Ingelheim Novartis Pharmaceuticals UK
Trixeo Aerosphere **Alternative treatments**: Trelegy Ellipta Trimbow NEXThaler Trimbow pMDI	Astra Zeneca UK GlaxoSmithKline UK Chiesi Chiesi
Metolazone 5mg tablets Xaqua **Alternative treatments**: Metolazone 2.5mg tablets (unlicensed)	 Renascience Pharma Various manufacturers
Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above Dexamfetamine 5mg tablets and 1mg/ml oral solution Amfexa brand 5mg, 10mg, 20mg tablets	 Various manufacturers Flynn Pharma Ltd
Solriamfetol (Sunosi®) for the treatment of excessive daytime sleepiness Sunosi 75mg, 150mg tablets	 Jazz Pharmaceuticals UK Ltd
Western Locality Shared Care: Methotrexate, gastroenterology – folic acid update Folic Acid 5mg tablets (generic)	 Various manufacturers

Items discussed and agreed by e-FIG

Sativex® for the treatment of spasticity in multiple sclerosis	GW Pharma Ltd
Alternative treatments:	
Botulinum toxin injections (Botox, Dysport, Xeomin)	Allergan Ltd, Ipsen Ltd, Merz Pharma UK Ltd
Intrathecal baclofen pumps	Various manufacturers

Name	Job Title	Declaration
Rebecca Lowe	Joint Formulary Pharmacy Technician	Have second job as a bank pharmacy technician at HMP Channings Wood, and locum in community pharmacies.

2. Minutes of the meeting held on Wednesday 25th January 2023 and Actions/Matters Arising

Minutes of the meeting held on Wednesday 25th January 2023

The minutes of the meeting held on Wednesday 25th January 2023 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. ***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.* ***25th January 2023 update:*** *This will be picked up as a partial review by the SMS Pharmacist.* *A Devon-wide review will be considered at a future date*	SMS Pharmacist SMS Pharmacist	On agenda 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. ***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. ***Post meeting note****: Potassium permanganate removed from South & West guidance for infected eczema (3rd Nov 2022).* *Review NICE guidance for infected eczema and update formulary if required.*	Formulary Team	Complete 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. ***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	Complete
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	Complete
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	Complete
23/11	Sodium zirconium cyclosilicate for treating hyperkalaemia: liaise with heart failure team.	Formulary Team	Complete

3. Report of e-FIG decisions:

In March 2023 the FIG was asked to consider two items through the e-FIG process:

Sativex for multiple sclerosis: (1st March 2023)

Responses received to the e-FIG indicated acceptance of the proposed formulary entry. The Devon Formulary has been updated with the accepted formulary entry.

West Devon shared care: Methotrexate, Gastroenterology Update (1st March 2023)

Responses received to the e-FIG indicated that further discussion was needed. The item was included on the meeting agenda.

4. Report of COVID-19 related changes to the formulary and Recent Drug Decisions

Report of COVID-19 related changes to the formulary (December 2022 to March 2023)

The Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

COVID-19 vaccination update

The Sanofi Pasteur COVID-19 vaccine, VidPrevtyn Beta, has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

The vaccine has been added to the Devon Formulary.

Update to the commissioning policies for the treatment of COVID-19

A verbal update was given at the January FIG meeting summarising the key changes to the UK interim commissioning policies for treatments for COVID-19 introduced at the end of November 2022.

The relevant formulary entries have been updated in line with the commissioning policies and the entries harmonised for some clinical content.

It was noted that NICE is due to publish a multiple technology appraisal for treatments for COVID-19 at the end of March 2023.

Recent drug decisions – (January 2023 to March 2023)

The FIG received a report of recent drug decisions.

5. NICE guidance NG196: Atrial fibrillation

NICE issued updated guidance for atrial fibrillation (NG196) in April 2021. A draft formulary update based on NG196 was seen by the FIG in 2022 and subsequently sent to consultants for review.

The final formulary guidance was presented to the FIG. It is intended that the new proposed guideline replaces the existing formulary guidance in its entirety.

Comments had been received from two specialists with reference to suspected paroxysmal atrial fibrillation undetected by 12 lead ECG recording. They questioned the suggestion of using 24-hour tapes for 'suspected asymptomatic atrial fibrillation' as without any qualification this implies screening.

The FIG considered and accepted the updated proposed formulary guidance with minor amendment. There was discussion about:

- The comments received from specialists regarding monitoring of patients with suspected asymptomatic paroxysmal atrial fibrillation. GPs present confirmed that they would only ask for 24-hour monitoring when patients are symptomatic. The chair proposed an amendment to the guidance to use 24-hour monitoring if there is a concern about asymptomatic episodes, for example in a patient presenting with a stroke or TIA. The Formulary team will go back to specialists.

ACTION: Formulary team to go back with the updated proposals to specialists who provided comments.

- It was agreed the Formulary team will publish the updated formulary entry if accepted by specialists.

ACTION: If accepted by specialist Formulary team to publish the updated formulary guidance for Atrial Fibrillation.

6. For discussion: Nail clippings in the diagnosis and treatment of fungal nail infections

This item was brought to the FIG for discussion. The current Devon Formulary guidance on the treatment of fungal nail infections recommends taking nail clippings, and only starting treatment if infection is confirmed by the lab.

When treatment is indicated, the formulary recommends terbinafine first line, with pulsed itraconazole for infections with candida and non-dermatophyte moulds. Routine prescribing of topical antifungals such as amorolfine 5% nail lacquer for the treatment of fungal nail infections is not currently recommended in the Formulary.

In 2022, the formulary team received emails from local GPs regarding a change in approach to nail clippings by local laboratories that was not in line with existing formulary guidance. The Formulary Team contacted local trusts to confirm arrangements. Feedback was mixed but indicated that some trusts are no longer routinely processing all requests for microscopy and culture for nail clippings or scrapings.

The Formulary Team undertook a scoping exercise of relevant national guidance on this subject. The scoping found that National guidance is in broad agreement that nail clippings should be used to confirm diagnosis and inform treatment choice.

Additional early consultation with dermatology teams is underway; responses have been received indicating that all are in favour of continued processing of nail clippings to confirm diagnosis.

To help inform further discussion with trust microbiologists the FIG was asked to consider the practical implications and clinical considerations of reduced availability of fungal microscopy / culture in the diagnosis and treatment of fungal nail infections in primary care.

A discussion took place the main points noted were that:

- National guidance and the opinion of local dermatologists is clear that a diagnosis from nail clippings is needed prior to commencement of treatment. This was also the view of FIG GPs.
- Making a clinical diagnosis in primary care can be difficult. Onychomycosis is often over-diagnosed clinically, with many nail conditions being incorrectly identified and treated as fungal infections.
- Microscopy and culture support selection of the most appropriate antifungal agent.
- Topical therapies are of limited use clinically, due to their lower efficacy and longer treatment duration.
- Systemic therapies are associated with side effects and may require monitoring e.g. LFTs.
- Treating empirically without a confirmed diagnosis increases costs from treatment and monitoring, as well as patient risks from side effects.
- There are medicolegal considerations for GPs prescribing drugs associated with hepatotoxicity without a confirmed diagnosis.
- Amorolfine should not be sold over the counter (OTC) if more than 2 nails are affected. This should be considered when advising OTC medicines.
- A consistent approach from all trust laboratories in Devon is preferred.
- National guidelines recommend confirmation of infection prior to the use of systemic therapies.

It was agreed that the Formulary Team would go back to the labs with a summary of the view of dermatologists and FIG GPs.

ACTION: Formulary Team to summarise the views of dermatologists and FIG GPs and go back to the labs.

7. Ketotifen 250microgram/ml single dose unit eye drops

An application for the addition of ketotifen 0.25mg/ml single dose unit (SDU) eye drops for the treatment of seasonal allergic conjunctivitis to the Devon Formulary has been received from a Consultant Ophthalmologist, Royal Devon University Hospitals (RDUH). The application is supported by another consultant ophthalmologist from RDUH and a consultant ophthalmologist from Torbay & South Devon NHS Foundation Trust.

Ketotifen 0.25mg/ml preservative-free SDU eye drops are licensed for the symptomatic treatment of seasonal allergic conjunctivitis from three years of age. One drop is to be administered twice daily.

Ketotifen is a histamine H1-receptor antagonist which has additional activities of mast cell stabilisation and inhibition of infiltration, activation and degranulation of eosinophils. Ketotifen has a wider mode of action than sodium cromoglicate, which is primarily a mast cell stabiliser and is administered up to four times daily.

Currently, there is no preservative-free eye drop for seasonal allergic conjunctivitis listed for North & East Devon. Sodium cromoglicate 2% preservative-free SDU eye drops are listed as a first-line option in South & West Devon only. Harmonisation of the preservative-free formulary options for seasonal allergic conjunctivitis across Devon is proposed, including that preservative-free options are classified as blue (second-line). Patients would be expected to have started treatment (either this year or historically) with the green (first-line) sodium cromoglicate preservative-containing multidose bottle, unless they are known to have an allergy to the preservatives in these multidose bottles.

A sodium cromoglicate preservative-free multidose bottle which is less expensive per dose than sodium cromoglicate SDU has been identified. The contents of the multidose bottle are to be used within 28 days of opening. In other sections of the formulary, both preservative-free multidose bottles and SDU are included as formulary options.

A Consultant Ophthalmologist had indicated that the advantage of SDU sodium cromoglicate preservative-free eye drops is that patients can have vials to hand if they experience acute allergic symptoms intermittently, so the cost saving of using a multi-dose bottle may be lost if it needs to be discarded every 28 days. The best value approach to treatment with preservative-free sodium cromoglicate therefore depends on the required dosage schedule. A note is proposed for addition to the formulary entry for sodium cromoglicate to take this point into account.

The FIG was asked to consider the product application in principle, the Formulary team will consult with specialists after the meeting.

The FIG considered and accepted:

- the addition of ketotifen 0.25mg/ml preservative-free SDU eye drops subject to minor amendment to the Devon Formulary as a blue (second-line) option.
- The addition of sodium cromoglicate 2% preservative-free multidose bottle eye drops to the Devon Formulary as a blue (second-line) option.
- The addition of sodium cromoglicate 2% preservative-free SDU eye drops for North & East Devon (to align with South & West Devon) and for these to be classified as blue (second-line).

There was discussion about:

- The possible environmental impact of SDU eye drops compared to the multi dose bottle
- The dose regimen at which sodium cromoglicate preservative-free multidose bottles stop being best value against single dose units needs to be determined.
- Note to be added to the sodium cromoglicate entry stating the circumstances in which sodium cromoglicate preservative free multi dose bottles and Ketotifen SDU provide best value.
- It was agreed that subject to consultation with ophthalmologists the Formulary team will publish the formulary entry for Ketotifen 0.25mg/ml SDU eye drops.

ACTION: Subject to consultation with specialists the Formulary team will publish the entry for Ketotifen 0.25mg/ml single dose unit eye drops.

- Sodium cromoglicate entry to be updated in line with discussion and brought back to FIG via the e-FIG process.

ACTION: Formulary Team to update entry for sodium cromoglicate and bring back to FIG via the e-FIG process.

8. Bevespi Aerosphere and Trixeo Aerosphere

Applications for Bevespi Aerosphere and Trixeo Aerosphere to be considered as additional formulary options have been received from a Respiratory Consultant, Torbay and South Devon NHS Trust. The applications were subsequently supported by three consultants from Royal Devon University Healthcare NHS Foundation Trust. The applicant was not able to join the discussion as the result of a study day for respiratory specialists, but they had indicated that they were happy for the discussion to take place in their absence.

The Bevespi Aerosphere pressurised metered dose inhaler (pMDI) contains formoterol, a long-acting beta2 agonist (LABA) and glycopyrronium, a long-acting muscarinic antagonist (LAMA). It is indicated as a maintenance treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Each single inhalation provides a delivered dose of 9 micrograms of glycopyrronium bromide equivalent to 7.2 micrograms of glycopyrronium and 5 micrograms of formoterol (as fumarate dihydrate). The recommended and maximum dose is two inhalations twice daily (morning and evening).

The Trixeo Aerosphere contains formoterol, glycopyrronium and budesonide, an inhaled corticosteroid (ICS). It is indicated as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA or a

combination of a LABA and a LAMA. Each single inhalation provides a delivered dose equivalent to 7.2 micrograms of glycopyrronium, 5 micrograms of formoterol and 160 micrograms of budesonide. The recommended and maximum dose is two inhalations twice daily (morning and evening).

The Aerosphere inhaler device is available only as Bevespi and Trixeo.

The meeting paper provided an overview of the formulary applications, relevant guidance from NICE, clinical evidence, financial considerations, environmental impact, prescribing data and the position of Bevespi and Trixeo Aerosphere in other formularies in southwest England.

The FIG considered the applications for the addition of Bevespi and Trixeo Aerosphere pMDIs. The FIG was undecided as to whether to accept the inclusion of these inhalers in the Devon Formulary. There was discussion about:

- The environmental impact of pMDI inhalers.
- Whether more choice is always preferable, it was suggested that it can be confusing to have too many options.
- Whether there is a clinical need for a LABA/LAMA pMDI. The formulary includes a soft mist inhaler (SMI) for patients with COPD who require a LABA/LAMA inhaler and for whom dry powder inhalers are not clinically appropriate. The FIG queried whether there is a specific patient group for whom a LABA/LAMA pMDI would be selected in preference to a SMI.
- The formulary already includes a triple therapy pMDI.

It was agreed that the Formulary team would ascertain from specialists whether there is a specific patient group for whom a LABA/LAMA pMDI would be selected in preference to a SMI.

ACTION: Formulary team to ascertain from specialists which patient groups would benefit from a LABA/LAMA pMDI in preference to a LABA/LAMA SMI.

It was agreed that was Bevespi and Trixeo be brought back to FIG when specialists can attend.

ACTION: Bevespi and Trixeo to be brought back to FIG when specialists can attend.

9. Metolazone 5mg tablets (Xaqua)

Licensed metolazone tablets have not been available in the UK since Sanofi-Aventis took the decision to discontinue the manufacturing of metolazone 5mg tablets in 2013. Since then, metolazone tablets have been available as unlicensed 2.5mg tablets which are imported into the U.K. The Devon Formulary lists metolazone 2.5mg tablets as an unlicensed special-order product. The 5mg unlicensed tablets are non-formulary.

The MHRA has granted a licence for metolazone 5mg tablets (Xaqua). Xaqua is licensed for the treatment of oedema related to congestive heart failure and oedema related to kidney diseases.

In January 2023 the MHRA published a Drug Safety Update article on metolazone advising prescribers and dispensers to use caution if switching patients between different metolazone preparations as the rate and extent of absorption of metolazone are formulation dependent.

The Devon Formulary entry is for metolazone 2.5mg tablets as an unlicensed special. An interim update was made to the formulary entry for metolazone following advice from NICE and the Specialist Pharmacy Service of the importance of drawing clinician's attention to the difference in bioavailability between Xaqua and unlicensed metolazone tablets.

At the same time, the ICB Medicines Optimisation team posted a communication on metolazone on the Medicines Optimisation Post Live.

The FIG was asked to hold an initial discussion on the inclusion of metolazone 5mg tablets (Xaqua) in the Devon Formulary in place of the unlicensed metolazone 2.5mg tablets and a proposed draft entry prior to the Formulary team consulting with the specialist teams.

Metolazone is currently included in the Devon Formulary as a blue (second-line) treatment for oedema in South & West Devon and an amber (specialist-input) option in North & East Devon. Harmonisation of the formulary classification for metolazone is required. The Formulary team will be consulting with heart failure specialists over a draft update to the formulary heart failure guidance which will include metolazone and will liaise with the renal teams over the draft entry for metolazone.

Review of metolazone entries in other formularies in southwest England found that Xaqua had not been adopted by all formularies.

An initial discussion took place:

- There was discussion about the Drug Safety Update on Metolazone.
- Metolazone is rarely prescribed in primary care and the experience of those present was that metolazone is generally prescribed at a daily dose below the lowest available dose of Xaqua.
- Torbay and South Devon Heart Failure Team is determining whether patients are suitable for switching to Xaqua on an individual patient basis The Formulary team will consult with heart failure teams and renal teams.

ACTION: Formulary team to consult with the heart failure and renal teams on a formulary entry for metolazone 5mg tablets (Xaqua).

10. MHRA Drug Safety Updates – (January 2023 -and February 2023)

The FIG received the MHRA Drug Safety Updates issued between January 2023 and February 2023.

January 2023

Xaqua (metolazone) 5mg tablets: exercise caution when switching patients between metolazone preparations – a paper on this topic was included on the agenda of the FIG meeting.

Topical testosterone (Testogel): risk of harm to children following accidental exposure. Key points from the article and a link to the Drug Safety Update will be included under formulary section 6.4.4 Male sex hormones and antagonists.

February 2023

There were no relevant articles, letters sent to healthcare professional or drug alerts in the February Drug Safety Update.

11. Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above

The formulary currently classifies dexamfetamine as an amber treatment for ADHD. A proposed SMS “shared care” prescribing guideline for children and young people aged 6 years and above was first considered by the FIG in December 2022. A separate guideline to support prescribing in adults is being developed and will come to a future FIG meeting.

In December the FIG accepted the proposed guideline for children, subject to some amendments and clarifications. Subsequently work has been undertaken to update the guidance in line with the discussion at the FIG meeting in December, including consulting with local specialists on the specific details relating to the interval and urgency for repeat blood pressure measurements.

In addition, the FIG were asked to consider that the agreed changes to the dexamfetamine guidance are applied to the methylphenidate, lisdexamfetamine and atomoxetine paediatric ADHD guidelines agreed in October 2022 prior to publication.

The final settlement of funding for SMS remuneration will be agreed via negotiations with the LMC.

The FIG considered the changes made to the initial draft, including the clarity of the wording around pregnancy and comments received from specialists regarding thresholds and action to be taken by the GP have been updated to be more specific.

The FIG accepted the proposed guideline for dexamfetamine for ADHD in children and young people with one minor amendment. It was agreed that the advice for individuals of childbearing potential should state that “Individuals of childbearing age should avoid pregnancy and take appropriate contraception while taking dexamfetamine.”

The FIG supported the adoption of the revised monitoring guidance to the recently agreed methylphenidate, lisdexamfetamine and atomoxetine guideline for children and young people aged 6 years and above.

ACTION: **Clinical Effectiveness Pharmacist – SMS Guidelines Lead to take the SMS prescribing guideline for dexamfetamine for ADHD in children and young people aged 6 years and above to the LMC for negotiation of remuneration.**

ACTION: **Clinical Effectiveness Pharmacist – SMS Guidelines Lead to publish the guideline following remuneration negotiations with the LMC.**

12. Solriamfetol for the treatment of excessive daytime sleepiness

In January 2022, NICE Technology Appraisal Guidance (TA758) was issued for solriamfetol for treating excessive daytime sleepiness in adults caused by narcolepsy with or without cataplexy only if modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable. Following publication of the guidance solriamfetol was added to the Formulary as a hospital only drug to meet the mandatory timeline for implementation of the TA.

A solriamfetol SMS guideline was considered by the Devon Formulary Interface Group (FIG) in August, and following additional amendments, in December 2022. During the December FIG meeting the committee requested clarity be sought from specialists about how the phrase "2 occasions" is defined with respect to the interval and urgency for repeat blood pressure and heart rate measurements. Feedback sought from local neurologists indicated that they considered GPs would be more familiar with diagnosing hypertension. The specialists recognised national guidance for the diagnosis of hypertension specifically NICE guideline [NG136]: Hypertension in adults: diagnosis and management.

Initial changes were proposed based on previous FIG GP feedback on the level of detail preferred in SMS prescribing guidelines. However, after the Board Pack was circulated to FIG members, additional feedback was received from the LMC suggesting that the guideline was too prescriptive regarding the number of times blood pressure should be checked. The feedback also highlighted that if blood pressure is consistently elevated in context of a recent dose increase the patient would fall under the remit of secondary care, as GPs would only be checking patients on a stable dose. LMC made the same point regarding dose changes for pulse rate.

The general point regarding dose changes is used in many of the national template protocols however it may not be appropriate here as the initial dosing schedule is 75mg for 3 days then increased to 150mg if necessary. No further dose changes are expected. The FIG was asked if it wished to remove references to this in the dosing table.

The FIG considered and accepted all the changes to the draft guideline. It was agreed to:

- remove reference to blood pressure or heart rate being elevated "in the context of recent dose change" from the guideline.
- Simplify the wording regarding actions to be taken when blood pressure is raised to "confirm raised blood pressure in line with good medical practice and NICE guideline NG136. If raised blood pressure is confirmed seek specialist advice to determine if dose reduction or discontinuation of solriamfetol is required."
- Simplify the wording regarding actions to be taken when heart rate is raised to "confirm increased heart rate in line with good medical practice. If tachycardia is confirmed, seek specialist advice to determine if dose reduction or discontinuation of solriamfetol required"

The Formulary team will update the proposed guideline in line with the discussion.

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to update the proposed guideline in line with the discussion and take to the LMC for negotiation of remuneration.

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to publish the guideline following remuneration negotiations with the LMC.

The FIG considered and accepted the proposed formulary entry for solriamfetol as an amber (specialist input) option to support publication of the final guideline.

ACTION: Formulary team to publish the updated formulary entry (amber classification) once the SMS guideline has been published

13. Western Locality Shared Care: Methotrexate, gastroenterology – folic acid update

At the beginning of March 2023, the FIG considered proposed updates to the West Devon Methotrexate Gastroenterology shared care guideline for the treatment of Crohn's disease via the e-FIG process.

The FIG had considered the folic acid dose and administration recommendations stated in the Devon Formulary and nine local methotrexate shared care prescribing guidelines in August 2021 following an enquiry from a GP regarding the dose of folic acid to be prescribed alongside methotrexate. At that time, the FIG had requested clarification in this guideline in respect of folic acid dosage for patients receiving methotrexate (Action 21/54). The Formulary Team reviewed several sources of national guidance. The broad consensus opinion based on national resources recommends a minimum folic acid dose of 5mg once weekly to reduce the toxicity of methotrexate; folic acid supplementation should be avoided on the day of methotrexate in case it adversely affects absorption.

Respondents to the e-FIG highlighted a recently published Specialist Pharmacy Service (SPS) webpage intended to guide appropriate dosing of folic acid with methotrexate in rheumatoid arthritis. The Formulary team had reviewed this webpage when preparing the eFIG paper, it broadly reflects the information originally considered by FIG in August 2021. The Formulary team noted that:

- The evidence does not provide a definitive answer regarding the optimal dose or timing.
- Folic acid 5mg weekly is expected to be high enough to prevent folate deficiency but may be increased to 10mg if the person experiences side effects. No evidence was found to support increasing the dose beyond 10mg, although higher / more frequent dosing appears to be unlikely to cause harm.
- The consensus is that folic acid should not be taken on the same day as Methotrexate.

The FIG considered and accepted the updated changes to the SMS guideline.

There was discussion about:

- The potential risks of differing advice for different patient groups prescribed methotrexate. A standard approach across Devon would be preferred. The Formulary team agreed that this could be something to work towards.
- The views of GPs present indicated that generally their patients take folic acid every day except the day on which they take methotrexate.
- The Clinical Effectiveness Pharmacist – SMS Guidelines Lead will consult with specialists to confirm they are happy with the proposed amendments.

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to confirm that west Devon gastroenterology specialists are happy with the proposed amendments to the guidelines.

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to publish updated guidelines following agreement with specialists.

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. ***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.* ***25th January 2023 update:*** *This will be picked up as a partial review by the SMS Pharmacist.* *A Devon-wide review will be considered at a future date.*	SMS Pharmacist SMS Pharmacist	Complete Closed
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	Complete
22/52	Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – Update Devon formulary as agreed by the Devon FIG.	Formulary Team	Complete
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
22/76	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. ***Post meeting note****: Potassium permanganate removed from South & West guidance for infected eczema (3rd Nov 2022).* *Review NICE guidance for infected eczema and update formulary if required.*	 Formulary Team	 Complete 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. ***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	Complete
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
22/103	Solriamfetol for the treatment of excessive daytime sleepiness in adults: seek clarity from specialists regarding repeat blood pressure and heart rate measurements.	Formulary Team	Complete
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	Complete
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	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

23/04	4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.	Formulary Team	Ongoing
23/12	NICE guidance NG196: Atrial fibrillation – go back with the updated proposals to specialists who provided comments.	Formulary Team	Complete
23/13	NICE guidance NG196: Atrial fibrillation – If accepted by specialists, publish formulary guidance for Atrial Fibrillation.	Formulary Team	Ongoing
23/14	For discussion: Nail clippings in the diagnosis and treatment of fungal nail infections – summarise the views of dermatologists and FIG GPs and go back to the labs.	Formulary Team	Complete
23/15	Ketotifen 250microgram/ml single dose unit eye drops Subject to consultation with specialists the Formulary team will publish the entry for Ketotifen 250microgram/ml single dose unit eye drops.	Formulary Team	Complete
23/16	Ketotifen 250microgram/ml single dose unit eye drops – reword note on sodium cromoglicate and bring back to FIG via the e-FIG process.	Formulary Team	Complete
23/27	Bevespi Aerosphere and Trixeo Aerosphere – ascertain from specialists which patient groups would benefit from a LABA/LAMA pMDI in preference to a LABA/LAMA SMI.	Formulary Team	Ongoing
23/28	Bevespi Aerosphere and Trixeo Aerosphere – bring back to FIG when specialists can attend.	Formulary Team	Ongoing
23/29	Metolazone 5mg tablets (Xaqua) – consult with heart failure and renal teams for metolazone 5mg tablets (Xaqua).	Formulary Team	Ongoing
23/30	Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above – take the SMS prescribing guideline for dexamfetamine for ADHD in children and young people aged 6 years and above to the LMC for negotiation of remuneration.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/31	Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above – publish the guideline following remuneration negotiations with the LMC	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Ongoing
23/32	Solriamfetol for the treatment of excessive daytime sleepiness – update the proposed guideline in line with the discussion and take to the LMC for negotiation of remuneration	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/33	Solriamfetol for the treatment of excessive daytime sleepiness – publish the guideline following remuneration negotiations with the LMC	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Ongoing

23/34	Solriamfetol for the treatment of excessive daytime sleepiness – publish the updated formulary entry (amber classification) once the SMS guideline has been published	Formulary team	Ongoing
23/35	Western Locality Shared Care: Methotrexate, gastroenterology – folic acid update – confirm that west Devon gastroenterology specialists are happy with the proposed amendments to the guidelines	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/36	Western Locality Shared Care: Methotrexate, gastroenterology – folic acid update – publish updated guidelines following agreement with specialists.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Ongoing