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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 17th July 2024

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Glen Allaway (Chair)	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Heidi Campbell	Pharmacist	NHS Kernow ICB
Andy Craig	GP	NHS Devon ICB
Stuart Crowe	GP	NHS Devon ICB
Jess Danielson	GP	NHS Devon ICB
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Alisha Kaliciak	GP	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
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
Susanna Pine	Advanced Healthcare Improvement Practitioner	Livewell Southwest
Dr Lee Dobson	Consultant in Respiratory Medicine	RDUH NHS FT
Dr David Kernick	Clinical Lead	Exeter Headache Clinic

Observers:

Hossam Awad	Trainee Pharmacist	RDUH NHS FT
Rachel Pye	Trainee Pharmacist	RDUH NHS FT
Rati Magura	Senior MO Pharmacist	NHS Devon ICB

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Glen Allaway explained the meeting etiquette.

Chairman's welcome

Glen Allaway welcomed attendees to the meeting of the Devon Formulary Interface Group.

The GPs FIG members present were identified.

Apologies

NAME	JOB TITLE	ORGANISATION
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon ICB
Nicola Diffey	Pharmacist	Livewell Southwest
Lucy Harris	GP	NHS Devon ICB
Susie Harris	Consultant Physician/Geriatrician	RDUH NHS FT
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust

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
Chronic heart failure • Dapagliflozin (Forxiga) • Empagliflozin (Jardiance) • Sacubitril valsartan (Entresto) • Various classes of drugs including diuretics, ACE inhibitors, adrenoreceptor blockers, beta-blockers, mineralocorticoid antagonists	Astra Zeneca UK Ltd Boehringer Ingelheim Ltd Novartis Pharmaceuticals UK Ltd Various manufacturers

Management of Giardiasis:
• Metronidazole – Various formulations
• Antigiardial drugs (unlicensed treatments) – Various formulations:
  ○ Tinidazole
  ○ Albendazole
  ○ Mebendazole
  ○ Mepacrine hydrochloride
  ○ Paromomycin
	Various manufacturers
	
	Various manufacturers
	Various manufacturers
	Various manufacturers
	Various manufacturers
	Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Atogepant for preventing migraine: NICE TA973 Atogepant (Aquipta) **Alternatives:** • Rimegepant (Vydura) • Eptinezumab (Vyepti) • Erenumab (Aimovig) • Fremanzumab (Ajovy) • Galcanezumab (Emgality)	 Abbvie Ltd Pfizer Ltd Lundbeck Ltd Novartis Pharmaceuticals UK Ltd Teva UK Ltd Eli Lilly and Company Ltd
Cytisine 1.5mg tablets (Cytisinicline) • Cytisine 1.5mg tablets **Alternatives** • Long-acting nicotine replacement therapy (24-hour transdermal patches, 16-hour transdermal patches) • Short-acting nicotine replacement therapy (Medicated chewing gum, lozenges, sublingual tablets, inhalators, nasal sprays, oromucosal sprays) • Nicotinic receptor agonists (Varenicline tablets (Champix)) • Serotonin and noradrenaline re-uptake inhibitors (Bupropion hydrochloride modified-release tablets (Zyban)) • Nicotine-containing e-cigarettes / vapes (Various e-cigarettes / vapes)	Bonteque Consulting Ltd / Consilient Health Ltd Various manufacturers Various manufacturers Pfizer (discontinued) GlaxoSmithKline UK 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
Aciclovir product application: • Aciclovir 30mg/g eye ointment **Alternative treatments:** Ganciclovir 0.15% eye gel	AGEPHA Pharma s.r.o. Thea Pharmaceuticals Ltd

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Budesonide orodispersible tablets for maintaining remission in eosinophilic oesophagitis (EoE) Jorveza (budesonide) orodispersible tablets **Alternatives:** Flixotide (fluticasone) Evohaler Budesonide nebuliser liquid – Proton pump inhibitors, generic and branded, including omeprazole (Losec), and lansoprazole	 Dr Falk Pharma UK Ltd GlaxoSmithKline UK Ltd Various manufacturers (including AstraZeneca UK Ltd) Various manufacturers (including Neon Healthcare Ltd, Pfizer Limited)
Drug Safety Update 1: Valproate containing medicines **Alternatives:** Various anti-epileptics, various antipsychotics	 Various manufacturers Various manufacturers
Drug Safety Update 2 Topiramate containing medicines **Alternatives** Various anti-epileptics, various medicines for migraine prophylaxis	 Various manufacturers Various manufacturers

Items discussed by e-FIG

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Low volume high protein ready to drink milkshake style ONS: • Fresubin PRO COMPACT **Alternatives:** • Fortisip Compact Protein • Other low volume high protein ready to drink milkshake style ONS • Low volume high protein powder milkshake style ONS	 Fresenius Kabi Nutricia Advanced Medical Nutrition Various manufacturers Various manufacturers

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Specialised Medicines Service (SMS) Guidelines: Once-weekly subcutaneous methotrexate for patients within adult dermatology services Subcutaneous methotrexate, preferred formulary brand for west Devon: Metoject PEN solution for injection pre-filled pen	 Medac GmbH
Biosimilar insulins • Insulin aspart (Novorapid) • Insulin aspart (Trurapi) • Insulin lispro (Admelog) • Insulin lispro (Humalog)	 Novo Nordisk Ltd Sanofi Sanofi Eli Lilly and Company Ltd

Name	Job Title	Declaration
Dr Jess Danielson	GP representative	Any other interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) under consideration. Please refer to 'types of conflict of interest' At my request I was provided with placebo devices for patient and peer education from Besins Healthcare UK Ltd and Gedeon Richter UK Ltd for Oestrogel and Lenzetto respectively. I am a BMS menopause specialist.
Rebecca Lowe	Joint Formulary Pharmacy Technician	Secondary employment at Day Lewis pharmacies
Dr David Kernick	Exeter Headache Clinic	Work as paid advisor to above manufacturing company. In receipt of lecture fees in the last year from manufacturing company/companies. Sorry but my books are with my accountant. Unable to give amounts but all under £1000 per company.

2. Minutes of the meeting held on 22nd May 2024 and Actions/Matters Arising

Minutes of the meeting held on 22nd May 2024

The minutes of the meeting held on 22nd May 2024 were approved.

Action log update

The Action Log was reviewed and updated.

3. Papers for information only

Recent Drug Decisions (May 2024 – June 2024

The FIG received a report of the recent drug decisions.

Devon Wound Formulary Group Harmonisation Task: update

The FIG received an update on the Devon Wound Formulary Group (DWFG) Harmonisation Task.

The Formulary team has been working with the DWFG to systematically harmonise the wound chapter product recommendations.

The focus of the DWFG has been to harmonise the wound formulary chapter between N&E and S&W Devon to reduce variation and ensure that where differences remain, these are explicitly considered and borne of necessity.

Following extensive discussions, the DWFG has reached agreements on over 80 wound products across the wound management chapter.

With the volume of recommendations suggested by the group, it was agreed at the September 2023 FIG that:

- Where the DWFG has made a Devon-wide recommendation for a product already recommended in either N&E or S&W Devon, this can be done without individual consideration by FIG.
    - The rationale being that one of the predecessor FIGs has previously agreed the inclusion of the wound product, and a product appropriate for one area of Devon is also appropriate for the other, provided there is specialist support.
- Where the DWFG wishes to remove a product that is currently included in either (or both) N&E / S&W Devon recommendations, this can be removed without formal consideration by FIG.

It was agreed at the September 2023 meeting that the FIG will be informed of these changes but will not be asked to take a decision on them. Rationales will be provided to the FIG by the DWFG.

A paper providing a list of those changes and associated rationales was presented to the FIG for information.

4. Report of e-FIG decisions

12th June 2024

On 12th June the FIG was asked to consider the following three items via the e-FIG process. The FIG accepted all the proposals.

1) A product application for Fresubin PRO COMPACT and the removal of Fortisip Compact Protein.

ACTION 24/42 The Formulary team has updated the formulary in line with the proposals to add Fresubin PRO COMPACT and remove Fortisip Compact Protein

2) SMS guidelines: Once weekly subcutaneous methotrexate for patients within adult dermatology services (West Devon only).

ACTION 24/43: Formulary Team to publish the SMS guideline for "Once-weekly subcutaneous methotrexate for patients within adult dermatology services (West Devon only)", pending confirmation of remuneration via LMC negotiations committee.

3) Biosimilar insulins, update. Proposed amendments to the formulary section on rapid-acting human insulin analogues.

ACTION 24/44: The Formulary team has updated the formulary in line with the proposals to include biosimilar rapid acting human insulin analogues.

27th June 2024

On 27th June the FIG was asked to consider the following two items via the e-FIG process. The FIG accepted both proposals.

1) Hormone Replacement Therapy (HRT for menopausal symptoms – Final decision)

ACTION 24/45: The Formulary Team to publish the updates to section 6.4.1 Female sex hormones and their modulators

There was discussion about the abbreviation "mcg" used in a BMS table included in the updates to section 6.4.1. At the July FIG meeting, the FIG confirmed that this was a recognised abbreviation for micrograms and although not good practice to use the abbreviated form when prescribing, agreed to keep the table as drafted.

2) Intrauterine progestogen-only devices – updated entries

ACTION 24/46: The Formulary Team to publish the updates to section 7.3.2.3 Intrauterine progestogen-only devices.

5. Management of Chronic Heart Failure

The formulary guidance on the management of chronic heart failure requires updating and covers heart failure with reduced ejection fraction (40% or less) only. NICE has taken the decision to update the pharmacological management section of NG106 following feedback from members of NICE's cardiovascular disease committee, and other topic experts, that the recommendations are out of date when compared to 2021 European Society of Cardiology (ESC) guidelines and to current UK clinical practice.

The ESC guideline recommends ACE inhibitors (or ARBs or ARNI's), beta-blockers, MRA and SGLT-2 inhibitors, for all patients with heart failure with reduced ejection fraction (HFrEF) to reduce mortality and hospitalisation. NICE noted that these drugs are recommended as equal first line treatments to be started in all patients which contrasts with the sequencing of pharmacological treatments for HFrEF recommended in the existing NICE guideline.

A draft formulary update was presented to the FIG for initial discussion. The draft incorporates ESC guidance and British Heart Failure Society guidance for HFrEF. The management of heart failure with mildly reduced or preserved ejection fraction is an evolving area and there is a more recent ESC update for this area to be reviewed before the final consultation with the heart failure teams.

The Formulary team has undertaken two consultations with the heart failure teams but responses have been received from the UHP team only.

The FIG undertook an initial discussion of the draft formulary guidance and feedback received from specialists. There was discussion about:

- Patients who are not referred to the specialist heart failure teams. The FIG GPs suggested that there are a significant number of patients that specialists are not aware of. Generally, patients who have preserved ejection fraction or those who are frail and elderly are not referred to specialists.
    - The FIG considered the proposed formulary guidance. Feedback was received on a range of areas. Further consultation will be undertaken with specialists.

ACTION 24/47: Formulary team to undertake further consultation with specialists.

ACTION 24/48: Formulary team to bring revised guidance to FIG via an appropriate route.

6. Management of giardiasis

Following a request from a GP with Specialist Interest in Microbiology, updated Devon-wide formulary guidance on the treatment of giardiasis has been developed based on RDUH and UHP internal trust guidance. It is intended that the updated draft guidance replaces the existing guidance in S&W Devon and is added for N&E Devon.

NICE does not have a separate antimicrobial guideline for the management of giardiasis. NICE CKS: Gastroenteritis covers the diagnosis and management of gastroenteritis in people aged from 1 month and over and includes limited recommendations regarding treatment of giardiasis based on the joint NICE/PHE publication on antimicrobial prescribing and the British National Formulary.

The proposed formulary guidance includes definition of giardiasis, symptoms, recommendations for suspected giardiasis (including screening procedures and hygiene and prevention advice) and primary care management options for confirmed giardiasis, including oral antibiotics, recurrent or reinfection advice, pregnancy and breastfeeding advice, and specialist input criteria.

Microbiology specialists provided feedback on initial draft guidance and proposed several second-line treatments. Given the range of alternative options, the lack of consensus on the correct approach, and potential issues in availability of unlicensed specials, no alternative options (unlicensed specials and/or combination regimens) were included in the draft formulary guidance. If metronidazole is unsuitable or unsuccessful, it is recommended that GPs contact specialists for individual advice.

The FIG considered and accepted the proposed formulary guidance with minor rewording.

There was discussion about the difficulties in obtaining 'specials' in the community. It was noted that specialist feedback indicates that metronidazole will be appropriate for the majority of cases, and that there may a small number of cases where conversations between the specialist and GP on an individual patient basis will be required to enable supply of an appropriate alternative treatment.

ACTION 24/49: Formulary Team to publish guidance on the management of giardiasis in line with the discussion.

7. Atogepant for preventing migraine (NICE TA973) and reclassification of rimegepant

The FIG was asked to consider the traffic light classification and draft formulary entry for atogepant for preventing migraine in line with NICE TA973 and the proposed reclassification of rimegepant for the prophylaxis of migraine. The proposal was for atogepant and rimegepant to be available for prescribing in primary care without specialist input (blue formulary option) to increase the options for GP initiation in light of the new safety measures for topiramate (MHRA Drug Safety Update June 2024). Rimegepant is currently included in the formulary as amber (specialist-input) for migraine prophylaxis and blue (second-line) for the acute treatment of migraine in line with the TA906 and TA919 committees' views on the appropriate setting for initiation of treatment.

The Clinical Lead at Exeter Headache Clinic joined the meeting for discussion of the item. He has indicated support for these proposals. The Formulary Team understand that the UHP and Torbay & South Devon teams support the blue traffic light classification for atogepant and rimegepant but at the time of the meeting had not received confirmation of this, so a decision in favour of the blue formulary classification would have been a decision in principle pending consultation with the teams.

A decision is required on the formulary entry for atogepant to meet the mandatory timeline for publishing the NICE TA973 in the formulary. Atogepant belongs to the same therapeutic class as Rimegepant. The licensing of atogepant was supported by two placebo-controlled randomised trials with a 12-week treatment period which evaluated use of atogepant separately in episodic and chronic migraine. The European Medicines Agency (EMA) considered the results to be statistically significant and clinically relevant.

TA973 indicates there is no clinical trial evidence directly comparing atogepant to other treatment options. Atogepant is considered to be a cost-effective option versus rimegepant for episodic migraine and is a lower cost than the secondary care options for chronic migraine. The annual cost of treatment with atogepant per patient is £2,368 which is slightly more than rimegepant at £2,354 per patient. The TA973 committee considered that atogepant would initially be prescribed and monitored in secondary care, but that there would be interest in being able to use it in primary care.

The proposal was for atogepant and rimegepant to be blue (second-line) formulary options for initiation in primary care in appropriate patients without specialist input and for the 12 week review of effectiveness required by NICE TA906 and TA973 to be undertaken in primary care. Where the TA criteria for continuation of treatment were not met, the GP should refer the patient to a specialist for consideration of other options. Draft formulary guidance for atogepant and rimegepant indicated GPs could seek specialist advice if they required support to initiate treatment, included patient groups who should be referred directly to specialists, and further supporting information.

The FIG considered the proposed formulary entry for atogepant and the reclassification of rimegepant for prophylaxis of migraine. The discussion included:

- whilst some FIG GPs supported the proposals, other FIG GPs considered that currently GPs in general do not have sufficient knowledge and experience of atogepant and rimegepant to accept responsibility for initiating treatment in primary care without specialist input. However, the FIG recognised that GP initiation without specialist input will be the direction of travel for prescribing atogepant and rimegepant in the future.
- the FIG decision was for atogepant and rimegepant to be started in primary care on the advice of a specialist (amber formulary option) and to include wording to support GPs who are confident to initiate treatment without specialist advice. The TA requirements for a review of effectiveness at 12 weeks is to be undertaken by primary care. This removes the current recommendation for rimegepant for the specialist to prescribe for 12 weeks and review effectiveness.
- the reduction in dose of atogepant when prescribed with certain medicines to be highlighted in the formulary entry and guidance, and the MO team to add a message to Scriptswitch.
- the need to avoid atogepant during pregnancy and seek advice from specialists to be stated in the formulary entry and guidance, and to refer to the SmPC
- the annual cost of treatment to be stated in the formulary entries. There are likely to be a lot of patients who will be eligible for treatment and the costs of atogepant and rimegepant are significantly higher than the cost of other treatments prescribed in primary care. The ICB is required to fund treatment in line with NICE TA criteria where the clinician considers the treatment to be appropriate for the patient.

ACTION 24/50: Add atogepant to the formulary as an amber option for use on the advice of a specialist, in line with NICE TA973.

ACTION 24/51: Formulary Team to update the rimegepant entry to allow GP prescribing on the advice of a specialist in line with the discussion.

ACTION: 24/52: Prophylaxis of migraine: undertake further consultation with specialists on the guidance for atogepant and rimegepant.

ACTION: 24/53: Prophylaxis of migraine: bring revised guidance to FIG via an appropriate route.

8. Cytisine 1.5mg tablets (Cytisinicline)

A joint application for inclusion of cytisine 1.5mg tablets in the Devon formulary was received from Livewell Southwest, Public Health Devon and Torbay Public Health. An Advanced Healthcare Improvement Practitioner attended the meeting for discussion on this item.

Local Authorities are the responsible commissioners for smoking cessation services; in Devon, that is split between Devon County Council, Torbay Council, and Plymouth City Council. All three local authorities have confirmed that cytisine will be funded via their commissioned services and requested inclusion of cytisine in the formulary as a green (first-line) treatment option for tobacco dependency.

Alternative first line options include nicotine replacement therapy (NRT), varenicline (unavailable since 2021) or vapes / e-cigarettes (not prescribable but supplied direct from some commissioned services).

Cytisine is an effective treatment for smoking cessation; it is administered orally in a reducing schedule over 25 days. A recent Cochrane network meta-analysis suggests it is one of the most effective interventions (alongside nicotine e-cigarettes, varenicline and combination NRT). NICE is in the process of updating NG209 to include cytisine as an option.

The FIG considered and accepted the addition of cytisine 1.5mg tablets (Cytisinicline) to the formulary with a 'green' first line classification subject to minor points of clarification.

The discussion included:

- cytisine (and other smoking cessation products) produce better outcomes when patients also receive behavioural support. An extra note highlighting referral to specialist services will be added to the sliders on NRT and oral therapies.
- cytisine is not recommended for use in those with renal or hepatic impairment. GPs requested clarification if there is any level of impairment in which cytisine may be used.
- cytisine should not be used in conjunction with other tobacco products.
- the SmPC requirement for highly effective contraception. The FIG GPs indicated that a GP would not routinely discuss contraception separately with a patient following a request from the specialist services to prescribe cytisine. They requested confirmation that an appropriate discussion regarding highly effective contraception is undertaken prior to requesting the GP prescribe cytisine. It was agreed that this should be documented on the letter from the specialist service to the GP recommending the prescribing of cytisine. The Formulary team will liaise with the specialist services to highlight the need to ensure that an individual has received appropriate advice on contraception and for this to be documented on the letter to the GP.

ACTION 24/54: Cytisine 1.5mg tablets: Formulary team to undertake further consultation with specialists in line with the discussion.

ACTION: 24/55 Cytisine 1.5mg tablets: Formulary team to bring revised entry to FIG via an appropriate route.

9. Bevespi Aerosphere and Trixeo Aerosphere

The Bevespi Aerosphere is a LABA/LAMA pressurised metered dose inhaler (pMDI) containing formoterol and glycopyrronium. Trixeo Aerosphere is a LABA/LAMA/ICS pMDI containing formoterol and glycopyrronium with the addition of budesonide. These products were considered by the FIG in March 2023 following an application from a Respiratory Consultant from Torbay and South Devon NHS Trust, 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 they were happy for the discussion to take place in their absence. Bevespi and Trixeo Aerosphere were proposed as additional formulary options by the applicant.

The current Devon-wide formulary options include two LABA/LAMA dry powder inhalers and a soft mist inhaler. Bevespi is the first LABA/LAMA to be available as a pMDI. At the time, the FIG was undecided whether to accept the proposed inclusion of Bevespi and Trixeo Aerosphere in the formulary for pragmatic reasons. In particular, the environmental impact of pMDI devices. In addition, the FIG was unsure whether there is a need to have both a soft mist inhaler (Spiolto Respimat) and a pMDI (Bevespi) LABA/LAMA inhaler. No response was received from the applicant to this question. Consultation with primary care respiratory champions resulted in mixed responses but identified a patient group who require a LABA/LAMA inhaler and are unable to use a DPI and SMI. Responses from the original consultation with specialists and feedback from a further consultation with specialists prior to this discussion were included in the meeting paper.

Currently, the formulary LABA/LAMA/ICS inhalers are two dry powder inhalers and Trimbow pMDI, which also contains formoterol and glycopyrronium but with the addition of beclomethasone. Trixeo Aerosphere has a slightly lower carbon footprint than Trimbow pMDI. Bevespi and Trixeo Aerosphere are the same cost as the formulary LABA/LAMA and LABA/LAMA/ICS options.

The proposal is for Bevespi and Trixeo Aerosphere to be included in the Devon Formulary as blue (second-line) options. With the exception of salbutamol and ipratropium, pMDIs are generally included as blue (second-line) options in the formulary, supporting steps to reduce the carbon footprint of inhaler use. It is accepted that there may be clinical or dexterity reasons for prescribing a pMDI.

A Consultant in Respiratory Medicine, RDUH NHS FT joined the meeting for discussion of this item.

The FIG considered and accepted the addition of Bevespi Aerosphere and Trixeo Aerosphere as blue second-line options. There was discussion about:

- Whether another LABA/LAMA/ICS pMDI is needed in the Devon Formulary.
- The environmental impact of pMDIs and the alternatives. Education of GPs on the prescribing of DPIs and SMI in preference to pMDIs, where clinically appropriate, is required generally and not only from a formulary perspective.
- Feedback from the consultations suggests the number of patients who require pMDIs is likely to be small.
- As indicated in the meeting papers, a review of the formulary guidance on COPD is likely to recommend more widespread use of LABA/LAMA inhalers compared to current recommendations.
- Ensuring that a compatible spacer for the Aerosphere pMDIs is included in the Devon Formulary.

ACTION 24/56: Formulary team to add Bevespi Aerosphere to the formulary as a blue (second-line) option in line with the discussion.

ACTION 24/57: Formulary team to add Trixeo Aerosphere to the formulary as a blue second-line) option in line with the discussion.

ACTION 24/58: Formulary team to update management of COPD and environmental impact of inhalers pages to include Bevespi and Trixeo Aerosphere

10. Aciclovir 30mg/g eye ointment

An application was received for the addition of aciclovir 30mg/g eye ointment to the Devon Formulary for the treatment of herpes simplex keratitis (HSK) as a green (first-line) option.

Aciclovir eye ointment was previously listed in the formulary for HSK, but it was discontinued in 2018 due to manufacturing issues around sustainable product supplies. At the time, there were no other aciclovir eye products on the market, so it was removed from the formulary. A UKMi memo advised ganciclovir 0.15% eye gel as the alternative; after a consultation with local specialists, this was accepted into the Devon Formulary as a green (first-line) option in N&E Devon, and an amber (specialist input) option in S&W Devon. The formulary entry for ganciclovir eye gel includes notes to highlight it is not licensed for under 18s, its teratogenic properties, and the need to use effective contraception during and after treatment.

Local specialist feedback is in support of inclusion of aciclovir eye ointment; in particular it is safe to use in children and those of childbearing potential.

A European Public Assessment Report indicated that the new aciclovir eye ointment was developed to be pharmaceutically equivalent to the discontinued product (Zovirax). The manufacturer (AGEPHA Pharma) has confirmed it is identical to Zovirax.

Prescribing aciclovir eye ointment in place of ganciclovir eye gel would result in an increase in expenditure in Devon, however aciclovir eye ointment is already in use in both primary and secondary care in Devon. Using primary care data from May 2023 to April 2024, if aciclovir eye ointment had been prescribed instead of ganciclovir eye gel there would have been an increase in approximately £6,500 pounds. The NHS Devon Head of Medicines Optimisation has confirmed that the potential increase in expenditure is acceptable. Feedback from the trusts shows they anticipate an increase in prescribing of aciclovir eye ointment.

The FIG considered and accepted the inclusion of aciclovir eye ointment into the formulary for the treatment of HSK as a green (first line) option. The FIG agreed that ganciclovir 0.15% eye gel be classified as amber (specialist input) Devon wide (a change from green in N&E Devon).

The discussion noted:

- that same day ophthalmological assessment may not always be possible and that it was appropriate for GPs to prescribe topical antivirals in primary care on the advice of a specialist with subsequent ophthalmological review.

ACTION 24/59: Formulary team to add aciclovir 30mg/g eye ointment to the formulary as a green (first line) option in line with the discussion.

ACTION 24/60: Formulary team to reclassify ganciclovir eye gel 0.15% as amber (specialist input) in N&E Devon in line with the discussion.

11. Budesonide orodispersible tablets for maintaining remission in eosinophilic oesophagitis (EoE)

Budesonide orodispersible tablets are licensed for the treatment of eosinophilic oesophagitis (EoE) in adults. They are the only product licensed in the UK for this condition. The 1mg tablets are already included in the Devon formulary as an option for inducing the remission of EoE in adults, in line with NICE TA708. Induction of remission is a red (hospital only) indication in the formulary. In 2020, the licensed indication for this product was extended to include the maintenance of remission for this condition.

This expanded indication was outside of the scope of NICE TA708 and NICE has confirmed that they do not plan to pursue a TA for this indication. An application has been received from a Specialist Pharmacist for Gastroenterology and Nutrition, supported by a consultant gastroenterologist, both from RDUH to consider expanding the indication of orodispersible budesonide in the Devon formulary to include the maintenance of EoE remission, as amber (specialist input), with the addition of a lower strength (500microgram) tablet.

The licensed dose range for the maintenance of EoE remission is 500micrograms to 1mg twice a day. Alternative approaches for maintenance of remission with corticosteroids are via oral topical administration of products designed for inhalation (off label). This involves spraying a metered dose corticosteroid inhaler into the mouth and swallowing, or mixing the contents of an inhalation nebule with a thickening agent which is then taken orally. Systemic corticosteroids are not recommended owing to a higher propensity for systemic adverse events. Alternative options to corticosteroids include the off-label use of PPIs, dietary restrictions, and endoscopic dilation.

The extension of the marketing authorisation for this product to include the maintenance of EoE remission was approved by the EMA based on the findings of a 48-week placebo-controlled RCT which showed that, compared to placebo, orodispersible budesonide had significantly higher rates of remission and significantly lower rates of relapse.

No studies have been published which directly compare orodispersible budesonide with alternative forms of topical corticosteroid delivery or with PPIs.

No clinical guidelines have been published by NICE in relation to EoE. In 2023, guidelines were published by the British Society of Gastroenterologists which recommend dietary restrictions, PPIs, and topical corticosteroids for the maintenance of EoE remission. They do not indicate a preference for one treatment option over another, however they state that where topical corticosteroids are indicated, orodispersible budesonide should be used over other unlicensed methods of administration.

Maintenance treatment with orodispersible budesonide costs between £2,613 and £2,620 per person per annum.

Limitations to coding datasets means that it is not possible to identify current local usage of other topical corticosteroids or PPIs for this indication. Prevalence data in NICE TA708 estimates that approximately 154 patients in Devon could be affected by EoE, for which maintenance treatment

would cost approximately £403,000 per annum. However, specialist feedback indicates that maintenance treatment with orodispersible budesonide would not be indicated for all patients. As such this is likely to represent an overestimate.

Prescribing activity for ICBs with established use of orodispersible budesonide for the maintenance of EoE remission suggests much lower activity in practice. A per capita comparison estimates treatment would only be required for approximately 17 patients in NHS Devon at an average cost of approximately £44,500 per annum. This would be between approximately £24,000 and £29,500 more than using currently available, unlicensed topical corticosteroids.

Local specialists were consulted in respect of this application. Feedback indicates that some specialists are already using orodispersible budesonide to maintain EoE remission, but that they support its addition to the Devon formulary with an amber classification.

The FIG considered the proposed changes to the Devon formulary entry for budesonide to include the maintenance of EoE remission with the addition of a 500microgram tablet.

There was discussion about:

- the level of expertise in primary care to review treatment and potential difficulties in discontinuing treatments that were initiated by specialists. It was agreed that the Clinical Effectiveness Pharmacist, NHS Devon would propose a 12 monthly review period to specialists with an associated update to the formulary entry.

The FIG agreed that the inclusion of maintenance of remission as an amber (specialist input) indication and the addition of the 500microgram tablet would be acceptable if specialists undertake a 12 monthly review of patients, and for this to be included in the formulary entry.

ACTION 24/61: Formulary team to update the entry in line with the discussion and consult with specialists.

ACTION 24/62: Formulary team to publish the updated entry if specialists are in agreement or bring back to FIG for further discussion if required.

12. MHRA Drug Safety Updates

May 2024

Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions.

- Over the coming year, topical steroids will be labelled with their potencies to aid correct selection and to simplify the advice to patients requiring multiple steroid products of differing potencies. These will be labelled ‘mild steroid’, ‘moderate steroid’, ‘strong steroid’, and ‘very strong steroid.
- A Drug Safety Update on Topical Steroid Withdrawal Reactions was issued in September 2021. Key points are included in formulary section 13.4 (Topical corticosteroids). Little new information has been identified and the MHRA has stated that the number of reports of these adverse reactions received must be put into context of the millions of people that have benefitted from topical steroid treatment without experiencing any problems.

- Formulary section 13.4 will be updated with a link to the new Drug Safety Update and new advice issued in this article.

ACTION 24/63 Formulary team to update formulary section 13.4

June 2024

Warfarin: be alert to the risk of drug interactions with tramadol.

- The MHRA has received a Coroner's report following the death of a patient who died from a bleed on the brain, following concurrent treatment with warfarin and tramadol. The Coroner raised concerns that the interaction between warfarin and tramadol was not well known and emphasised the need to highlight this interaction to healthcare professionals.
- The formulary entry for tramadol will be updated with a weblink to the article. The current formulary prescribing guidance for anticoagulation for S&W Devon includes advice on starting new medicines for patients receiving coumarin anticoagulants. Review and harmonisation of the formulary prescribing guidance for anticoagulation across Devon is planned.

ACTION 24/64: Formulary team to update tramadol entry with a link to the article

Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme

The MHRA issued a Drug Safety Update in 2022 advising of a new review into the risk of neurodevelopmental disorders in children with prenatal exposure to topiramate. The pregnancy prevention requirements in place at that time were reiterated. The formulary entry for topiramate and relevant formulary guidance were updated accordingly.

The MHRA has completed its review and concluded that the use of topiramate during pregnancy is associated with significant harm to the unborn child (both from the confirmed risks of congenital malformations and low birth weight and the potential risk of neurodevelopmental disorders). The MHRA has introduced a pregnancy prevention programme (PPP) for topiramate which applies to all indications. Topiramate should not be used:

- in pregnancy for prophylaxis of migraine
- in pregnancy for epilepsy unless there is no other suitable treatment

Topiramate should not be used in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled. These conditions are also applicable to female patients who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy. This aims to ensure that all women of childbearing potential:

- are using highly effective contraception (at all times during treatment with topiramate and for 4 weeks after the last dose)
- have a pregnancy test to exclude pregnancy before starting topiramate
- are aware of the risks from use of topiramate

In line with the approach adopted for valproate-containing medicines, a new formulary page on the safety measures for topiramate is under development. The page will cover actions for clinicians from the healthcare professional guides for epilepsy and migraine, and signpost to additional resources. Contraceptive advice for topiramate is included on the formulary guidance page for

contraception under 'Drug interactions with contraception' and will be included on the new formulary page for topiramate. The new formulary page will be circulated to the relevant specialists for review and brought to the FIG for agreement via the appropriate route.

ACTION: 24/65: MHRA Drug Safety Update (June 2024): topiramate safety measures - consult with specialists regarding new formulary guidance page and bring to FIG via an appropriate route.

Oral valproate-containing medicines: safety measures

A draft new formulary page on the safety measures for oral valproate-containing medicines was presented to the FIG in March 2024. Following the meeting, the section on contraception was updated to include additional information based on FSRH guidance for contraception for patients receiving teratogenic medicines. The draft page was sent to ICS medicines safety officers and identified clinical leads from the relevant specialties within each provider trust. Comments received from specialists have been incorporated into the new formulary page.

The FIG considered and accepted the proposed formulary page subject to the retention of 'Refer any new patient to a specialist prescriber for diagnosis and initiation of treatments' under the actions for GPs from the healthcare professional guide, which had been queried by a consultant neurologist.

The discussion noted that guidance from the MHRA for men currently receiving valproate is expected.

ACTION 24/66: MHRA Drug Safety Update: Oral valproate containing medicines: Formulary team to publish the guidance page in line with the discussion.

13. Any Other Business

CPRC recruiting new GP members

Glen Allaway notified the notified the group that new GPs members are being sought for the Clinical Policy Recommendation Committee (CPRC) which he also Chairs. Information will be included in a forthcoming GP Bulletin. Glen is happy to talk to any GP interested in joining CPRC.

Change in FIG membership

It was announced that this was Larissa Sullivan's last FIG meeting. The FIG thanked Larissa for all the work she had done during her time as a FIG member. Larissa will be very much missed on the group.