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

Meeting of the Devon Formulary Interface Group

Minutes

7th February 2024

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Susie Harris (Chair)	Consultant Physician/Geriatrician	RDUH NHS FT
Glen Allaway	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Heidi Campbell	Pharmacist	NHS Kernow ICB
Andy Craig	GP	NHS Devon ICB
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Sarah Marner	Senior MO Pharmacist	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
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

NAME	JOB TITLE	ORGANISATION
Dr Lucy Craven	GP Partner and BMS Menopause Specialist	Budleigh Medical Centre
Dr Kirsty Gillies	GP with extended role in women's health	Rolle Medical Partnership
Dr Stephanie Lamb	Consultant in Obstetrics and Gynaecology	UHP

Observers:

NAME	JOB TITLE	ORGANISATION
Dr Lucy McGavin	Consultant Neurologist	UHP

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Susie Harris explained the meeting etiquette.

Chairman's welcome

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

Apologies

NAME	JOB TITLE	ORGANISATION
Beverly Baker	Non-Medical Prescribing Lead	NHS Devon
Nicola Diffey	Pharmacist	Livewell
Rebecca Lowe	Joint Formulary Pharmacy Technician	NHS Devon

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
Transdermal oestrogens for HRT • Oestrogel pump • Sandrena gel sachets • Lenzetto transdermal spray **Alternative treatments:** Estradiol transdermal patch (Evorel) Various estradiol transdermal patches Oral estradiol Oral conjugated equine oestrogen (Premarin)	 Besins Healthcare UK Ltd Orion Pharma UK Ltd Gedeon Richter UK Ltd Theramax HQ UK Ltd Various manufacturers Various manufacturers Pfizer
Micronized progesterone for HRT Utrogestan oral capsules Gepretix capsules **Alternative treatments:** Various oestrogen/progestogen oral and transdermal HRT Mirena	 Besins Healthcare UK Ltd Exeltis UK Ltd Various manufacturers Bayer PLC
Conjugated equine oestrogen for HRT Premarin Premique low dose **Alternatives** Oral estradiol	 Pfizer Ltd Pfizer Ltd Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Evorel transdermal patch Various estradiol transdermal patches Oestrogel pump Sandrena gel sachets Lenzetto transdermal spray	Theramax HQ UK Ltd Various manufacturers Besins Healthcare UK Ltd Orion Pharma UK Ltd Gedeon Richter UK Ltd
Empagliflozin for chronic kidney disease Empagliflozin (Jardiance) Dapagliflozin (Forxiga) **Alternative treatment:** Canagliflozin (Invokana) Ertugliflozin (Steglatro)	 Boehringer Ingelheim Ltd Astra Zeneca Ltd Napp Pharmaceuticals Ltd Merck Sharp and Dohme (UK) Ltd
Type 2 diabetes Dulaglutide (Trulicity) Exenatide (Byetta, Bydureon) Liraglutide (Victoza) Lixisenatide (Lyxumia) Semaglutide (Ozempic and Rybelsus) Tirzepatide (Mounjaro) Various medicines including DPP-4 inhibitors, metformin, pioglitazone, sulfonylurea, insulin	 Eli Lilly and Company Ltd AstraZeneca UK Ltd Novo Nordisk Limited Sanofi Novo Nordisk Limited Eli Lilly and Company Ltd Various manufacturers
Management of eczema • Various emollients (creams/ointments/gels etc.) • Various topical corticosteroids (generic and branded **[e.g. Eumovate, Clobavate, Betnovate RD, Audavate])** • Topical calcineurin inhibitors i.e. tacrolimus (including **Protopic**) and pimecrolimus (including **Elidel**) • Various dry bandages and medicated dressings • Various systemic biologics and immunosuppressives • Various non/sedating antihistamines • Phototherapy • Various cow's milk protein free formulae	 Various manufacturers Various manufacturers (including GlaxoSmithKline UK Ltd, Teva UK Ltd, Haleon UK Ltd, Accord-UK Ltd) Various manufacturers (including LEO Pharma and Viatris UK Healthcare Ltd) Various manufacturers Various manufacturers Various manufacturers Various providers Various manufacturers
Acute asthma management: paediatric and young children • Short-acting beta2 agonists (SABAs) – including salbutamol and terbutaline (various formulations) • Corticosteroids including prednisolone and Hydrocortisone (various formulations) • Oxygen	 Various manufacturers Various manufacturers Oxygen – Air Liquide Healthcare
APO-go PFS and APO-go POD APO-go PFS and APO-go POD	 Britannia Pharmaceuticals Limited

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Alternatives APO-go ampoules and APO-go PEN Dacepton solution for infusion vials Duodopa intestinal gel Produodopa solution for infusion	 Britannia Pharmaceuticals Limited EVER Pharma UK Ltd AbbVie Ltd AbbVie Ltd
Triptan harmonisation • Sumatriptan, generic and branded (e.g. Imigran) • Rizatriptan, generic and branded (e.g. Maxalt) • Frovatriptan, generic and branded (e.g. Migard) • Almotriptan generic • Naratriptan, generic and branded (e.g. Naramig) • Eletriptan, generic and branded (e.g. Relpax) • Zolmitriptan, generic and branded (e.g. Zomig)	 Various manufacturers, including GlaxoSmithKline UK Ltd Various manufacturers, including Organon Pharma UK Ltd Various manufacturers, including A. Menarini Farmaceutica Internazionale SRL Various manufacturers Various manufacturers, including GlaxoSmithKline UK Ltd Various manufacturers, including Viatris UK Healthcare Ltd Various manufacturers, including Grunenthal Ltd
Azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults – extension of guideline to cover South Devon • Azathioprine	 Various manufacturers
Drug Safety Update: Valproate • Epilim • Episenta **Alternative treatments** • Various anti-epileptics, various antipsychotics	Various manufacturers Sanofi Desitin Pharma Various manufacturers
Drug Safety Update: Isotretinoin • Roaccutane **Alternative treatments** Various topical products and antibiotics	Various manufacturers Roche Products Ltd Various manufacturers

Items discussed and agreed by e-FIG

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Management of suspected DVT/PE: COVID-19 • Edoxaban tablets (**Lixiana**) • Rivaroxaban tablets (**Xarelto**) • Apixaban tablets (including generics and **Eliquis**) • Dabigatran etexilate capsules (**Pradaxa**) • Warfarin sodium tablets • Phenindione tablets	 Daiichi Sankyo UK Ltd Bayer Plc Various manufacturers (including Bristol-Myers Squibb Pharmaceuticals Ltd) Boehringer Ingelheim Ltd Various manufacturers Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Nicotine dependence: **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	 Various manufacturers Various manufacturers Pfizer (discontinued) GlaxoSmithKline UK Various manufacturers
Proposal to include daridorexant 25mg and 50mg tables in line with NICE TA922 **Management of insomnia, including daridorexant:** • Daridorexant tablets (**Quviviq**) **Alternatives:** • Cognitive behavioural therapy for insomnia (CBT-I) • Non-benzodiazepine hypnotics (z-drugs) i.e. zopiclone & zolpidem • Melatonin, various formulations • Other drugs historically used for insomnia i.e. antihistamines, antidepressants, benzodiazepines etc.	 Idorsia Pharmaceuticals UK Ltd Various providers Various manufacturers Various manufacturers Various manufacturers
Rimegepant for acute migraine: **Alternative treatments:** • Paracetamol • NSAIDs • Anti-emetics • Sumatriptan • Rizatriptan • Frovatriptan • Almotriptan	Pfizer Ltd Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers
Asymptomatic bacteriuria in pregnancy: Nitrofurantoin, various formulations Amoxicillin, various formulations Cefalexin, various formulations	 Various manufacturers Various manufacturers Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Management of insomnia, including daridorexant: • Daridorexant tablets (**Quviviq**) **Alternatives:** • Cognitive behavioural therapy for insomnia (CBT-I) • Non-benzodiazepine hypnotics (z-drugs) i.e. zopiclone & zolpidem • Melatonin, various formulations • Other drugs historically used for insomnia i.e. antihistamines, antidepressants, benzodiazepines	Idorsia Pharmaceuticals UK Ltd Various providers Various manufacturers Various manufacturers Various manufacturers
Lithium carbonate modified release tablets • Priadel 200mg, 400mg • Camcolit 400mg • Liskonum 450mg	Essential Pharma M Essential Pharma Ltd Teofarma S.r.l.

Name	Job Title	Declaration
Dr Lucy Craven	GP Partner at Budleigh Medical Centre	Bayer provided a partial grant towards my coil training in 2021. I am almost a British menopause society menopause specialist and have interests in women's health and contraception through my work as a GP. Im also a member of the FSRH. No other conflicts
Barbara Fort	Parkinson's Clinical Nurse Specialist The applicant for Item 9 – APO-go PFS and APO-go POD	Apomorphine hydrochloride hemihydrate - APO-go POD - Britannia provides equipment and staff support.
Dr Kirsty Gillies	GP with Extended role in women's health	I work as a GP with an extended role in women's health. I teach locally and national about women's health to healthcare professionals. I'm a member of the FSRH, PCWHF and BMS. I am a British menopause society specialist. I also hold the advanced menopause certificate from the FSRH. I provide private menopause consultations under St Erme medical and have consulting rights in the Exeter Nuffield. I am involved with the development of women's health hubs with the ICB for better NHS care for menopause patients. I have never been offered payment, gifts or

		sponsorship by drug companies for speaking or travelling to conferences.
Dr Stephanie Lamb	Consultant Obstetrics and Gynaecology	I chair the Peninsula early pregnancy and emergency gynaecology meetings. James Harrison, key account manager for Gedeon Richter UK, sponsored the Peninsula EPU/EGU meeting November 2023. He discussed Ryeqo for the treatment of fibroids. April Rosson, National Key Account Manager for Besins Healthcare, sponsored the Peninsula EPU/EGU meeting November 2022. She discussed Dimetrum for the treatment of endometriosis.

Name	Job Title	Declaration for e-FIG items
Rebecca Lowe	Joint Formulary Pharmacy Technician	Works as a bank pharmacy technician at HMP Channings Wood, and as a locum pharmacy dispenser in community pharmacy.

2. Minutes of Devon FIG meetings

Devon FIG meeting 6th December 2023

The minutes of the meeting held on 6th December 2023 were approved.

Extraordinary Devon FIG meeting 15th December 2023

The minutes of the meeting held on 15th December 2023 were approved.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
22/61	Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin.	Formulary team	Ongoing
22/62	Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group.	Formulary team	Ongoing
22/98	Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients.	Formulary Team	Ongoing
23/04	4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.	Formulary Team	Complete
23/42	Management of Hypertension (Update) – following consultation with specialists, bring draft guidance back to the FIG via the e-FIG process if required.	Formulary Team	Ongoing
23/48	MHRA Drug Safety Updates – April 2023: update the relevant formulary sections with recommendations from the MHRA Drug Safety Updates March 2023 and April 2023.	Formulary Team	Complete
23/49	MHRA Drug Safety Updates – April 2023: write to MHRA to ask for clarification on frequency of monitoring for hepatic adverse reactions for patients receiving nitrofurantoin.	Formulary Team	Complete
23/59	Update the relevant formulary sections with recommendations from MHRA Drug Safety Updates May and June 2023.	Formulary team	Complete
23/62	NICE TA Tirzepatide for type 2 diabetes and treatment pathway - consult with specialists on the formulary entry for tirzepatide and type 2 diabetes pathway.	Formulary Team	Complete
23/66	NICE TA599: Sodium zirconium cyclosilicate (SZC) for treating hyperkalaemia (consideration of reclassification from red to amber) - liaise with trust laboratories over a method of identifying serum potassium results for patients receiving SZC via the FIG GP representative for the Devon Pathology Optimisation Group.	Formulary team	Ongoing
23/68	Melatonin for use in adult patients – bring revised formulary guidance on insomnia to a future meeting.	Formulary Team	Complete

23/69	Melatonin for use in adult patients – add RBD in Parkinson's disease as an indication to the melatonin entry in line with the discussion.	Formulary Team	Ongoing
23/72	Guanfacine for attention deficient hyperactivity disorder (ADHD) in children and young people aged 6 – 17 years – submit guideline to LMC for negotiation of remuneration with ICB Primary Care Team.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Ongoing
23/73	Update relevant formulary sections with recommendations for the MHRA drug safety Updates July and August 2023.	Formulary Team	Complete
23/74	Update the formulary guidance for COVID-19 medicines in non-hospitalised patients in line with the discussion and bring back to the FIG by an appropriate route for ratification.	Formulary Team	Complete
23/75	Asymptomatic bacteriuria in pregnancy - bring the guidance back to the FIG for ratification via the most appropriate route.	Formulary Team	Complete
23/76	Asymptomatic bacteriuria in pregnancy – contact the microbiologist leading the peninsula wide work to request that any relevant outcomes are communicated to the Formulary Team	Formulary Team	Ongoing
23/77	Management of eczema – liaise with specialists regarding a harmonised classification for topical calcineurin inhibitors for eczema and bring back to the FIG via an appropriate route	Formulary Team	Ongoing
23/78	Infected eczema - liaise with specialists regarding the FIG discussion and update the proposed formulary entry for Infected eczema in line with feedback and bring back to the FIG via an appropriate route.	Formulary Team	Ongoing
23/79	Management of suspected Deep Vein Thrombosis (DVT) and pulmonary embolism: COVID-19 update - bring the guidance back to the FIG to be ratified via an appropriate route	Formulary Team	Complete
23/80	NICE TA922 daridorexant for the treatment of long-term insomnia – drug entry to be brought back to the FIG for ratification via an appropriate route.	Formulary Team	Complete
23/81	Formulary guidance for insomnia to be brought back to FIG via an appropriate route	Formulary Team	Complete
23/82	Section 4.10.2 Nicotine dependence – update the proposed formulary guidance for nicotine dependence in line with the discussion and bring back to FIG via an appropriate route.	Formulary Team	Complete

23/83	NICE TA919 rimegepant for treating migraine – drug entry to be brought back to the FIG for ratification via an appropriate route.	Formulary Team	Complete
23/84	MHRA Drug Safety Updates (September to November) – update the relevant Devon Formulary sections with recommendations for the MHRA Drug Safety Updates from September and November	Formulary Team	Complete
23/85	MHRA Drug Safety Updates (October) – Formulary Team to bring article on isotretinoin for discussion at a future meeting.	Formulary Team	Ongoing
23/86	COVID-19 treatments for non-hospitalised patients – update and publish the revised guidance in line with the FIG discussion	Formulary Team	Complete

3. Papers for information only

Recent drug decisions (November 23 – January 2024)

The FIG received a report of the recent drug decisions.

COVID guidance and entry updates (community pharmacy)

The FIG received an update on COVID guidance and entry updates (community pharmacy).

It was noted that the Formulary Team had been approached by Torbay & South Devon COVID-19 Medicines Delivery Unit specialist over community pharmacists being uncertain how to order Paxlovid and molnupiravir as these medicines were new to them. The Formulary team has updated the formulary guidance on COVID-19 treatments and the formulary entries for Paxlovid and molnupiravir with advice for community pharmacists on ordering these medicines, the 5-day treatment window, and under the entries a link to the Community Pharmacy England website on stocking COVID-19 antivirals.

4. Report of e-FIG Decisions

December 2023

In December 2023 the FIG was asked to consider four items via the e-FIG process:

- Proposal to update formulary guidance for management of suspected DVT / PE: COVID-19 update.
- Proposal to update formulary section for nicotine replacement products.
- Proposal to include daridorexant 25mg and 50mg tablets in line with NICE TA922.
- Proposal to update rimegepant formulary entry to include acute treatment of migraine in line with NICE TA919.

All the proposals were accepted, and the relevant information has been published on the Devon Formulary.

January 2024

In January 2024 the FIG was asked to consider four items via the e-FIG process:

- Minutes of the meeting held on 27th September 2023:
- Proposal to update formulary guidance for asymptomatic bacteriuria screening (ASB) in pregnancy:
- Proposal to update formulary guidance for the management of insomnia:
- Proposal to update electrocardiogram (ECG) monitoring to the Specialised Medicines Service Guideline: Priadel (Lithium) for patients in adult services:

As of 29th January, the e-FIG was not quorate, so the e-FIG was extended by one week. Two further responses were received from GPs making the e-FIG quorate. The minutes of the FIG meeting held on 27 September 2023 were accepted as were the three other proposals, the formulary will be updated shortly.

ACTION: Formulary Team to update the Devon Formulary in line with the January 2024 e-FIG decisions.

5. Product Applications

The Formulary team apologised for the lateness of the papers for these items and acknowledged that FIG members and guests had not had sufficient time to read them. Considering this, taking a final decision has been deferred to March 2024

A GP from Budleigh Medical Centre, a GP from Rolle Medical Partnership and a Consultant in Obstetrics and Gynaecology from UHP attended the meeting for discussion of product applications.

Removal of conjugated equine oestrogens

Conjugated equine oestrogens (CEE) 300microgram, 625micrograms, and 1.25mg tablets (Premarin) are included in the Devon Formulary as a first-line oestrogen alongside estradiol 1mg and 2mg tablets (Elleste Solo). Premique modified release tablets (CEE 300mcg / medroxyprogesterone 1.5mg) are included as a first-line continuous oestrogen-progestogen option alongside oral products containing estradiol / norethisterone.

A request has been received for the removal of CEE-containing products on the basis of “an increasing body of evidence to demonstrate that non-body-identical oestrogens are more likely to promote the development of breast cancer than estradiol”. Six citations were provided in support of the request.

The risk of breast cancer with HRT has been reviewed for the update to NICE guidance for menopause (NG23). The following statement is included in the draft NG23 guidance:

> *‘There is no difference in the increase in breast cancer risk between oestradiol and conjugated equine oestrogen when given at standard therapeutic dosage’.*

CEE-containing products are prescribed significantly less frequently than other first-line options and as of December 2023, their price increased significantly.

If the formulary oral estradiol option and oral estradiol-progestogen option is prescribed in place of CEE-containing products, the annual reduction in cost for the primary care prescribing budget would be around £115,077, which would only be realised if prescribing of HRT in Devon moves away from products containing CEE.

The FIG considered and accepted that CEE tablets and Premique modified release tablets (CEE 300mcg / medroxyprogesterone 1.5mg) be removed as formulary options.

The discussion noted that:

- The change to the formulary options had originally been proposed on the basis of lower breast cancer risk from products that do not contain CEE. However draft NICE guidance due to be published in 2024 states that there is no difference in the increase in breast cancer risk between estradiol and CEE when given at standard therapeutic doses,
- removal of these products from the Devon Formulary is on the basis that this will be cost saving.

It was agreed that the formulary would be updated alongside any changes to other HRT products following the FIG meeting scheduled to take place in March 2024.

ACTION: Following the FIG meeting in March, CEE tablets and Premique modified release tablets (CEE 300mcg / medroxyprogesterone 1.5mg) to be removed as formulary options

Transdermal oestrogens for HRT

Three transdermal estradiol products were proposed for addition to the Devon Formulary, Lenzetto 1.53mg/dose spray, Oestrogel Pump-Pack 0.06% gel, and Sandrena 500 microgram and 1mg gel sachets, for use as HRT either alone in women with no uterus or with oral micronised progesterone for women with a uterus.

Requests for the addition of these treatment options to the Devon Formulary have been received from specialist teams at University Hospitals Plymouth NHS Trust and Torbay & South Devon NHS trust and from a group of GPs with an interest in menopause based in North Devon.

Currently, the first-line formulary options are oral oestrogen for women without a uterus and for women with a uterus, either oral combined oestrogen-progestogen or oral oestrogen plus Mirena (levonorgestrel IUS) if acceptable to the patient. For patients who experience progestogenic adverse effects with the first-line oral oestrogen-progestogen, there is also a second-line oral option with an alternative progestogen. The formulary transdermal patches (oestrogen alone or combined oestrogen-progestogen) are also second-line options. The formulary recommends considering transdermal rather than oral HRT for women who are at increased risk of venous thromboembolism. Guidance from NICE NG23 (menopause), NICE Clinical Knowledge Summaries, the British Menopause Society (BMS) and the Royal College of Obstetrics and Gynaecology have identified specific clinical indications for transdermal HRT; the BMS also include patient preference. There is some similarity between the clinical indications for transdermal use and in some cases the indications relate to areas which have been reviewed by NICE for the forthcoming update to NICE NG23, due to be published in 2024. It is proposed the indications for transdermal use are reviewed if first-line use of the proposed transdermal products is not supported by the FIG.

Placebo-controlled randomised phase III trials for Lenzetto spray, Oestrogel and Sandrena gel have shown statistically significant reductions in the daily frequency and severity of moderate to severe hot flushes. There is a paucity of comparative data. Application reactions to the active treatments were reported in small numbers of patients in the trials, typically fewer than 5% of those receiving active treatments.

A cost effectiveness analysis of interventions for menopausal symptoms was conducted to support the NICE NG23 guidance issued in 2015. However, there was significant uncertainty in the analysis of relative treatment effects and the NG23 committee decided not to use the results of the analysis.

The specialists explained their reasons for wanting additional transdermal products in the formulary' including patient preference, flexibility of dosing and reasons of safety and tolerability which had been raised in the meeting papers.

Micronised progesterone for HRT

Micronised progesterone 100mg capsules have been proposed for addition to the Devon Formulary for endometrial protection in women with a uterus receiving a transdermal oestrogen (Lenzetto spray, Oestrogel and/or Sandrena gel). Requests for the addition of oral micronised progesterone to the Devon Formulary have been received from the NDDH and UHP specialist teams and the North Devon GPs with an interest in menopause. The applicants suggested improved tolerability and an improved safety profile for micronised progesterone compared with synthetic progestogens.

Currently, the first-line formulary options for women with a uterus are either oral combined oestrogen-progestogen or oral oestrogen plus Mirena (levonorgestrel IUS) if acceptable to the patient. For patients who experience progestogenic adverse effects with the first-line oral oestrogen-progestogen containing norethisterone, there is also a second-line oral option with an alternative progestogen, dydrogesterone. The formulary combined oestrogen-progestogen patches are also second-line options.

Comparative evidence from RCTs was sought on the tolerability of micronized progesterone compared with the formulary progestogen options at the same dose as the products listed in the formulary. One small RCT was identified comparing micronized progesterone with Mirena. No cost effectiveness analysis was identified which assessed micronised progesterone prescribed separately to an oestrogen.

Financial impact

EPACT2 primary care prescribing data shows that from September 2022 to August 2023 (inclusive), the total cost of Oestrogel, Lenzetto spray and Sandrena gel prescribed in primary care in Devon was £651,931. During the same period, the total cost of oral micronised progesterone to the primary care drug budget for the 12 month period was £676,653.

The financial impact of the proposals is uncertain. Lenzetto gel, Oestrogel and Sandrena gel were compared to the formulary first-line options to determine the estimated impact on the primary care prescribing budget if the proposed products are accepted for addition to the formulary as first-line options. The impact was variable, depending on the dose used and the comparator product. For individuals requiring oestrogen only, there was one scenario where use of Oestrogel could be cost saving, but in all other scenarios first line use of the proposed transdermal oestrogens would result in significantly increased costs.

Consideration was also given to the likely financial impact of recommending these products as a second-line option. The impact was variable depending on the dose used and the comparator product. For individuals requiring oestrogen only, there were some scenarios where second-line use of Oestrogel or Lenzetto could be cost saving, but others where routine use would result in significantly increased costs.

The use of the proposed transdermal oestrogens plus the proposed micronised progesterone in place of current formulary first- and second-line oral continuous oestrogen-progestogen options would result in increased annual costs for all products. However, using Oestrogel plus micronised progesterone in place of current formulary recommended transdermal continuous combined patches would likely result in lower costs. Financial assessments for Sandrena and Lenzetto (each with micronised progesterone) compared to transdermal continuous combined patches were variable, and many scenarios increased costs.

A discussion took place regarding the addition of the proposed transdermal oestrogen products and oral micronised progesterone to the Devon Formulary as first-line or second-line options:

- Additional work is required to refine the proposals with specialists
- FIG GPs highlighted the need for additional guidance to guide product selection.
- Specialists present highlighted that the importance of patient choice and that Mirena insertion services are not routinely available across Devon.

ACTION: Formulary Team to bring transdermal oestrogens for HRT and micronised progesterone for HRT back to the March FIG meeting for discussion.

6. NICE TA942: Empagliflozin for treating chronic kidney disease - Including update to type 2 diabetes mellitus pathway

NICE technology appraisal TA942

TA942 'Empagliflozin for treating chronic kidney disease' was issued on 20 December 2023. To meet the mandatory timeline for publishing Technology Appraisals (TAs) in the Devon Formulary, the FIG was asked to consider the proposed update to the formulary entry for empagliflozin under section 6.1.2 (Antidiabetic drugs).

Empagliflozin is the second Sodium-Glucose co-transporter 2 (SGLT2) inhibitor to be licensed for the treatment of chronic kidney disease (CKD). The licensing of empagliflozin for this indication is supported by a pivotal clinical trial (EMPA-KIDNEY) which evaluated cardio-renal outcomes in patients with CKD. The trial enrolled patients with evidence of progressive CKD who were receiving either an ACE inhibitor or ARB unless such treatment was either not tolerated or not indicated. The primary outcome was a composite of time to kidney disease progression and cardiovascular death.

The risk of kidney disease progression or cardiovascular death was significantly reduced with empagliflozin treatment compared with placebo. The primary endpoint was mainly driven by the eGFR reduction ≥40% surrogate marker of kidney disease progression.

It is proposed that empagliflozin is a blue (second-line) option for the management of CKD as empagliflozin is recommended as an add-on to standard care under TA942 and some patients who are eligible for empagliflozin under NICE TA942 do not meet the criteria for referral to a renal specialist set out in NICE NG203 and implemented locally.

Updates to the formulary entries for empagliflozin and dapagliflozin were proposed to include new SmPC dosing recommendations for prescribing in CKD and the NICE NG203 threshold for initiation of ACE inhibitor or ARB. The note on type 2 diabetes for both drugs has been updated to make reference to the earlier place in therapy for SGLT2 inhibitors under NICE guidance NG28.

The draft formulary entry was sent to diabetes specialists and renal specialists in Devon for review. Responses indicated the proposed entry was acceptable, with minor amendments which were included in the proposed updates to the entries presented to the FIG.

The recommended daily dose of empagliflozin for chronic kidney disease is 10mg once daily. Empagliflozin is available in a pack of 28 tablets. The cost of 28 days' supply is £36.59 and the annual cost is £475.67.

The FIG considered and accepted empagliflozin as a blue (second-line) formulary option for chronic kidney disease.

The FIG also agreed that the updates to the formulary entries for empagliflozin and for dapagliflozin were clear and clinically appropriate. Subject to one typographical correction.

The discussion noted that:

- The TA recommendations for dapagliflozin and empagliflozin for the management of CKD differ.
- the FIG acknowledged that the criteria of NICE Technology Appraisals cannot be amended or further restricted locally.

Type 2 diabetes pathway

The FIG agreed the update to the formulary guidance for type 2 diabetes to incorporate the new treatment pathway, based on NICE guidance NG28, at the September 2023 meeting (pending consultation with specialists following the FIG meeting). At the request of a specialist, it was proposed that a statement on combination treatment with a SGLT2 inhibitor and a GLP-1 receptor agonist is removed. A reference to the latest update on the national shortage of GLP-1 receptor agonist has been added and following the publication of TA942, empagliflozin has been added as an option for the management of CKD in patients with type 2 diabetes.

The FIG considered and accepted the update to the type 2 diabetes mellitus pathway.

ACTION: Formulary Team to publish the NICE TA942: Empagliflozin for treating chronic kidney disease.

ACTION: Formulary Team to publish the type 2 diabetes mellitus pathway

7. Management of eczema

In September 2022, dermatologists in UHP produced an eczema treatment pathway document with the intention of reducing inappropriate referrals to secondary care. The UHP document included several non-formulary options and was not fully aligned to existing formulary guidance. The current formulary guidance has been reviewed and amended based on NICE CG57 on atopic eczema in

children, in consultation with local paediatricians and dermatologists. The NICE guideline is specific to children, but the proposed formulary guidance is applicable to all ages.

This item was discussed at the last FIG, which was not quorate; there was broad agreement with the guidance, but additional specialist consultation was requested to understand their preferred approach to the initiation of topical calcineurin inhibitors (TCIs). Local specialists were asked their opinion on three approaches on the initiation of TCIs ranging from GPs prescribing following initiation by specialists to GPs initiating without specialist involvement.

Feedback from specialists suggests a consensus that GPs may initiate TCIs without the involvement of a specialist. Based on this feedback, the guidance has been updated to classify TCIs as blue (second line) options, appropriate for GP initiation without specialist involvement, when eczema has not been controlled by topical corticosteroids. The availability of advice and guidance for GPs requiring specialist input when considering initiating topical calcineurin inhibitors is also highlighted.

The FIG considered and accepted the reclassification of TCIs from amber (specialist input) to blue (second line) in the South and West presentation of the Devon Formulary. The discussion additionally noted that:

- Steroids and TCIs can be used at the same time but not on the same area of skin. This will be clarified in the formulary guidance.
- Information regarding cow's milk should be clarified and updated on other formulary pages.

It was agreed that the Devon Formulary be updated in line with the discussion.

ACTION: Formulary Team to update the Devon Formulary guidance on eczema in line with the discussion.

8. Acute asthma management: paediatric and young children

Dr Keira Goss (Strategic Clinical Advisor & ICS Devon Lead for Asthma for Children & Young People) has been working with Dr Tom Debenham (Clinical Lead GP), and the Devon Referral Support Service (DRSS) to review and update the clinical referral guideline (CRG) for acute asthma in children and young people (CYP).

The draft CRG contained drug management advice for acute asthma which was broadly in line with existing formulary recommendations, but with additional emphasis and detail in some areas. Dr Goss has also produced a one-page flowchart to guide assessment and management.

Since drug management advice is the remit of the formulary, it has been agreed that this information will be removed from the CRG. The formulary team had been asked to undertake a review of existing guidance on the management of acute asthma to see if any updates are required. In addition, it has been proposed that the acute asthma treatment flowchart could be hosted as a formulary asset, agreed and maintained via the Devon FIG.

The flowchart was taken to the FIG meeting for an early consultation. There are some points requiring clarification. Although the existing flowchart is limited to CYP, it has been suggested that consideration should be given to whether it can be extended to cover management of acute asthma in adults.

The FIG was asked to review the proposed guidance. In particular:

- Whether there are any specific points which require consideration/clarification?
- Whether the flowchart is clear and easy to follow?
- Would including the flowchart as a formulary asset be helpful for local clinicians?
- Are there any questions for local specialists regarding management of acute asthma?

The FIG considered the pathway for the management of acute asthma: paediatric and young children. The discussion agreed that:

- The flowchart was clear and educational, but not exactly in line with national guidance.
- Opinions were mixed on whether the flowchart is necessary.
- It is not the remit of the formulary to produce guidance on the management of acute or life threating conditions when there is clear national guidance.
- CRGs are not the place for drug management guidance.
- The flowchart may be a useful educational resource but would need to follow the national guidance and be updated rapidly following any changes to the source material.
- Feedback to Dr Goss should include that the 'Higher risk children' box should be more prominent and should allow for a lower threshold for admission if GPs feel it is required.
- the Formulary Team will feedback on the FIG discussion to the lead author.

ACTION: Formulary Team to feedback on the FIG discussion to the lead author of the flowchart for acute asthma.

9. APO-go PFS and APO-go POD

An application has been received from a Parkinson's Nurse at RDUH to add APO-go POD to the formulary. APO-go POD is a cartridge containing apomorphine solution for subcutaneous infusion. The applicant has highlighted that it is a pre-filled ready to use cartridge that is easier to use.

Inclusion of APO-go pre-filled syringe (PFS) is also proposed; APO-go PFS is already extensively in use in Devon. Apomorphine is currently amber (specialist input) in N&E Devon, and red (hospital only) in S&W Devon. APO-go PFS is already included in the formulary for use in S&W Devon.

For both APO-go POD and PFS, the infusion rate is set dependent on patient need, with infusions running for waking hours only unless the patient experiences severe nighttime problems.

APO-go products are included in most of the formularies across the Southwest although mostly as hospital/specialist only.

The regulatory authority considered APO-POD and APO-go PFS to be line extensions of the original APO-go products, and determined that there was no need for determining the bioavailability or showing bioequivalence as the subcutaneous route provides 100% bioavailability.

The cost per mg of apomorphine is the same regardless of APO-go ampoules, APO-go PFS, and APO-go POD, however APO-go Pen (already listed in the formulary) is more expensive.

APO-go PFS represents the majority of primary care apomorphine prescribing in Devon between Nov 2022 and Oct 2023; APO-go PEN and Dacepton cartridges were used significantly less. There was no prescribing of APO-go POD. APO-go POD / APO-go PFS are not available from local

wholesalers. The company was contacted to understand routes of supply. They indicated that APO-go products are usually supplied via secondary care, however community pharmacy can order direct if they set up an account.

- The FIG considered and accepted the inclusion of APO-go POD 100mg/2ml solution for infusion cartridges into the Devon Formulary for North & East Devon.
- The FIG considered and accepted the inclusion of APO-go PFS 50mg/10ml solution for infusion pre-filled syringes into the Devon Formulary for North & East Devon.
- The FIG accepted the proposed updates to the formulary entry without amendment.

The pharmacy representatives from T&SD and UHP confirmed that these products are accepted for use in their trusts and therefore may be added as red (hospital only) for South & West Devon.

ACTION: **Formulary team to add the APO-go POD 100mg/2ml solution for infusion cartridges and APO-go PFS 50mg/10ml solution for infusion pre-filled syringes to the Devon Formulary as amber (specialist input) in N&E Devon and as red (hospital only) in S&W Devon.**

10. Triptan harmonisation: Including proposal to align formulary traffic light classification of frovatriptan across Devon

The FIG was asked to consider harmonisation of triptan recommendations across South & West and North & East Devon, including a proposal to align the formulary traffic light classification of frovatriptan to blue (second line). Frovatriptan is currently blue (second line) in N&E Devon and an amber (specialist input) in South & West Devon.

Triptans are a primary care treatment. Specialists at UHP and Torbay & South Devon Hospital have asked that all triptans be included on the formulary on the basis that they are cheaper than rimegepant. The Formulary team has looked at other formularies across the Southwest region, most have four triptans some only three.

The FIG considered the proposal to align the formulary traffic light classification of frovatriptan across Devon and discussed the specialists' request for all triptans to be included in the Devon Formulary.

The discussion noted that:

- Frovatriptan triptan could be classified as blue (second line).
- It was agreed that a range of triptans should be available, however it is important to be familiar with the triptans being prescribed.
- If all triptans were included, there is a risk of increasing costs by starting patients on a higher cost triptan when a less expensive triptan may be as effective.
- Once a patient has tried several triptans which have not worked, GPs will start to question the diagnosis and seek specialist advice, and some patients may lose confidence in their GP. They are often less happy to try another triptan.
- If several triptans have been tried without success, an alternative treatment such as rimegepant may be required.
- The FIG did not wish to include all triptans in the formulary.

The Formulary team will work with specialists to provide more guidance to primary care.

ACTION: **Formulary team to work with specialist to provide more guidance to primary care.**

11. Azathioprine for the treatment of autoimmune chronic active hepatitis (AIH) in adults – extension of guideline to cover South Devon

The prescribing of azathioprine in primary care in Devon is supported by nine SMS guidelines, depending on locality and specialty. These guidelines define the specialist, GP and patient responsibilities associated with "shared care" and outline monitoring requirements to support safe prescribing.

In May 2022, a Devon-wide guideline was published covering the use of oral azathioprine and mercaptopurine for the treatment of inflammatory bowel disease (IBD) in adults. This guideline updated and replaced three existing gastroenterology guidelines, including a historic South Devon guideline which covered the use of azathioprine for the treatment of autoimmune chronic active hepatitis (AIH). However, this left a gap in South Devon & Torbay where the previous guideline existed. The specialist team at Torbay and South Devon NHS Foundation Trust has asked that the existing West Devon guideline is extended to cover South Devon.

The following amendments were proposed to the existing guideline:

- Minor amendments throughout to reflect the extended geographical / provider coverage.
- GP responsibilities:
  - Updated vaccine information (in line with the more recently published Devon-wide guideline for azathioprine / 6-mercaptopurine for IBD).
  - Recommendation to seek specialist advice regarding pregnancy included for clarity.
- Monitoring:
  - Minor amendment to specialist monitoring to reflect that baseline chest x-ray is not undertaken for all patients (it is "considered").
  - Updated MCV threshold to reflect different "normal" ranges reported by the acute trust labs (in line with other SMS guidelines covering more than one trust footprint).
  - LFT threshold wording shortened for brevity (test and threshold remain the same).
- Updated contact details

No significant resource impact is expected as these patients were already having azathioprine prescribed and monitored in primary care under the withdrawn South Devon gastroenterology guideline.

SMS remuneration will be as per the General Practice SMS framework. Final settlement of funding is agreed with a Local Medical Committee (LMC) negotiations meeting. Since this is extension of an existing guideline to an additional area without significant changes to individual responsibilities, LMC has indicated agreement with continued funding at the existing level.

The FIG considered and accepted the proposed amendments and extension of the West Devon SMS guideline for azathioprine for the treatment of autoimmune AIH in adults to cover South Devon.

ACTION: **Formulary team to publish the accepted South and West Devon SMS guideline for azathioprine for the treatment of AIH in adults.**

12. MHRA Drug Safety Updates (December 2023 – January 2024) ▪ Isotretinoin: new safety measures ▪ NPSA: Valproate: new regulatory measures for oversight of prescribing

December 2023

Aripiprazole (Abilify and generic brands): risk of pathological gambling
Aripiprazole tablets are included in the Devon Formulary as an amber formulary option for the treatment of schizophrenia in adults and in adolescents from 15 to 17 years in line with TA213, and the treatment of moderate to severe manic episodes in adolescents with bipolar 1 disorder in line with TA292. Aripiprazole prolonged release injection is a red (hospital-only) formulary option for the treatment of schizophrenia in adults.

- There has been an increase in the number of Yellow Card reports of gambling disorder and pathological gambling associated with aripiprazole use; concerns have also been raised about a lack of awareness of this issue.
- The SmPC contains information on pathological gambling and other impulse control disorders.

The formulary entry for aripiprazole tablets and aripiprazole injection will be updated with the key points and a weblink to the article.

Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions

- Hydroxocobalamin injection is a green (first-line) Devon-wide formulary option for the treatment of megaloblastic anaemia. Cyanocobalamin tablets are an amber formulary option in South & West Devon only. Hydroxocobalamin and cyanocobalamin contain cobalt. There are case reports in the literature describing cobalt sensitivity-type reactions in patients being treated for vitamin B12 deficiency.
- Cobalt allergy is estimated to affect 1 to 3% of the general population. Healthcare professionals prescribing vitamin B12 products to patients with known cobalt allergy should advise patients to be vigilant for signs and symptoms of cobalt sensitivity and treat as appropriate.

A weblink to the article will be included in the formulary entries for hydroxocobalamin tablets and cyanocobalamin injection.

Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months
A National Patient Safety Alert on valproate medicines was issued on 28th November 2023 followed by a MHRA safety update on 12th December. Organisations are requested to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semi-sodium (valproate). A summary of the new safety measures was provided in the meeting papers.

Letters sent to healthcare professionals and drug alerts in November 2023

Valproate National Patient Safety Alert

On 28 November 2023, the MHRA issued a National Patient Safety Alert that asked organisations to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate).

January 2024

Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell): new safety and educational materials to support regulatory measures in men and women under 55 years of age

The new safety measures were the subject of a NPSA and Drug Safety Update issued 18th December 2023. This update includes links to the new safety and educational materials which were not available when the NPSA and Drug Safety Update on valproate medicines were issued. Weblinks to these materials will be included in an update to the Devon Formulary covering the new valproate safety measures.

Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate

Systemic and inhaled fluoroquinolones are associated with a risk of serious, disabling, long-lasting and potentially irreversible adverse reactions, estimated to occur in at least between 1 and 10 people in every 10,000 who take a fluoroquinolone.

Restrictions to the use of fluoroquinolones were introduced in 2019 to minimise the risk of these reactions. The MHRA has reviewed the effectiveness of these measures in the UK and sought the advice of the Commission on Human Medicines (CHM). As a result of this review a reminder about these risks was published in the August 2023 issue of Drug Safety Update. The MHRA has now taken additional regulatory action to update the indications for all systemic fluoroquinolones to state they should only be used when other commonly recommended antibiotics are inappropriate. Situations where other antibiotics are considered to be inappropriate are where:

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

Quinolone antibiotics are included as treatment options in the Devon Formulary in line with national guidance. The Formulary team will liaise with the Devon Antimicrobial Stewardship Group, trust microbiologists and relevant specialists over the formulary indications for quinolone antibiotics. Proposals to update the formulary will be brought to a future meeting for discussion and FIG decision.

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

A recent European regulatory review recommended ‘atrial fibrillation’ should be listed as a common adverse reaction (may affect up to 1 in 10 people) in the product information of medicines containing omega-3-acid ethyl esters. Patients taking omega-3-acid ethyl ester medicines for the treatment of hypertriglyceridaemia should be advised to seek medical attention if they develop symptoms of atrial fibrillation.

The formulary entry for omega-3-acid ethyl ester medicines will be updated with key points and a weblink to the article.

ACTION: **Formulary Team to update the relevant Devon Formulary sections with recommendations from the MHRA Drug Safety Updates for December 2023 and January 2024.**

MHRA: Isotretinoin (Roaccutane): introduction of new safety measures

Isotretinoin is a red (hospital-only) option in the Devon Formulary. The current formulary entry is in line with previous SmPC recommendations for isotretinoin and British Association of Dermatology guidance on the interpretation of SmPC recommendations, and states that isotretinoin may only be prescribed from the Dermatology Department under the supervision of a Consultant Dermatologist.

The Drug Safety Update issued in October 2023 was discussed at the December 2023 FIG meeting. The October update included an article on the introduction of new safety measures for isotretinoin. As this was an extensive article and additional supporting documentation had been developed by professional organisations, it was proposed that a summary of the changes and draft update to the formulary guidance and entry for isotretinoin be brought to a future FIG meeting for discussion.

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

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

An extensive package of additional supporting documents has been developed by the BAD, British Dermatology Nursing Group (BDNG) and other stakeholders to support these changes.

The Formulary team is reviewing the guidance and will bring an updated entry for isotretinoin to a future meeting.

A discussion took place. It was noted that:

- Nationally produced referral forms and guidance on steps to take pre-referral are not necessarily appropriate for GPs as a GP will refer a patient for a specialist opinion on the management of acne and not specifically for the initiation of isotretinoin.
- There will be an extended formulary entry. The role of GPs/specialists will be clarified with links included to national guidance.
- Discussions are ongoing at system level.

ACTION: **Formulary team to bring an updated formulary entry for isotretinoin to a future meeting.**

NPSA: Valproate: new regulatory measures for oversight of prescribing

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

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

The NPSA indicates that a system-wide approach to the implementation of valproate safety measures is required. The MHRA is asking organisations to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate). This follows a comprehensive review of safety data, advice from the Commission on Human Medicines and an expert group, and liaison with clinicians and organisations. The aim of the measures is:

- to ensure valproate is only used if other treatments are ineffective or not tolerated, and that any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the Pregnancy Prevention Programme (PPP).
- to reduce initiation of valproate to only in patients for whom no other therapeutic options are suitable.

The regulatory measures mean:

A. Valproate must not be started in *new* patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.

B. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

The Formulary team explained that this had been brought to the FIG for information. A system wide group has been set up as recommended in the NPSA. A Formulary team member joined the first ICB / system meeting on valproate. Further information on the system-wide approach was provided by the Medicines Optimisation team formulary representative.

The Formulary team are reviewing the available material to identify information which should be included or linked to from the formulary webpage. An update to the formulary on the new safety measures for valproate medicines will be brought to a future FIG meeting for discussion.

ACTION: Formulary team to bring a formulary update on valproate safety measures to a future meeting.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
22/61	Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin.	Formulary team	Ongoing
22/62	Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group.	Formulary team	Ongoing
22/98	Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients.	Formulary Team	Ongoing
23/42	Management of Hypertension (Update) – following consultation with specialists, bring draft guidance back to the FIG via the e-FIG process if required.	Formulary Team	Ongoing
23/66	NICE TA599: Sodium zirconium cyclosilicate (SZC) for treating hyperkalaemia (consideration of reclassification from red to amber) - liaise with trust laboratories over a method of identifying serum potassium results for patients receiving SZC via the FIG GP representative for the Devon Pathology Optimisation Group.	Formulary team	Ongoing
23/69	Melatonin for use in adult patients – add RBD in Parkinson's disease as an indication to the melatonin entry in line with the discussion. *Post meeting note: Awaiting data from acute trusts in respect of patient numbers to assess likely impact on primary care prescribing budget.*	Formulary Team	Ongoing
23/72	Guanfacine for attention deficient hyperactivity disorder (ADHD) in children and young people aged 6 – 17 years – submit guideline to LMC for negotiation of remuneration with ICB Primary Care Team.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/76	Asymptomatic bacteriuria in pregnancy – contact the microbiologist leading the peninsula wide work to request that any relevant outcomes are communicated to the Formulary Team	Formulary Team	Complete
23/77	Management of eczema – liaise with specialists regarding a harmonised classification for topical calcineurin inhibitors for eczema and bring back to the FIG via an appropriate route	Formulary Team	Complete
23/78	Infected eczema - liaise with specialists regarding the FIG discussion and update the proposed formulary entry for Infected eczema in line with feedback and bring back to the FIG via an appropriate route.	Formulary Team	Ongoing

23/85	MHRA Drug Safety Updates (October) – Formulary Team to bring article on isotretinoin for discussion at a future meeting.	Formulary Team	Complete
24/01	Report of e-FIG decisions: January 2024 – update the Devon Formulary in line with the January 2024 e-FIG decisions. *<u>Post meeting note:</u> ASB update published. Lithium SMS published. Insomnia guidance – publication paused pending development of guidance on deprescribing hypnotic drugs (on March agenda).*	Formulary team	Ongoing
24/02	Product Applications: Removal of conjugated equine oestrogens - Following the FIG meeting in March, CEE tablets and Premique modified release tablets (CEE 300mcg / medroxyprogesterone 1.5mg) to be removed as formulary options. *<u>Post meeting note:</u> Pending consideration of remaining HRT proposals (on March agenda).*	Formulary team	Pending
24/03	Product Applications: Bring transdermal oestrogens for HRT and micronised progesterone for HRT back to the March FIG meeting for discussion.	Formulary team	On March agenda
24/04	Publish NICE TA942: Empagliflozin for treating chronic kidney disease - Including the update to type 2 diabetes mellitus pathway.	Formulary team	Complete
24/05	Type 2 diabetes mellitus pathway to be published.	Formulary Team	Complete
24/06	Management of eczema: UHP Treatment Pathway - update the Devon Formulary guidance on eczema in line with the discussion.	Formulary team	Pending
24/07	Acute asthma management: paediatric and young children - feedback on the FIG discussion to the lead author of the CRG for acute asthma.	Formulary team	Complete
24/08	Formulary team to add the APO-go POD 100mg/2ml solution for infusion cartridges and APO-go PFS 50mg/10ml solution for infusion pre-filled syringes to the Devon Formulary as amber (specialist input) in N&E Devon and as red (hospital only) in S&W Devon.	Formulary team	Complete
24/09	Triptan harmonisation: Including proposal to align formulary traffic light classification of frovatriptan across Devon – Work with specialists to provide more guidance to primary care.	Formulary team	Ongoing
24/10	Publish the accepted South and West Devon SMS guideline for azathioprine for the treatment of AIH in adults.	Formulary team	Complete
24/11	MHRA Drug Safety Updates (December 2023 January 2024) Formulary Team to update the relevant Devon Formulary Sections with recommendations from the MHRA Drug Safety Update for December and January 2024.	Formulary team	Pending

24/12	MHRA Drug Safety Update: Isotretinoin (Roaccutane): introduction of new safety measures. Bring an updated formulary entry for isotretinoin to a future FIG meeting.	Formulary team	On March agenda
24/13	MHRA Drug Safety Update: bring a formulary update on valproate safety measures to a future meeting.	Formulary team	On March agenda