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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 25th September 2025

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Glen Allaway (Chair)	GP	NHS Devon ICB
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Jess Danielson	GP	NHS Devon ICB
Lucy Harris	GP	NHS Devon ICB
Susie Harris	Consultant Physician/Geriatrician	RDUH NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Alisha Kaliciak	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
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust
Charlie Thomas	Senior Medicines Optimisation Pharmacist	NHS Devon ICB
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Name	Job Title	Organisation
Dr Lee Dobson	Consultant in Respiratory Medicine	RDUH NHS FT
Dr Paddy English	Consultant in Diabetes, Endocrinology, Acute and General Internal Medicine	UHP NHS Trust
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon ICB

Observers:

Name	Job Title	Organisation
Rayyan Zadjali	Trainee Pharmacist	RDUH NHS FT

In attendance:

Name	Job Title	Organisation
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.

It was noted that Heidi Campbell had stepped down from the group. The group thanked Heidi for her contributions.

Apologies

Name	Job Title	Organisation
Andy Craig	GP	NHS Devon ICB
Stuart Crowe	GP	NHS Devon ICB
Nicola Diffey	Pharmacist	Livewell Southwest
Nick Keysell	GP	NHS Devon ICB
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB

Charlie Thomas attended the meeting in the absence of Sarah Marner.

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 attention deficit hyperactivity disorder (ADHD) in adults** **Alternative treatments:** • Dexamfetamine • Lisdexamfetamine (Elvanse, Elvanse Adult) • Methylphenidate • Atomoxetine	Takeda UK Ltd Various manufacturers Takeda UK Ltd Various manufacturers Various manufacturers
Management of acne – including application for Aklief (trifarotene) cream: Aklief (trifarotene) cream 50microgram/g cream **Alternative treatment options for acne vulgaris** • **Topical monotherapy:**	 Galderma UK Ltd

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
○ Benzoyl peroxide cutaneous gel (generic and branded **[e.g. Acnecide]**) ○ Azelaic acid cutaneous gel & cutaneous cream (generic and branded **[e.g. Differin]**) ○ Adapalene cutaneous gel & cutaneous cream (generic and branded **[e.g. Skinoren, Finacea]**) • **Topical fixed combinations:** ○ Benzoyl peroxide with clindamycin cutaneous gel (generic and branded **[e.g. Duac Once Daily]**) ○ Tretinoin with clindamycin cutaneous gel (generic and branded **[e.g. Treclin]**) ○ Adapalene with benzoyl peroxide cutaneous gel (generic and branded **[e.g. Epiduo]**) • **Oral preparations for acne:** ○ Various oral antibiotics (e.g. doxycycline, lymecycline, oxytetracycline, erythromycin, trimethoprim) ○ Oral isotretinoin capsules **Other alternative acne vulgaris treatment options:** ○ Various other acne vulgaris treatment options including oral corticosteroids, hormonal contraceptives, secondary care led treatments [e.g. CO_2 laser treatment, punch elevation, or glycolic acid peel]	Various manufacturers (including Galderma UK Ltd) Various manufacturers (including LEO Pharma) Various manufacturers (including Galderma UK Ltd) Various manufacturers (including Stiefel Laboratories UK Ltd) Various manufacturers (including Uniphar) Various manufacturers (including Galderma UK Ltd) Various manufacturers Various manufacturers Various manufacturers and various providers
Management of Chronic Obstructive Pulmonary Disease (COPD) • **Various inhaled treatments for COPD, including:** ○ Short acting bronchodilators (i.e. salbutamol, terbutaline, ipratropium) ○ Long-acting bronchodilators (i.e. various inhaled LABA and LAMA inhalers) ○ Combination inhalers (i.e. various ICS+LABA, LABA+LAMA and ICS+LABA+LAMA combination inhalers) • **Other treatments for COPD including azithromycin, theophylline, oral corticosteroids, and roflumilast (Daxas)**	Various manufacturers including: AstraZeneca UK Limited, Boehringer Ingelheim Limited, Chiesi Limited, Cipla EU Ltd, GlaxoSmithKline UK, Glenmark Pharmaceuticals Europe Ltd, Lupin Healthcare (UK) Ltd, Novartis Pharmaceuticals UK Ltd, Orion Pharma (UK) Limited, Sandoz Limited, TEVA Pharma B.V., Zentiva. Various manufacturers including AstraZeneca UK Limited
Treatment of seborrhoeic dermatitis • Betamethasone valerate 0.025% cream/ointment (**Betnovate RD**) / 0.1% scalp application (**Betnovate**) / Clobetasone 0.05% cream/ointment (**Eumovate**)	GlaxoSmithKline UK Ltd

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
• Clotrimazole 1% cream (generic and branded **[Canesten]**) • Hydrocortisone 1% cream/ointment • Ketoconazole 2% cream (**Daktarin Gold/Intensiv, Nizoral**) • Ketoconazole 2% shampoo (generic and branded **[Dandrazol, Nizoral]**) • Miconazole 2% cream (**Daktarin**, **Daktarin Aktiv**) • Mometasone furoate 0.1% scalp application (**Elocon**) • Pimecrolimus 1% cream (**Elidel**) • Tacrolimus 0.03% ointment (**Protopic**) • Tacrolimus 0.1% ointment (generic and branded [**Protopic**])	Various manufacturers (including Bayer Plc) Various manufacturers McNeil Products Ltd, Thornton & Ross Ltd Various manufacturers (including Crescent Pharma Ltd, Thornton & Ross Ltd) McNeil Products Ltd, Thornton & Ross Ltd Organon Pharma (UK) Ltd Viatris UK Healthcare Ltd LEO Pharma Various manufacturers (including LEO Pharma)
Finerenone for chronic kidney disease in type 2 diabetes Finerenone (Kerendia)	Bayer plc
Vibegron for overactive bladder syndrome Vibegron (Obgemsa) **Alternative:** Mirabegron (Betmiga)	Pierre Fabre Ltd Astellas Pharma Ltd
Xonvea (doxylamine / pyridoxine) 10mg/10mg gastro-resistant tablets: **Alternative treatment options for nausea & vomiting of pregnancy:** • Promethazine hydrochloride tablets • Cyclizine tablets • Metoclopramide tablets • Prochlorperazine maleate tablets • Ondansetron tablets	Exeltis UK Ltd Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers
Continuous glucose monitoring in diabetes	Manufacturers of glucose monitoring systems for diabetes, such as Abbott, Dexcom, Gluco Rx, Medtronic, Medtrum Ltd, Senseonics Inc, Ypsomed Ltd *(list not exhaustive)*
Topiramate containing medicines **Alternatives** Various anti-epileptics, various medicines for migraine prophylaxis	Various manufacturers Various manufacturers
Valproate containing medicines **Alternatives:** Various anti-epileptics, various antipsychotics	Various manufacturers Various manufacturers

Items discussed by e-FIG

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Sodium Fluoride	Various manufacturers including Colgate-Palmolive (UK) Ltd, Manx Healthcare Ltd, Morningside Healthcare Ltd, Sigma Pharmaceuticals PLC
Once-weekly oral methotrexate for patients within adult gastroenterology services (Devon wide)	Various manufacturers
Proposed Changes to Formulary Products: Removal of Asacol 800mg modified release gastro-resistant tablets • Asacol MR gastro-resistant tablets • Octasa MR gastro-resistant tablets • Various generic and branded mesalazine	 AbbVie Ltd Tillotts Pharma UK Ltd Various manufacturers
Proposed Changes to Formulary Products: Olanzapine orodispersible sugar free tablets • Olanzapine orodispersible tablets • Olanzapine orodispersible tablets sugar free	 Various manufacturers Various manufacturers

Name	Job Title	Declaration
Dr Paddy English	Consultant in Diabetes, Endocrinology, Acute and General Internal Medicine	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Sponsorship received by our department by Abbott to facilitate attendance at the ATTD (Diabetes Technology Conference) in Florence in February 2024 and these monies used by me to attend
Rebecca Lowe	Joint Formulary Pharmacy Technician	I have a secondary position as a pharmacy technician for Day Lewis pharmacies.

2. Minutes of the meeting held on 17th July 2024 and Actions

Minutes of the meeting held on 17th July 2024

The minutes of the meeting held on 17th July 2024 were approved subject to one amendment to the section on the Management of Chronic Heart Failure to replace the paragraph:

'The ESC guidelines state that 'class I therapeutics', which include ACEi's or ARNI's, beta-blockers, MRA and SGLT-2 inhibitors, should be recommended for all patients with heart failure with reduced ejection fraction (HFrEF) to reduce mortality and hospitalisation. These are recommended as equal first line treatments to be started in all patients, and up-titrated to the doses used in the clinical trials, or maximally tolerated doses if this is not possible. This contrasts with the sequencing of pharmacological treatments for HFrEF recommended in the existing NICE guideline.'

with

'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.'

Action log update

The action log was reviewed.

3. Matters Arising

Recent Drug decisions (July 2024 to August 2024)

The FIG received a report of the recent drug decisions.

Devon FIG Annual Report (1st April 2023 – 31 March 2024)

The FIG received and accepted the Devon FIG annual report for the period 1st April 2023 to 31st March 2024. The annual report provides an account of the activity and governance processes of the NHS Devon Formulary Interface Group (FIG).

During the period of the report there were some changes to the membership:

- Graham Simpole (MO pharmacist) and Tom Kallis (community pharmacist) stepped down in July and October 2023 respectively.
- Dr Stuart Crowe, Dr Jess Danielson, Dr Lucy Harris, and Dr Alisha Kaliciak were welcomed to the FIG as GP representatives in March 2024.

It was noted that secondary care representation remains low, currently only one consultant representative position is filled. There are four consultant representative vacancies on the Devon FIG and work is ongoing to recruit additional consultant members. This issue has been escalated internally within NHS Devon. Specialist engagement with section reviews and product applications

has also been difficult to obtain at times. It is hoped that this can be improved with greater consultant representation on the FIG to follow up / encourage colleagues within the trusts.

The FIG recognised the extent of updates to treatment guidance and product applications considered over the year, including a wide range of clinical areas such as atrial fibrillation, COVID-19, insomnia, and type 2 diabetes mellitus. It was noted that formulary updates had supported significant cost saving opportunities totalling over £1million per year. The role of the formulary and FIG in supporting safe use of medicines via drug safety updates and Shared Care" / SMS guidelines was also highlighted.

The new Formulary & Referral website was launched in October 2023, designed to optimise layout and presentation automatically for tablet and mobile phone users as well as traditional computer displays. It includes advanced search functionality (including predictive drop down and results filters) and an A-Z drug list to support browsing.

The annual report will be submitted to the Clinical Policy Recommendation Committee (CPRC) of the ICB for assurance, before being made publicly available via the Devon Formulary and Referral website.

The FIG thanked Dr Susie Harris for Charing the FIG during the period of the annual report. The FIG members and the Formulary Team were also thanked for their hard work and contribution to ensuring the success of the Devon Formulary.

ACTION 24/72: Submit the FIG Annual Report to the Devon Clinical Policy Recommendation Committee for assurance.

4. e-FIG Decisions

5th August 2024

Proposed changes to formulary products: Sodium fluoride

The FIG accepted the updated Devon Formulary entry for Sodium Fluoride. The Formulary has been updated.

Specialised Medicines Service (SMS) Guidelines: Once-weekly oral methotrexate for patients within adult gastroenterology services (Devon wide)

The FIG accepted the SMS guideline for once-weekly oral methotrexate for patients within adult gastroenterology services (Devon wide). The guideline has been published.

29th August 2024

Proposed removal of formulary product: Asacol (meslazine) 800 MR gastro-resistant tablets

The FIG accepted the removal of Asacol 800 MR gastro-resistant tablets. The formulary has been updated.

Proposed changes to formulary products: olanzapine orodispersible tablets

The FIG accepted the updated formulary entry for olanzapine in line with the e-FIG proposals. The Devon Formulary has been updated.

Proposed changes to Formulary Guidance: International Travel

During the e-FIG process comments had been received from two GPs suggesting that patients should be encouraged to carry their repeat prescriptions as proof that they need their medicines rather than obtain a letter from their GP. Subsequently, the Formulary team reviewed online resources including the GOV.uk website: it was noted that requirements differ depending on the medicines and country being visited.

An amendment was proposed to the formulary guidance suggesting that patients check with the relevant embassy or high commission of the country being visited for local rules and regulations on importing or transporting medicines, including documentation required.

The FIG considered and accepted the proposed amendment.

ACTION 24/73: Formulary team to publish guidance on international travel.

5. Clinical Policy Recommendation Committee (CPRC) Updates

Guanfacine for ADHD in adults

The FIG was asked to take a decision in principle on proposed updates to the formulary entry for guanfacine, pending organisational sign off by NHS Devon ICB of the clinical commissioning policy discussed by the Clinical Policy Recommendation Committee.

Guanfacine is a selective alpha-2A-adrenergic receptor agonist licensed for the treatment of ADHD in people aged 6 to 17 years of age. It is not licensed for adults with ADHD; the SmPC for Intuniv states that “the safety and efficacy of guanfacine in adult and the elderly with ADHD has not been established. Therefore, guanfacine should not be used in this group”. The British National Formulary (online) and Maudsley Prescribing Guidelines (14th Edition, 2021) do not include the unlicensed use of guanfacine as a recognised treatment option for ADHD in adults.

Within NHS Devon, guanfacine is routinely commissioned for the management of ADHD in children and adolescents (where stimulants and atomoxetine are ineffective, not tolerated, or not suitable), but there is no commissioning position in NHS Devon for its use in adults. The CPRC voted in favour of not recommending the routine commissioning of guanfacine in adults with ADHD. The CPRC discussion included the issue of interim prescribing responsibilities for patients transitioning from child and adolescent services to adult mental health services as there can be delays in treatment reviews. Consequently, a request was made to consider pragmatic guidance in the Devon formulary and the existing guanfacine “Shared Care” / SMS guideline to support interim prescribing of guanfacine for patients transitioning to adult services if there are such delays.

The FIG considered and accepted in principle the update to the formulary entry for guanfacine and to the existing “Shared Care” / SMS guideline for guanfacine for ADHD in children and adolescents aged 6 – 17 years, pending ratification and publication of the clinical commissioning policy.

The discussion included:

- There is no specific timeline for the change in medication as a person moves from childhood to adulthood, a degree of liaison between adult and paediatric services will be needed.
- It was highlighted that specialist services were unhappy with the CPRC position and that guanfacine tends to be used at the end of the pathway for more difficult patients.
- It was noted that other options such as a stimulants that may not have been tolerated in childhood may be tolerated in adulthood.

ACTION 24/74: Formulary team to publish amendments to the guanfacine drug entry once the clinical commissioning policy has been ratified.

ACTION 24/75: Formulary team to publish amendments to the guanfacine "Shared Care" / SMS guideline once the clinical commissioning policy has been ratified.

6. Management of Chronic Obstructive Pulmonary Disease (COPD)

Current Devon Formulary guidance on the management of COPD was developed in consultation with local specialists and is largely based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) Global Strategy for Prevention, Diagnosis and Management of COPD 2019 Report, with additional supporting information and recommendations based on NICE Guideline NG115: COPD in over 16s: diagnosis and management (2018, last updated 2019). The 2024 GOLD Report has been published and includes a number of changes to the management of COPD, which prompted a review of formulary guidance in consultation with local specialists.

A consultant in respiratory medicine from RDUH NHS FT joined the meeting for discussion of this item.

Proposed updates include revised recommendations for initial pharmacological treatment and follow up treatment, including:

- LABA+LAMA is now recommended for all patients in group B.
- Groups C and D have been combined into new group E which includes all patients with ≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization, regardless of symptom score.
  - These patients are now recommended LABA+LAMA as initial treatment, with triple therapy (ICS+LABA+LAMA considered for those with blood eosinophils ≥ $0.3x10^9$/L)
- Dual therapy with ICS + LABA is no longer recommended (if ICS indicated, GOLD suggests triple therapy with ICS+LABA+LAMA is superior).

No changes are proposed to the formulary traffic light classifications of any inhaled therapies.

GOLD no longer refers to asthma and COPD overlap, instead emphasizing that these are different disorders, which may co-exist in an individual patient. If a concurrent diagnosis of asthma is suspected, GOLD recommends pharmacotherapy should primarily follow asthma guidelines. it was therefore proposed that the current formulary information on asthma - COPD overlap is withdrawn.

During consultation, local specialists indicated that inhalers are not the key intervention, and that priority should be given to non-pharmacological management of COPD. The formulary team confirmed that formulary guidance on the management of COPD continues to recommend

strategies such as smoking cessation, vaccination and pulmonary rehabilitation. Diagnosis of COPD is outside the scope of the formulary guidance.

Additional work is underway on two requests received from a specialist. These are:

- development of a flow chart / visual summary for clarity when considering initiating inhaled therapies in primary care
  - supporting visual summaries (based on those in GOLD, but including local drug choices) are in development, these will be finalised once the approach to treatment has been agreed by FIG.
- consideration of reclassification of roflumilast from red (hospital only) to amber (specialist input) for use in line with NICE TA461. This item will be subsequently brought to FIG for a decision.

Following initial consultation, a revised draft was recirculated to the specialists for comment. A response received resulted in some small additional changes which were presented to the FIG. It is proposed that a final specialist consultation is undertaken following the FIG meeting.

The FIG considered and accepted with minor amendments the proposed Formulary entry for the management of COPD. The discussion noted:

- specialist feedback regarding lack of access to spirometry services and pulmonary rehabilitation in all parts of Devon – these have been raised previously to commissioners. Resource decisions relating to provision of services such as spirometry or pulmonary rehabilitation are beyond the remit of the formulary, or the Devon FIG. Specialists have been advised to discuss these points with service commissioners.
- oral antibiotic therapy – referral into a respiratory consultant may not be necessary in all cases; GPs can also be recommended to prescribe following Advice & Guidance from the specialist team.

ACTION 24/76: Formulary team to update the draft COPD guidance in line with the discussion and circulated to specialists for final consultation.

ACTION 24/77: Formulary team to publish the updated COPD guidance if specialists are in agreement or bring back to FIG if required.

ACTION 24/78: Formulary team to withdraw the asthma-COPD overlap syndrome guidance.

7. Management of acne – including application for Aklief (trifarotene) cream

A two-part paper was presented to the FIG: part one considered a proposed update to formulary guidance on the management of acne vulgaris; part two considered an individual product application for Aklief (trifarotene) cream.

Proposed update to formulary guidance on the management of acne vulgaris

Revised formulary guidance on the management of acne was proposed in line with NICE guideline (NG198) Acne vulgaris: management (published 25 June 2021, last updated December 2023). The recommendations in the NICE guideline represent a change from existing formulary guidance. Current formulary guidance recommends initial treatment of mild acne with a single topical agent, dual therapy with combination topical agents is now recommended first line for acne of any severity.

For maintenance treatment for acne NICE recommends considering a fixed combination of topical adapalene and topical benzoyl peroxide. If this is not tolerated, or if one component of the combination is contraindicated, consider topical monotherapy with adapalene, azelaic acid, or benzoyl peroxide.

Proposals included updated guidance on the management of acne and the addition of a higher strength Epiduo (0.3% / 2.5%) gel, a lower strength benzoyl peroxide and clindamycin (3% / 1%) gel, and Aklief (trifarotene 50 microgram/g) cream.

For the period of June 2023 to May 2024 e-PACT2 primary care prescribing data show a total expenditure of £368,152.49 for topical preparations for acne, including £22,032.84 of non-formulary prescribing.

Whilst there are some changes to the NICE recommendations, for instance the use of topical combination therapy as first line for mild to moderate acne, many other recommendations (including maintenance therapy) remain the same. Primary care prescribing data do not link to patient details such as acne severity, and there is uncertainty in what proportion of existing prescribing of topical monotherapy is in combination with other treatments i.e. oral antibiotics (with additional acquisition costs). Patients may switch between treatments depending on the severity of acne and response to treatment. The financial impact of the updated recommendations is therefore uncertain.

Part two: addition of Aklief (trifarotene) 50microgram/g cream

An application was received from a consultant dermatologist at RDUH NHS Foundation Trust for addition of Aklief (trifarotene) 50microgram/g cream, a novel fourth-generation topical retinoid, as an alternative to other available retinoids in patients with facial and / or truncal acne, either in combination with other topical therapies, or as monotherapy where a fixed combination product is not tolerated, or one component is contraindicated.

The applicant proposed that Aklief should be the same traffic light classification as adapalene (currently a green [first line] option), however, as part of the update to formulary guidance it is proposed that single agent topical retinoids are reclassified to blue (second line) in line with NICE NG198. It was noted that Aklief cream is not included in the NICE guideline 198 on the management of acne vulgaris; where topical retinoid monotherapy is indicated, NICE recommends adapalene 0.1%.

Trifarotene (Aklief) is recommended as an option for use within NHS Wales and accepted for use within NHS Scotland.

A European Public Assessment Report (EPAR) published by the Swedish Medical Products Agency (Läkemedelsverket) was reviewed. The EPAR indicates that the regulators considered data from two phase 3 studies of identical design, comparing Aklief to vehicle cream in patients with moderate facial and truncal acne. Statistically significant differences in acne lesion counts were reported, which the regulatory agency considered to be modest but clinically relevant. Side effects were reportedly consistent with the known effects of topical retinoids.

Aklief cream is £27.75 for 75g. The cost per gram is the same as the current formulary products containing topical retinoid monotherapy (adapalene 0.1% cream and gel).

Dermatology specialists were initially contacted to provide input on the inclusion of trifarotene. A second round of feedback was requested following the update to proposed acne guidance in line

with updated NICE guidance. Feedback is yet to be received and an email with the FIG outcome will be circulated to garner responses from specialists.

FIG discussion

The FIG was asked whether it accepted updated guidance on the management of acne, proposed reclassification of formulary options in line with NICE guidance, and the addition of higher strength Epiduo (0.3% / 2.5%) gel, a lower strength benzoyl peroxide and clindamycin (3% / 1%) gel, and Aklief (trifarotene 50 microgram/g) cream.

The FIG considered and accepted the proposals subject to minor amendment, the draft guidance will be re-circulated to specialist for final consultation. The discussion noted that:

- the NICE guideline suggests that combination therapy is more effective than monotherapy.
- the FIG was unclear about the need for an additional topical retinoid monotherapy (trifarotene) and the potential for wastage. However, GPs felt that it may be useful for there to be an additional option for patients requiring monotherapy, and the proposal is likely to be cost neutral.

ACTION 24/79: Update the draft guidance on the management of acne in line with the discussion and recirculate to specialists for final consultation.

ACTION 24/80: Publish the updated guidance on the management of acne if specialists are in agreement or bring back to FIG if required.

ACTION 24/81: Formulary team to add Epiduo 0.3%/2.5% gel and benzoyl peroxide/ clindamycin 3%/1% gel to the formulary as green (first line) options for the treatment of acne.

ACTION 24/82: Formulary team to add trifarotene 50micrograms/g cream to the formulary as a blue (second line) option for the treatment of acne.

8. Treatment of seborrhoeic dermatitis

Daktacort cream is currently listed in the formulary as a blue (second line) option for the treatment of seborrhoeic dermatitis with inflamed skin. In May 2024, Daktacort was discontinued and removed from the UK market. This prompted a review of the formulary guidance for seborrheic dermatitis; revised guidance was developed using the NICE Clinical Knowledge Summary (CKS), British Association of Dermatologists (BAD) guidance and advice from local specialists.

Local specialists had requested topical calcineurin inhibitors be added as an *off-label* option for treatment if topical corticosteroids are ineffective or not appropriate; this treatment option is supported in BAD guidance and has been added to the proposed guidance as amber (specialist input).

Combination steroid and antimicrobial creams are not recommended in the NICE CKS and considering the different treatment durations recommended for the constituent drugs (up to 4 weeks for antifungal vs 2 weeks for steroid), these are not included in the proposed guidance.

Whilst there are some changes to the treatment recommendations, the first line choices are broadly the same as current guidance, with additional second line options. It is not possible to estimate the

financial impact of the updated recommendations as topical corticosteroid, topical antifungals, and topical calcineurin inhibitors are used extensively for other indications.

The FIG considered and accepted the proposed formulary guidance with minor amendment to make clear that a short course of mild to moderate steroids is an addition for the treatment of inflamed skin.

ACTION 24/83: Formulary team to update the draft guidance on the treatment of seborrhoeic dermatitis in line with the discussion and recirculate to specialists for final consultation.

ACTION: 24/84: Formulary team to publish the updated guidance on the treatment of seborrhoeic dermatitis if specialists are in agreement or bring back to FIG if required.

9. Finerenone for treating chronic kidney disease in type 2 diabetes: NICE TA877

Finerenone is a new mineralocorticoid receptor antagonist (MRA).

NICE published TA877 in March 2023. The TA committee concluded that finerenone may initially be prescribed in secondary care but will likely be prescribed in primary care once experience grows. Finerenone was included in the Devon Formulary as a red formulary option, with a view to considering reclassification to amber (specialist-input) at a later date.

TA877 recommends finerenone as an option for stage 3 and 4 CKD (with albuminuria) associated with type 2 diabetes in adults, only as an add-on to optimised standard care, which should include (unless they are unsuitable), an ACE inhibitor or ARB and SGLT2 inhibitor.

The annual cost of treatment per patient is £477. Applying the NICE estimated financial impact gives an estimated annual cost of prescribing finerenone in Devon of £88,463 which is equivalent to the annual cost of treatment for 185 patients.

It was proposed that finerenone is reclassified from red to amber (specialist input) with the level of input from the specialist team at initiation to be decided. Amber is in line with the majority of formularies across England.

Initiation of finerenone is dependent on eGFR and serum potassium levels. Continuation of treatment is dependent on the serum potassium level.

The Formulary Team has undertaken a consultation with local renal specialists and diabetes specialists.

The FIG considered and accepted the reclassification of finerenone as an amber (specialist-input) medication. The preference of the FIG was for the specialist to start treatment with finerenone, prescribe and monitor until the dose is stabilised before asking primary care to take on long-term prescribing and monitoring.

ACTION 24/85: Formulary team to publish updated finerenone in line with the discussion.

10. Vibegron for treating symptoms of overactive bladder syndrome: NICE TA999

Vibegron is a new beta-3 adrenoreceptor agonist with a similar mechanism of action to mirabegron.

NICE issued technology appraisal TA999 'Vibegron for treating symptoms of overactive bladder syndrome' on 4th September 2024. There was a 30-day implementation period for TA999.

TA999 recommends vibegron in the same place in therapy as mirabegron that is if antimuscarinic medicines are not suitable, do not work well enough or have unacceptable side effects. An indirect treatment comparison suggested vibegron is likely to work as well mirabegron and is likely to be cost saving compared with mirabegron.

The annual cost per patient of treatment with vibegron is £323.72 which is £28 lower than the annual cost of mirabegron.

It was proposed that vibegron is a blue (second line) formulary option in line with mirabegron. Updates were proposed to the formulary guidance for lower urinary incontinence symptoms (LUTS) in men and urinary incontinence for women to incorporate vibegron in the same place in therapy as mirabegron. In addition, the information on dose in the mirabegron entry was clarified and a draft update to the entry included.

The FIG considered and accepted the addition of vibegron as a blue (second line) option for treating symptoms of overactive bladder syndrome. There was discussion about the lack of blood pressure problems identified during the development of vibegron. Mirabegron is contraindicated in patients with severe uncontrolled hypertension. It was noted that the vibegron trials did not include patients with hypertension who were contraindicated for mirabegron. The Formulary team was asked to look further into the work conducted on blood pressure for vibegron and, if appropriate to add a note on the trial exclusion criteria for hypertension to the formulary entry for vibegron. It was also noted that although approved by NICE vibegron was not currently available, however, the manufacturers had indicated it would be available shortly.

ACTION 24/86: Formulary team to add vibegron to the Devon Formulary as a blue (second line) option for treating symptoms of overactive bladder syndrome in line with the discussion NICE TA999.

ACTION 24/87: Formulary team to publish the updated mirabegron entry, guidance on management of LUTS in men, and guidance on management of urinary incontinence in women in line with the vibegron (TA999) discussion.

11. Xonvea (doxylamine/pyridoxine) 10mg/10mg gastro-resistant tablets - including initial discussion on additional proposed updates to guidance on Nausea and Vomiting in Pregnancy (NVP)

An application has been received from a Clinical Pharmacist, Community Perinatal Services, DPT for the inclusion of Xonvea to the Devon Formulary. The application was supported by a Consultant in Obstetrics and Gynaecology, RDUH NHS Foundation Trust. Xonvea is a combination product containing an antihistamine (doxylamine succinate) and vitamin B6 (pyridoxine hydrochloride). It is indicated for the treatment of NVP in pregnant women who are aged 18 years or older who do not respond to conservative management (i.e., lifestyle and diet change).

The applicant proposed that Xonvea should be included alongside existing therapies (which are all used *off-label*) as a green (first line) treatment option for NVP not responsive to lifestyle and diet changes in line with updated national guidelines. There are currently no other licensed pharmacological treatments available in the UK for the treatment of NVP.

The initial dose is two tablets once daily at bedtime for two days, increased if necessary to one tablet in the morning and two tablets at bedtime, further increased if necessary to: maximum dose, one tablet in the morning, one tablet mid-afternoon and two tablets at bedtime.

The MHRA published a Public Assessment Report (PAR) for Xonvea. This indicates that Xonvea has the same active ingredients, route of administration, dosage form, strength and conditions of use as a product which was previously available in the UK before being withdrawn for non-medical reasons. The PAR states that the clinical pharmacology of doxylamine succinate and pyridoxine hydrochloride is well-known with a history of well-established use due to the previously licensed originator product. The MHRA considered data from an 8-arm, placebo-controlled, 7-day study undertaken in the USA in 1975; the regulator concluded this demonstrated the clinical contributions of doxylamine succinate and pyridoxine hydrochloride in the product but could not demonstrate superiority of Xonvea over its mono-components. In addition, data from a placebo-controlled phase III study showed a greater improvement in symptoms for Xonvea compared to placebo at days 3, 4, 5, 10 and 15. The MHRA concluded that differences in Pregnancy-Unique Quantification of Emesis (PUQE) scale scores at each time point represented clinically meaningful improvements compared to placebo.

A small double blind randomized controlled trial comparing ondansetron with doxylamine/ pyridoxine for NVP was also identified. Since the doxylamine/pyridoxine doses are not the same as those in Xonvea and the formulation differs it is of limited relevance.

National guidance from NICE and the Royal College of Obstetricians and Gynaecologists (RCOG) on the management of nausea and vomiting of pregnancy include doxylamine/pyridoxine as a first-line option for NVP requiring drug treatment, alongside a range of alternative options (*off-label* but established practice). Xonvea is not recommended for use within NHS Scotland, nor is it recommended for use within NHS Wales.

The acquisition cost of Xonvea 10mg/10mg gastro-resistant tablets is £28.50 for 20 tablets. Compared with the current formulary recommended oral NVP treatment options, doxylamine/ pyridoxine tablets are the most expensive oral tablet formulation. Depending on the dose required and the drug it replaces, use of doxylamine/pyridoxine tablets would be expected to increased drug acquisition costs by between £17.47 to £39.14 per patient per week.

It is not possible to make a reasonable estimation of the current spend on drugs for NVP as they are used extensively for other indications. In addition, it is not known what proportion and/or which of those products doxylamine/pyridoxine tablets might replace, and at which doses. The absolute budget impact of recommending doxylamine/pyridoxine tablets in the formulary for NVP is therefore uncertain, however it is expected to result in increased expenditure.

Local obstetrics and gynaecology specialists were asked for their views on the proposed addition of Xonvea (doxylamine/pyridoxine) tablets to the formulary and were in support of inclusion. During the consultation, local specialists suggested changes to formulary guidance, to include additional options (as per RCOG). The RCOG guideline on the management of nausea and vomiting of pregnancy (February 2024) includes chlorpromazine as a first line option, and oral domperidone as

a second line option for mild-moderate NVP requiring treatment, these are currently not included in the Devon Formulary NVP guidance. RCOG also recommends prochlorperazine as a first line option and ondansetron as a second line option; current formulary guidance recommends prochlorperazine as second line, and ondansetron as third line.

When the existing formulary guidance was developed with local specialists, domperidone was not included as, although it was recommended by RCOG, at the time it was not recommended by NICE CKS, use is associated with a small increased risk of serious cardiac side-effects, and duration is limited to seven days. Ondansetron was recommended third line locally due to concerns regarding safety. In addition, lower maximum doses were recommended locally for several drugs as the guidance was intended to support GPs prescribing in primary care and it was noted that some RCOG doses were much higher than GPs would usually use, and patients requiring such doses would likely require specialist involvement.

The FIG considered and accepted Xonvea (doxylamine/pyridoxine) 10mg/10mg tablets to the formulary as a blue (second line) option for nausea and vomiting in pregnancy. The FIG accepted the proposed formulary entry for Xonvea. The FIG also considered and accepted the proposed formulary guidance on NVP subject to minor amendment - reclassification of cyclizine to green.

The FIG was asked about support for including additional pharmacological options for NVP in the formulary, and whether there is likely to be support for increasing the maximum recommended doses of treatments in line with RCOG.

The discussion noted:

- guidance from the General Medical Council (GMC) in respect of prescribing off label medicines,
- that Xonvea has not been shown to be more effective than the alternatives, and that it was more expensive.
- that the FIG did not feel Xonvea should be included in the Devon Formulary as a first line (green) option. Xonvea was accepted as a blue (second line) option to be included as an alternative with a note that it is more expensive than other options. The FIG noted that some women may request Xonvea.
- that the FIG felt that existing guidance provided enough options for NVP; GPs are likely to use medicines and doses they are familiar with. Specialists may need to use or recommend additional options or higher doses in more severe cases; the formulary guidance does not prevent this.

ACTION 24/88: Formulary team to add doxylamine/pyridoxine 10mg/10mg tablets to the formulary as a blue (second line) option for nausea and vomiting in pregnancy in line with the discussion.

ACTION 24/89: Formulary team to publish amendments to formulary guidance on nausea and vomiting in pregnancy in line with the discussion (reclassify cyclizine to green, include doxylamine/pyridoxine 10mg/10mg tablets as a second line option).

12. Continuous Glucose Monitors: Freestyle Libre 2 Plus, Dexcom ONE+ and FreeStyle Libre 3

Continuous glucose monitors (CGM) are small, wearable devices which measure glucose levels in the user's interstitial fluid. There are two forms of CGM: intermittently scanned devices (isCGM) which require the user to actively take a measurement by bringing their reader into close proximity of their sensor, and real time devices (rtCGM) which do not require an active reading to be taken – the sensor automatically passes the glucose level to the reader in real time. Both forms of CGM are available on the NHS via prescription issued by a patient's GP. There are also some real time CGM devices which are only available from specialist secondary care diabetes teams.

Hybrid closed loop (HCL) systems are comprised of a CGM, an insulin pump and an algorithm that links the function of the two. This allows insulin release to be automated in line with readings from the CGM. Access and funding arrangements for HCL systems for type 1 diabetes is covered by NICE TA943, published in December 2023. This TA has a 5-year implementation period. NHS England is guiding ICBs through this period and has identified key priority groups for HCL initiation. These groups include children and young people, current insulin pump users, and individuals who are pregnant or planning a pregnancy. The ICB has established a working group to coordinate a local response to the NHS implementation plan. The internal ICB working group will also be working with a system wide steering group to aid roll out of this technology by providers.

A consultant in Diabetes, Endocrinology, Acute and General Internal Medicine joined the meeting for discussion of this item.

Three new CGM systems were proposed for inclusion in the formulary, these were Dexcom One+, Freestyle Libre 2 plus, and FreeStyle Libre 3.

Dexcom ONE+ and FreeStyle Libre 2 plus are upgraded systems to replace the current formulary options of Dexcom ONE and FreeStyle Libre 2 (both of which are due to be discontinued in the coming months).

Dexcom ONE+

Dexcom ONE+ was added to the drug tariff in May 2024, and is a real time CGM system. Dexcom ONE+ offers some advancements on the current Dexcom ONE system. The key differences include a reduction in sensor warm up time, and the integration of a transmitter inside the sensor. With the previous Dexcom ONE system the transmitter was separate to the sensor, meaning that it had to be replaced as an individual item every 3 months. Dexcom ONE+ also works with the Dexcom follow app, which was not the case with Dexcom ONE. This feature allows a user's glucose reading to be shared remotely with friends, family, and clinicians. No feedback was received in this consultation regarding the clinical benefit this feature provides. In previous consultations regarding CGM specialists have noted that this feature is helpful, particularly in children and young people, or those who may have difficulties with communicating symptoms of hypoglycaemia. Dexcom has confirmed to the Clinical Effectiveness Team that Dexcom ONE will be withdrawn from the market in May 2025, meaning that current users of the system will need to transfer to Dexcom ONE+ or another CGM system at that point.

Mixed feedback was received from local specialists regarding the need for any additional training to guide transitions from Dexcom ONE to Dexcom ONE+. The Clinical Effectiveness Team raised this with Dexcom, who suggested that additional formal training is not required for most users.

Dexcom has created a transition guide aimed at users which was proposed for addition to the formulary entry. In patients who need additional support Dexcom is also offering free online nurse led training sessions, again it was proposed that a link to this option was added to the formulary entry. The annual cost of Dexcom ONE+ is similar to Dexcom ONE so no additional expenditure is expected from the addition of Dexcom ONE+ into the formulary.

FreeStyle Libre 2 plus

FreeStyle Libre 2 plus is an upgraded version of the FreeStyle Libre 2 CGM system. When a smart phone is used as a reader device the FreeStyle Libre 2 plus acts as a real time CGM, however when a standalone reader device is used the system functions as an intermittently scanned CGM. The key updates between the FreeStyle Libre 2 and Freestyle libre 2 plus system is a reduction in approved user age from 4 to 2, and a change in sensor life span from 14-15 days. Currently Freestyle Libre 2 plus is being considered as a standalone CGM system, it is possible for the Freestyle Libre 2 plus to be linked with the Omnipod 5 insulin pump to form a hybrid closed loop. Abbott (the manufacturer) has confirmed that they intend to withdraw Freestyle Libre 2 in June 2025.

With regards to the transition between Freestyle Libre 2 and Freestyle Libre 2 plus, local specialist feedback indicated that no additional user training is required. Abbott has confirmed this, however, users will need to be informed that the sensor life is now 15 instead of 14 days. However, the app or reading device will inform users when they need to change their sensor, (this is the case with FreeStyle Libre 2 as well so current users should be familiar with this function). Abbott has created two user to guides to support the transition between devices; these documents will be made available via the formulary entry. The annual system cost of FreeStyle Libre 2 plus is the same as the existing system meaning no additional expenditure is expected from the addition of FreeStyle Libre 2 plus into the formulary.

FreeStyle Libre 3

FreeStyle Libre 3 is a real time CGM system; it can act as a standalone alone rtCGM but also links with the mylife YpsoPump insulin pump and the CamAPS algorithm to form a hybrid closed loop system. When used as standalone rtCGM, FreeStyle Libre 3 has an annual running cost which is nearly £200 higher than FreeStyle Libre 2 or Dexcom ONE. When FreeStyle Libre 3 was launched in January, the Clinical Effectiveness Team undertook a consultation with local specialists. Feedback indicated that any benefits FreeStyle Libre 3 may provide did not likely justify the increased costs associated with the device when it was used as a standalone CGM system.

The ICB is currently working with providers to plan the implementation of HCL systems for the management of type 1 diabetes. Currently, there are 3 HCL systems that are able to be used in pregnancy. The system with the lowest assumed 4 year running costs utilises FreeStyle Libre 3 as its CGM device. When used as part of a HCL system, FreeStyle Libre 3 can result in a per-patient saving in the region of £700 over 4-years compared with other HCL systems. When considered in line with the total number of pregnancies in people living with type 1 diabetes over the same period a system level saving of £54,600 may be possible. This HCL system is also the only option for use in pregnancy where the CGM sensors can be prescribed in primary care. The other systems require all equipment used to be directly procured by specialist secondary care teams.

It was proposed that FreeStyle Libre 3 is added to the formulary with a note stating that it is only to be used as a part of a hybrid closed loop system in pregnancy.

The FIG considered and accepted the addition of Freestyle Libre 2 Plus, Dexcom ONE+ and FreeStyle Libre 3 with amber classifications, with minor amendment. There was discussion about:

- The complexity of facilitating roll-out of HCL systems in line with NICE and NHS England recommendations.
- As the workforce develops in primary care it may be more common for CGM devices to be initiated via primary care health professionals. As such it was recommend that the formulary wording relating to initiation in primary care was amended to ensure that it is clear when this is acceptable.
- It was also noted that intermittently scanned CGM devices are now being phased out. As such it was recommend that the format and wording of the formulary page was amended to reflect this.

ACTION 24/90: Formulary team to add Dexcom ONE+ and FreeStyle Libre 2 plus to the formulary as amber (specialist input) options in line with discussion.

ACTION 24/91: Formulary team to add FreeStyle Libre 3 to the formulary as an amber option only for use as part of a hybrid closed loop in women who are pregnant in line with discussion.

13. MHRA Drug Safety Updates

Update on MHRA Safety updates reported to FIG in July 2024

June 2024

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

The Formulary Team is consulting with specialists regarding a new formulary guidance page on topiramate safety measures and will bring to FIG via an appropriate route.

July and August 2024

Two MHRA Drug Safety Updates were issued between July 2024 and August 2024 and were presented to the FIG.

July 2024

Epimax Ointment and Epimax Paraffin-Free Ointment: reports of ocular surface toxicity and ocular chemical injury

Epimax Ointment and Epimax Paraffin-Free Ointment are not listed in the Devon Formulary. The Epimax range is available to purchase over-the-counter and is prescribable as a medical device on FP10.

The Drug Safety Update addresses Epimax Ointment and Epimax Paraffin-Free Ointment and refers to a Field Safety Notice issued by the company in June 2024 following reports of ocular surface toxicity across the UK. The Safety Update advises healthcare professionals not to prescribe or advise use of Epimax Ointment or Epimax Paraffin-Free Ointment on the face. Action to take if

these products come into contact with the eye is included and healthcare professionals are advised to follow advice in the 2024 Field Safety Notice. The 2024 Field Safety Notice reported that Epimax Ointment and Epimax Paraffin-Free Ointment product ingredients and consistency are likely to lead to them taking longer to remove/wash out, if inadvertently introduced into the eye, compared to the rest of the products in the Epimax range. Product information will be updated to restrict use of the product to the body and to not use the product on the face, to wash hands after use and to further emphasise the warnings about avoiding contact with the eyes.

Although the Drug Safety Update applies to products which are non-formulary, key points and a link to the update have been included in the formulary section on emollients for awareness.

Letters sent to healthcare professionals and drug alerts in June 2024

There were no letters or drug alerts of relevance to the formulary.

August 2024

Yellow Card Biobank: call to contribute to study of genetic links to side effects

This article provided information on the biobank. No update was required for the formulary.

Letters sent to healthcare professionals and drug alerts in July 2024

Abecma (idecabtagene vicleucel), Breyanzi (lisocabtagene maraleucel), Carvykti (ciltacabtagene autoleucel), Kymriah (tisagenlecleucel), Tecartus (brexucabtagene autoleucel) and Yescarta (axicabtagene ciloleucel) (CD19- or BCMA-directed CAR T-cell therapies): risk of secondary malignancy of T-cell origin

A healthcare professional communication has been issued by the companies in agreement with the EMA and the MHRA. Since approval, the product information has advised that patients treated with these products may develop secondary malignancies. The product information will be updated to include the new information concerning secondary malignancy of T-cell origin, which suggests that the CAR T-cell therapy was involved in disease development. Patients treated with CAR T-cell products should be monitored life-long for secondary malignancies.

Tisagenlecleucel, brexucabtagene autoleucel and axicabtagene ciloleucel are recommended by NICE TAs and are listed in the Devon Formulary as red (hospital-only) options to be used in line with TA criteria. A reference to the communication will not be included in the formulary entries as the SmPCs for these products indicate they are only to be administered in qualified treatment centres and that patients are to be expected to be enrolled in a registry for long-term follow-up.

September 2024

Valproate use in men: as a precaution, men and their partners should use effective contraception

This Drug Safety Update was issued after completion of the papers for this meeting and will be discussed at the next FIG meeting. The Formulary team will review the additional safety measures and consider their implications for the formulary page on safety measures for valproate-containing safety measures.
