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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 6th December 2023

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
Heidi Campbell	Pharmacist	NHS Kernow ICB
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Rebecca Lowe	Joint Formulary Technician	NHS Devon ICB
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Name	Job Title	Organisation
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon
Dr David Kernick	Clinical Lead	Exeter Headache Clinic
Dr Alex Degan	Primary Care Medical Director	Devon ICS
Dr Ray Sheridan	Elderly Care Consultant and Clinical lead for RDUH Covid Medicines Delivery Unit	RDUH

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Glen Allaway acted as meeting chair in the absence of Susie Harris.

Glen Allaway explained the meeting was not quorate and that although it would be possible for the group to discuss the agenda items, decisions would need to be ratified either through the e-FIG process or at a future meeting of the group.

Chairman's welcome

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

Apologies

NAME	JOB TITLE	ORGANISATION
Susie Harris	Consultant (Elderly Care)	RDUH
Andy Craig	GP	NHS Devon
Chris Sullivan	Deputy Care Pharmacist	DPT
Jess Parker	GP	NHS Devon
Lucy McGavin	Consultant Neuroradiologist (Dr McGavin had requested to attend the meeting as an observer)	UHP
Natasha Wood	Headache Specialist Nurse (agenda item 13)	UHP

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
COVID-19 medicines: • Nirmatrelvir and ritonavir tablets (**Paxlovid**) • Molnupiravir capsules (**Lagevrio**) • Remdesivir IV infusion (**Veklury**) • Sotrovimab IV infusion (**Xejudy**)	 Pfizer Ltd Merck, Sharpe and Dohme UK Ltd Gilead Sciences Ltd GlaxoSmithKline UK
Asymptomatic bacteriuria in pregnancy: • Nitrofurantoin, various formulations • Amoxicillin, various formulations • Cefalexin, various formulations	 Various manufacturers Various manufacturers 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 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

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
• Various non/sedating antihistamines • Phototherapy • Various cow's milk protein free formulae	Various manufacturers Various providers Various manufacturers
Infected eczema: • Various emollients (creams/ointments/gels etc.) • Topical corticosteroids • Topical antibiotics (including generic fusidic acid and **Fucidin**) • Systemic antibiotics including flucloxacillin, clarithromycin, and erythromycin (various formulations)	 Various manufacturers Various manufacturers Various manufacturers (including LEO Pharma) Various manufacturers
Management of suspected DVT and PE: • 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
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

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
Ryeqo for uterine fibroids:	Gideon Richter Ltd
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
AYMES ActaSolve Protein Compact **Alternatives:** • Fortisip Compact Protein • Various Compact Protein Oral Nutritional Supplementation	AYMES Nutrition Nutricia Ltd Various manufacturers

Name	Job Title	Declaration
Dr Alex Degan	Primary Care Medical Director	Shareholder in above manufacturing company/companies: My wife has shares in Pfizer. Work as paid advisor to above manufacturing company/companies: I have worked as advisor to various pharmaceutical companies in the form of advisory boards or similar on a number of occasions in the past 3 years although I don't believe I have offered services to any of the manufacturers of COVID meds for over 3 years.

Dr David Kernick	Clinical Lead Exeter Headache Clinic	Work as paid advisor to above manufacturing company/companies Have given advisory work for Pfizer.
Nick Keysell	GP	Any other interests (Including personal or family medical conditions) which could be seen as influencing views of the drug (s) under consideration. I am a regular attender to the COVID medicines steering group. There is pressure to alter the formulary prescribing to support the CMDUs. I will voice my opinions in the FIG discussions, but feel it is important the FIG are aware of the potential for unconscious bias from myself.
Rebecca Lowe	Joint Formulary Technician	Any other interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) under consideration. Part time roles as community pharmacy locum and bank pharmacy technician at prison pharmacy.
Dr Ray Sheridan	Elderly Care Consultant and Clinical Lead for RDUH COVID Medicines Delivery Unit	Have taken part in a trial for the above drug(s)/device(s). Please give brief details below of any declared interest: PI for RECOVERY trial – I didn't receive any funding for that role which was a non-commercial NHS Public Health Study.

2. Minutes of the meeting held on 27th September 2023 and Actions/Matters Arising

Minutes of the meeting held on 27th September 2023

Subject to ratification by a quorum of the FIG through an appropriate route, the minutes of the meeting held on 27th September 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
22/80	Pharmacological treatment for type 2 diabetes (NICE NG28): bring the formulary guidance for the pharmacological treatment of Type 2 diabetes to a future meeting.	Formulary Team	Complete
22/92	Report of e-FIG decisions: November 2022: Treatment of vaginal candidiasis - seek the views of specialists on the use of vaginal creams which require insertion using an applicator during pregnancy and bring revised guidance back to the FIG via the appropriate route. ***Post meeting note****: to be included under a wider review including recurrence of vaginal candidiasis*	Formulary Team	Closed
22/98	Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients.	Formulary Team	On agenda
23/02	Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin – Proposed Formulary Entry to be amended in line with the discussion and added to the local formulary.	Formulary Team	Complete
23/04	4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.	Formulary Team	On agenda
23/28	Bevespi Aerosphere and Trixeo Aerosphere – bring back to FIG when specialists can attend. ***Post meeting note****: Formulary team are consulting with primary care respiratory champions.*	Formulary Team	Closed
23/29	Metolazone 5mg tablets (Xaqua) – consult with heart failure and renal teams for metolazone 5mg tablets (Xaqua). ***Post meeting note****: included under the review of chronic heart failure*	Formulary Team	Closed
23/41	Management of Hypertension (Update) – consult with specialist on proposed guidance.	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
23/46	Sodium zirconium cyclosilicate for treating hyperkalaemia: consideration of reclassification – work with specialists on the prescribing guidance.	Formulary Team	Complete
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	Ongoing
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	Ongoing
23/53	Insulins undertake consultation with adult and paediatric specialists. Any significant changes will be brought back to the FIG via an appropriate route.	Formulary Team	Complete
23/55	Chronic heart failure (including NICE TA902) - Consult with heart failure specialists.	Formulary Team	Complete
23/58	Priadel (lithium) update – present the lithium guideline to the LMC for negotiation of remuneration.	SMS Guidelines Lead	Complete
23/59	Update the relevant formulary sections with recommendations from MHRA Drug Safety Updates May and June 2023.	Formulary team	Ongoing
23/60	Lurasidone in adults and children – accepted formulary entry for lurasidone in adults and children to the Devon Formulary.	Formulary Team	Complete
23/61	TA906 Rimegepant for preventing migraine - publish the agreed formulary entry for rimegepant	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	Ongoing
23/63	Negative Pressure Wound Therapy (NPWT) – publish updated guidance.	Formulary Team	Complete
23/64	Add Glucagon 500micrograms and 1mg pre-filled pens (Ogluo) for adults to the formulary and update the GlucaGen HypoKit entry in line with the discussion	Formulary Team	Complete
23/65	Remove ActivHeal Silicone Foam Border from the Formulary and publish the agreed Formulary entries for the Allevyn Gentle and Allevyn Life products	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
23/67	Reclassification of sildenafil for secondary Raynaud's phenomenon/digital ulceration in systemic sclerosis – publish the formulary entry for Sildenafil in line with the discussion.	Formulary Team	Complete

23/68	Melatonin for use in adult patients – bring revised formulary guidance on insomnia to a future meeting.	Formulary Team	On agenda
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
23/70	Guanfacine for attention deficient hyperactivity disorder (ADHD) in children and young people aged 6 – 17 years – Feedback to specialists that it would be useful if they could provide a patient-held chart for recording height and weight rather than this being recorded in two separate places.	Formulary Team	Complete
23/71	Guanfacine for attention deficient hyperactivity disorder (ADHD) in children and young people aged 6 – 17 years – Update the SMS Guidelines in line with the discussion.	Formulary Team	Complete
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	Ongoing

3. Matters Arising

FIG membership update

Tom Kallis, Community Pharmacist formally stepped down from the FIG in October.

Tom was a co-opted member of the FIG, representing community pharmacy. The Formulary Team is not immediately seeking to find a replacement as there are now several alternative routes by which the group can seek a community pharmacy perspective in relation to specific agenda items when required.

The FIG thanked Tom for his input.

Updated Declaration of Interest (DoI)

Following the meeting in September additional information was received from Rebecca Stuckey (specialist headache nurse, UHP) which should have been included on her DoI. The information states that:

'I presented two posters and gave a talk to other headache specialists and received £2,074.70 as an honorarium for Teva in 2022'.

This has been discussed with the Chair; this declaration would not have resulted in Ms Stuckey being excluded from discussions and it is considered unlikely that it would have materially affected the discussion. It was noted for completeness and transparency.

Report of e-FIG decisions

The FIG accepted the inclusion of Aymes ActaSolve Protein Compact as an amber (specialist input) low volume high protein powder milkshake style Oral Nutritional Supplement for patients with higher protein requirements who also have a small appetite and may struggle to drink a larger volume of fluid. The FIG accepted the proposed formulary entry.

The Formulary has been updated.

Launch of new Formulary & Referral website

The new Devon Formulary & Referral website was launched on 31st October, after a year of designing, developing, and testing with colleagues in DRSS and the external developer.

All the existing guidance and drug recommendations have transferred across to the new website. The multiple-choice quizzes were taken down from the website during transition, this provided an opportunity for them to be updated and reintroduced.

Improvements to the new site include:

- Easier navigation, with improved search functionality which can also be viewed in a drop-down list. Users can more easily filter between formulary and referral results.
- Improved layout of the website pages to make browsing easier.
- Switching between the North and East Devon presentation and the South and West Devon presentation is much easier with a colour coded “switch to” button on each page.
- The highly requested A-Z drug page has been added, offering quicker product identification and traffic-light classification at a glance.
- Full optimisation on mobile devices, including recognition of device rotation, zoom capabilities, and toggle functions to ease viewing.

It was noted that there had been early issues with existing hyperlinks, which have been fixed. FIG members were asked to report any issues or problems to the Formulary Team. Hyperlinks to contact forms can be found at the bottom of each page.

A discussion took place:

- FIG members were asked to promote the Devon Formulary within their organisations.
- Positive comments have already been received from users and colleagues at other ICBs and external organisations.
- The FIG congratulated the Formulary team, in particular Darren Wright who led on delivery of the project, for the successful launch of the new Devon Formulary website. It was noted that the website is widely used by both primary and secondary care and that it is a highly regarded and valuable resource for all users.

4. Items for Information

Recent Drug Decisions

The FIG received a report of the recent drug decisions.

5. COVID-19 medicines in non-hospitalised patients

The Primary Care Medical Director Devon Integrated Care System and the Clinical Lead for the RDUH Covid Medicines Delivery Unit (CMDU) joined the meeting for the discussion of this item.

NICE issued TA878 for COVID-19 treatments at the end of March recommending Paxlovid and sotrovimab for patients at risk of progression to severe COVID-19 who do not require hospitalisation. At the same time, the oral antivirals, Paxlovid and molnupiravir, were made available to prescribe on FP10.

COVID-19 treatments are currently classified as 'red' hospital only treatments in the formulary. The FIG considered draft formulary guidance for COVID-19 treatments for non-hospitalised patients including proposals to reclassify Paxlovid from red (hospital-only) to green (first-line) and molnupiravir from red to amber (specialist input) (to be prescribed in primary care on the advice of a specialist) at its meeting in July. At that time, the FIG was undecided on whether it is clinically appropriate for Paxlovid and molnupiravir to be reclassified from hospital-only treatments. The FIG considered that a decision would need to be taken in the context of the service provided by the CMDUs.

It was agreed that the Formulary team would update the proposed guidance in line with the discussions and bring this to a future meeting.

Key areas of concern from the FIG discussion in July were:

- the extensive list of drug interactions for Paxlovid and the clinical significance of these interactions.
- Whether the support offered to primary care by the CMDUs outlined in the draft clinical referral guidance would change in the future and there were some questions over the future of the RDUH service for the trust and the ICB to resolve.

There has been no change to the treatment pathway since the discussion in July.

All patients must meet all initial assessment criteria for a COVID-19 treatment before a decision can be taken on the appropriate treatment. There is advice and guidance from the CMDU at a number of points in the treatment pathway. If the patient meets the initial criteria for a COVID-19 treatment, the GP may assess the patient's suitability for initiating Paxlovid in primary care without specialist support, or alternatively a GP can refer the patient for the CMDU to assess suitability for Paxlovid and prescribe a COVID-19 treatment if required.

At the time of the July FIG meeting, Paxlovid was green in only four formularies in England. This included the formularies for Cornwall & Isles of Scilly, Dorset and Somerset. The Formulary Team contacted the relevant Medicines Management teams for information on the pathways supporting the green formulary classification. At the time, a primary care pathway was under discussion in Cornwall and the CMDU was providing the service. In Dorset and Somerset, the secondary care CMDUs have closed and the ICBs have commissioned COVID-19 primary care services to support GPs. In Dorset and Somerset, GPs can either assess a patient for suitability for Paxlovid and prescribe if appropriate, or they can refer a patient to the COVID-19 primary care service. Unlike Devon, there is no support from CMDU specialists. The primary care service is run by a PCN in Dorset and the Out of Hours service in Somerset.

Recently, NICE has undertaken a rapid appraisal of the TA878 recommendations for Paxlovid to consider additional patient groups at risk of progression to severe COVID-19. There is no date for publication yet. NHS England has sent a submission to NICE requesting the proposed additional patient groups are reconsidered with an extended implementation period of one year rather than the usual three months. The NICE Executive has indicated they are minded to accept the proposals from NHS England. When the update to the TA is published, it will be scheduled for discussion by the FIG.

The local CMDU specialists, the ICS COVID-19 service lead and the DRSS GP representative for COVID-19 were consulted over the update to the draft formulary guidance for COVID-19 medicines in non-hospitalised patients following the FIG discussion in July. The FIG was asked to consider updated draft formulary guidance to identify whether there were any areas where clarity was required which the Formulary team could work on with the CMDU specialists before a final decision is taken.

The FIG considered and accepted in principle the proposed formulary guidance with minor amendment. The FIG did not specifically discuss the reclassification of Paxlovid and Molnupiravir. COVID-19 medicines in non-hospitalised patients will be brought back to FIG for ratification via an appropriate route.

ACTION: Formulary team to 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.

6. Asymptomatic bacteriuria (ASB) in pregnancy

In 2019 formulary guidance was agreed, supported by antimicrobial specialists in Devon, to recommend routine screening for ASB early in pregnancy as it is a risk factor for pyelonephritis, low birth weight and premature delivery. The recommendation was based on three NICE guidelines and a national clinical guideline from the Scottish Intercollegiate Guidelines Network (SIGN).

A review of the antenatal screening programme by the UK National Screening Committee (UK NSC) in November 2020 reported that there is a lack of available data to inform population screening strategies for ASB in pregnancy in the UK. The outcome of the review is that population screening for ASB in pregnant women is not currently recommended in the UK. Following the review, NICE Guideline CG62: Antenatal care for uncomplicated pregnancies was updated and replaced by NICE Guideline NG201: Antenatal care. NICE no longer includes a recommendation on routine testing for ASB in its updated antenatal care guidance. However, a recommendation for routine screening of pregnant women remained in NICE Guideline NG109 (Urinary tract infection (lower): antimicrobial prescribing) until this was removed in May 2022. Despite this change, NG109 retains recommendations on managing ASB. It is unclear how ASB would be identified in pregnant women, in order to be treated in line with the NICE recommendations, without routine screening.

The updates were initially considered by the FIG in August 2022. The formulary team had contacted maternity and microbiology specialists regarding whether the existing formulary guidance should be amended. Early specialist feedback suggested there was still a place for screening for ASB in pregnancy. The Local Maternity Neonatal System, which includes senior midwives and obstetric leads Devon-wide, had suggested a delay in discussions until the Saving Babies' Lives Care Bundle (SBLCB) was published in June 2023. The updated SBLCB guidance does not refer to the review

by UK NSC or the update to NICE NG109, but supports screening for ASB in all high or intermediate risk pregnant women at booking, and prompt treatment of ASB.

Local specialist feedback supports continued screening for ASB in pregnancy. A formulary update was proposed, which recognises the position statement from the UK NSC but indicates that routine screening is supported by local maternity specialists and the SBLCB guidance from NHS England to reduce the risks of preterm birth, acute pyelonephritis, and neonatal low birthweight.

It was noted that the SBLCB recommends screening for ASB in pregnant women at intermediate or high risk of preterm birth; feedback from RDUH specialists in Exeter indicated that they will continue to screen in all patients at booking, rather than waiting for a risk assessment.

The FIG considered and accepted in principle the proposed formulary guidance subject to one amendment. The discussion noted the conflicting national guidance. A piece of peninsula wide work to consider this issue is understood to be planned by local pathology teams. In light of this, it was agreed to retain the current position that all women be screened rather than risk missing ASB in any pregnant women, given the risk of preterm birth and pyelonephritis.

ACTION: Formulary Team to bring the guidance back to the FIG for ratification via the most appropriate route.

It was agreed that the Formulary Team would contact the microbiologist leading the peninsula wide discussions and ask them to update the formulary team with any relevant outcomes from the work.

ACTION: Formulary Team to contact the microbiologist leading the peninsula wide work to request that any relevant outcomes are communicated to the Formulary Team.

7. Management of eczema

A Devon-wide update to current formulary guidance on the management of eczema was proposed.

The current guidance has been reviewed and amended based on an update to NICE Clinical Guideline (CG57) Atopic eczema in under 12s: diagnosis and management (07 June 2023), in consultation with local paediatricians and dermatologists from the acute trusts in Devon. The NICE guideline is specific to children, but the proposed formulary guidance is applicable to all ages.

Responses were received from specialists at RDUH, T&SD, and UHP. The feedback included comments on the traffic light classification for topical calcineurin inhibitors; these are currently amber (specialist-input) in South & West Devon and blue (second-line) in North & East Devon. Harmonisation of the classification to amber Devon-wide was proposed in the draft update to the formulary guidance. In response, some specialists noted that NICE CG57 recommends topical calcineurin inhibitors be initiated only by physicians (including general practitioners) with a special interest and experience in dermatology, and that experienced GPs should therefore be able to initiate treatment with topical calcineurin inhibitors, with specialist support via Advice & Guidance if required. Based on the feedback submitted by specialists the FIG was asked for their views on appropriate initiation of topical calcineurin inhibitors.

The FIG undertook an initial discussion regarding the formulary guidance for the management of eczema. The discussion noted:

- broad agreement with the guidance, including recommending larger volumes of emollients (in line with NICE) and the movement of drug entries for topical calcineurin inhibitors to a page for drugs used in eczema.
- Additional consultation with specialists was needed to understand their preferred approach to the initiation of topical calcineurin inhibitors and to support a consistent, Devon-wide traffic light classification.

ACTION: **Formulary team to liaise with specialists regarding a harmonised classification for topical calcineurin inhibitors for eczema and bring back to the FIG via an appropriate route.**

8. Infected eczema

The current formulary guidance for infected eczema differs between N&E Devon and S&W Devon. The same topical antibiotics are listed in both areas; however, systemic antibiotics are listed in N&E Devon only. Both presentations contain similar key points, including a warning against antibiotic use where there is no visible sign of infections.

The proposed new guidance harmonises the recommendations and has been updated in line with NICE Guideline NG190 'Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing', which includes both systemic and topical antimicrobial options for adults ages 18 years and older, pregnant women, and children and young people. Additional advice has been included, including the signs and symptoms of infected eczema, when to routinely offer a topical or oral antibiotic, and general advice when an antibiotic is given. It was also proposed to relocate guidance on infected eczema from the formulary page on the management of eczema to the infections chapter.

Local specialists were consulted regarding the proposed antimicrobial recommendations, responses were limited to a consultant microbiologist from Torbay.

The FIG considered the proposed formulary guidance for Infected Eczema. The discussion included:

- whether topical fusidic acid is effective
- feedback from the microbiologist that allergy or another infection should be considered if there is no improvement with use of fusidic acid
- that doxycycline, which is included in the current North & East Devon guidance is not included in the NICE guidance. The FIG wished to seek local specialist advice on whether doxycycline should be retained as a treatment option
- relocation of the guidance to the infections chapter of the formulary.

It was agreed that the formulary guidance for infected eczema be updated in line with the discussion and brought back to the FIG via the most appropriate route.

ACTION: **Formulary Team to 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 the most appropriate route.**

9. Management of suspected Deep Vein Thrombosis (DVT) and pulmonary embolism (PE): COVID-19 update

In August 2023, NICE reviewed the evidence on the use of Wells score and D-dimer in the diagnostic pathways for PE and DVT in people with COVID-19, and updated recommendations to the guidance.

There is an increased risk of venous thromboembolism (VTE) in people with COVID-19 and diagnosis of VTE in this population can be complicated. Patients may present with symptoms like PE, and with elevated D-dimer levels even in the absence of VTE. However, limited evidence suggested that raising the D-dimer threshold for recommending imaging in people with COVID-19 would probably increase the number of missed VTE diagnoses.

The NICE committee decided that the current pathway for diagnosing PE or DVT, including the use of D-dimer testing, is still appropriate for people with COVID-19, and as such most of the Devon Formulary guidance is unchanged. NICE noted that healthcare professionals would still have a high suspicion of PE for people who rapidly deteriorate with symptoms indicative of PE.

Specialists were consulted on the update to the NICE guidance, the only response received was from a Nurse Consultant in Thrombosis & Chair Thrombosis Committee / Trust VTE lead, UHP, who also involved in the NICE Guideline update. The respondent was happy with the proposed formulary changes and noted that the guidance applied only to in-patients at UHP, as the trust does not use any prophylaxis in patients with COVID-19 who are managed at home, and prophylaxis for in-patients is discontinued before discharge. No response was received from the other trusts.

Amendments to the current formulary guidance were proposed to reflect the updated guidance from NICE, specifically “Do not stop short-term anticoagulation when used for primary venous thromboembolism (VTE) prevention in people with COVID-19”.

The FIG considered the proposed amendments to the Formulary guidance. No amendments were requested. It was agreed that the Formulary would bring this guidance back to the FIG to be ratified via an appropriate route.

ACTION: Formulary team to bring the guidance back to the FIG to be ratified via an appropriate route.

10. Management of insomnia in adults including NICE TA922 Daridorexant for treating long-term insomnia

At the meeting in September 2023 the FIG discussed the use of melatonin for the management of insomnia in adults. This item was part of a larger piece of work to understand the use of melatonin in adult patients. At that meeting the FIG agreed in principle that modified release melatonin should be included in the formulary as a treatment option for insomnia in patients aged 55 years and over. This indication is in line with the licence for Circadin 2mg modified release tablets. The FIG requested updated guidance for the treatment of insomnia, and deprescribing guidance for hypnotic drugs, to include melatonin.

The FIG considered draft guidance for the management of insomnia, which includes the use of melatonin. The hypnotic deprescribing guidance will be brought to the FIG for review at a future meeting.

The draft insomnia guidance was based on guidance from the British Association of Psychopharmacology and a NICE Clinical Knowledge Summary (CKS). Since the previous meeting NICE TA922 has been published which recommends the use of daridorexant for long term insomnia; the draft formulary guidance therefore also included daridorexant. The draft guidance and proposed daridorexant entry were circulated to local specialists for comment.

Daridorexant is the first dual orexin receptor antagonist (DORA) to be licensed in Europe. It is available as 25mg and 50mg tablets; the recommended daily dose is 50mg to be taken within 30 minutes of bedtime. The price per tablet is £1.40.

The licensing of daridorexant is supported by randomised placebo-controlled trials which showed statistically significant improvements in wakefulness after sleep onset (the total number of minutes that a person is awake after having initially fallen asleep) and sleep latency (time taken to fall asleep) for the 50mg dose. Secondary outcomes suggested clinically relevant improvements in subjective total sleep time and daytime functioning. The 25mg dose failed to demonstrate consistent and robust efficacy results in the trials, however, the EMA considered that the data could support a 25mg dose when a clinician judges a lower dose to be appropriate, for example in patients already treated with a CNS depressant.

NICE TA922 recommends daridorexant for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:

- cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
- CBTi is not available or is unsuitable.

The TA also states that the length of treatment should be as short as possible. Treatment should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, effectiveness should be re-assessed at regular intervals.

The TA committee regarded CBTi as the standard first-line treatment for people with long-term insomnia but understood that access to it varies. Placebo was the comparator for the NICE TA. The TA committee noted that daridorexant would be offered mainly in primary care by GPs; they explained that it would be good to have a longer-term treatment option in primary care. Daridorexant was therefore proposed as a ‘green’ or ‘blue’ option in the Devon formulary. A more detailed entry than normal was proposed as this is a new class of drug in the UK that clinicians may not be familiar with.

The FIG considered and accepted in principle that daridorexant for the treatment of long-term insomnia in line with TA922 be classified as ‘blue’ (second line) in the Devon Formulary. The FIG also accepted in principle a small update to the proposed entry under the note on drug interactions with reference to the use of daridorexant with concomitant CNS depressants. TA922 will be brought back to the FIG for ratification via an appropriate route.

ACTION: 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.

The Formulary guidance for insomnia was also discussed. Some minor amendments for consistency were requested. The discussion noted that pharmacological interventions should be second line where CBTi is first line. The proposed guidance will be brought back to FIG via an appropriate route for final agreement.

ACTION: Formulary guidance for insomnia to be brought back to FIG via an appropriate route.

11. Section 4.10.2 Nicotine dependence

In January 2023, FIG had an initial discussion on a draft update to formulary recommended nicotine replacement products, pending further consultation with specialist service providers and responsible commissioners. Local Authorities (via Public Health teams) are the responsible commissioners for Smoking cessation services; in Devon, the responsibility for commissioning and funding these services lies with Devon County Council, Torbay Council, and Plymouth City Council.

At the January meeting, the FIG accepted the proposal to harmonise formulary recommendations (pending specialist consultation). However, several points of clarification were requested including:

- the availability of smoking cessation services in Devon, and how GPs (and other primary care health professionals) can refer people into them.

  Commissioner feedback indicated that level 2 services are available from some community pharmacies and GP practices, however there is no single up to date list of current providers. The draft formulary entry has therefore been updated to reflect that level 2 services may be available but provides a hyperlink to the Devon level 3 service (Stop For Life Devon) and the Plymouth and Torbay Clinical Referral Guidelines (CRGs) so that healthcare professionals who wish to signpost people to a local service are able to do so.

  It was suggested that self-referral information could also be hosted on the My Health Devon website. CRGs and My Health Devon are maintained by Devon Referral Support Services (DRSS) who can support development and maintenance of relevant pages if appropriate. Commissioners and providers have been encouraged to liaise with DRSS to ensure that existing CRGs are up to date (or in the case of Devon County Council commissioners / providers, to develop a new CRG), and to discuss the information available via the My Health Devon website.

- prescribing advice regarding duration of prescribing of NRT, and patients who relapsed after a prior quit attempt. There were anecdotal reports of patients requesting long term prescribing, or “just in case” prescriptions to keep NRT on hand in case they found themselves in stressful situations or were tempted to start smoking again.

  Specialist feedback on these points varied extensively. The updated draft reflects the range of options, including patient groups who may benefit from longer term use of NRT, and the availability of specialist service support.

A consultation had taken place with specialists and commissioners. Comments received and the draft proposals were presented to the FIG.

The FIG considered the draft formulary guidance for section 4.10.2 Nicotine dependence. A discussion took place, it was agreed that key points from the November 2023 MHRA Safety Update on e-cigarette use or vaping should be added. The discussion also noted that the long-term use of NRT is safer than smoking.

ACTION: Formulary team to update the proposed formulary guidance for nicotine dependence in line with the discussion and bring back to FIG via an appropriate route.

12. Ryeqo for uterine fibroids - update

The Formulary team reported that work is ongoing. This item will be brought back to the FIG for discussion at a future date following consultation with specialists.

13. Rimegepant for acute migraine

The Clinical Lead for the Exeter Headache Clinic, who participated in the process for developing the NICE TAs for rimegepant, joined the meeting for the discussion.

Rimegepant is licensed for both acute and prophylactic treatment of migraine in adults. TA906 'Rimegepant for preventing migraine' was issued by NICE in July 2023 and was discussed by the FIG in September 2023. The formulary entry for rimegepant in line with TA906 has been published on the Devon Formulary website. TA919 'Rimegepant for treating migraine' was issued on 18th October.

The recommend dose of rimegepant for the acute treatment of migraine is one 75mg lyophilisate, which is also the maximum dose of rimegepant in 24 hours. The price per tablet is £12.90. The European Medicines Agency considered the overall effect size for rimegepant for the acute treatment of migraine to be modest but noted the incomplete response to currently available acute migraine medications and limitations to their use due to cardiovascular safety concerns. NICE also recognised there is an unmet need for a new treatment when triptans are contraindicated or not tolerated.

Following the meeting the Formulary Team will be consulting with the headache services over updating the formulary guidance for the acute treatment of migraine and harmonisation of the formulary triptans.

Based on TA919 recommendations, the proposed formulary classification for rimegepant for the acute treatment of migraine is blue (second-line). The clinical lead for the Torbay and South Devon service and the UHP team support the formulary classification of blue. The clinical lead for the Exeter headache service confirmed support for this classification at the meeting.

The FIG were asked for views on the proposed blue (second-line) formulary classification of rimegepant for acute migraine. The FIG considered and accepted in principle the 'blue' (second-line) formulary classification of rimegepant for acute migraine. The FIG also agreed that note 1 of the formulary entry 'Rimegepant is licensed for both acute treatment and prophylaxis of migraine. Patients should not take an additional 75mg lyophilisate for acute treatment of migraine on the same day as receiving rimegepant for prophylaxis of migraine.' is clear.

The discussion noted that:

- There is a lack of robust evidence for patients with cardiovascular disease. The rimegepant SmPC has no contraindications for cardiovascular conditions. It was agreed that the draft entry will be updated to list the exclusion criteria relevant to cardiovascular conditions from the pivotal clinical trial for the acute treatment of migraine..
- The appropriate treatment for an acute migraine attack when patients are receiving rimegepant for the prophylaxis of migraine was raised. As rimegepant is an amber (specialist-input) formulary option for the prophylaxis of migraine, the specialist would be expected to advise on options for the acute treatment of migraine.
- TA919 recommends rimegepant for patients who have failed two triptans. The specialist present suggested that alternative options could include a third triptan or a different formulation of a triptan.
- Work to update the Formulary guidance for acute migraine and harmonisation of the formulary triptans will be undertaken as a separate piece of work.

The Formulary team will bring 'Rimegepant for acute migraine' back to the FIG for ratification via an appropriate route.

ACTION: NICE TA919 rimegepant for treating migraine – drug entry to be brought back to the FIG for ratification via an appropriate route.

14. MHRA Drug Safety Updates – (September to November)

September 2023

Statins: very infrequent reports of myasthenia gravis

A recent European review recommended new warnings on the risk of new onset or aggravation of pre-existing myasthenia gravis with multiple statins. The findings of this review were considered by the Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the recommendations, and recommended that the MHRA inform healthcare professionals and patients of the newly identified risk.

A weblink to the article will be included in the introductory text to Devon Formulary section 2.12 (Statins).

Fluoroquinolone antibiotics: suicidal thoughts and behaviour

The MHRA has received a Coroner's report following the death of a patient who died by suicide after being treated with ciprofloxacin. The patient had no previous history of depression or mental health problems. The Coroner raised concerns about the potential risk of suicidal behaviour in patients taking ciprofloxacin, the potential for increased risk in patients with depression, and the need to highlight this to healthcare professionals. Warnings on the potential for psychiatric adverse drug reactions to occur with ciprofloxacin and other fluoroquinolones are included in the product information and the patient information leaflet has advice for patients on psychiatric reactions.

Key points and a weblink to the article will be included in the introductory text to Devon Formulary section 5.1 (Quinolones) alongside other Drug Safety Update articles for quinolones.

Letters sent to healthcare professionals and drug alerts in August 2023

Ozempic (semaglutide), Rybelsus (semaglutide) and Victoza (liraglutide): GLP-1 Receptor Agonists Supply Shortage in the UK

This letter refers to the National Patient Safety Alert for GLP-1 agonists issued in July 2023 which has been included in the Devon Formulary, and the shortage of Saxenda which is indicated for weight management. Stocks of GLP-1 agonists are not expected to be available until mid-2024.

Xalkori (crizotinib): Vision disorders, including risk of severe visual loss, need for monitoring in paediatric patients

Crizotinib is included in the Devon Formulary as a red (hospital-only) option in line with NICE TAs for the treatment of adults only. This letter pertains to the treatment of paediatric patients with specific types of lymphoma or myofibroblastic tumours.

Given that paediatric specialists have been notified directly and this is a known risk of treatment, the formulary entry for crizotinib has not been updated with a link to the letter.

October 2023

Isotretinoin (Roaccutane): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age

Isotretinoin is included in the Devon Formulary as a red (hospital-only) drug to only be prescribed from the Dermatology Department under the supervision of a Consultant Dermatologist.

The MHRA has strengthened the safe use of isotretinoin through the introduction of additional oversight of the initiation of isotretinoin in patients under 18 years and through improved assessment and monitoring of mental health and sexual function issues. Healthcare professionals are asked to review these new measures and supporting materials and integrate them into their clinical practice when referring patients and when prescribing or dispensing isotretinoin.

The Formulary team will review the new guidance and supporting documents. Key points will be included in a future Drug Safety Update meeting paper, including a draft update to the isotretinoin formulary entry and guidance, for discussion.

Valproate: dispense full packs of valproate-containing medicines

Following a consultation, the Government has amended the Human Medicines Regulations 2012 (HMRs) to require manufacturer's original full pack dispensing of valproate-containing medicines.

Letters sent to healthcare professionals and drug alerts in September 2023

Azathioprine 75 mg & 100 mg tablets: Risk of overdose if wrong dose prescribed or dispensed

Azathioprine 75 mg & 100 mg tablets are being launched in the UK. These two new strengths of azathioprine are not currently available in the UK (only 25mg and 50mg have been marketed previously), therefore caution is required when prescribing and dispensing this product range to ensure that the patient receives the dose intended. The Devon Formulary includes azathioprine 25mg and 50mg tablets. Key points and a weblink to the letter will be included under the formulary entries for azathioprine.

November 2023

Ozempic (semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products

Falsified Ozempic and Saxenda products have been found in the UK, including falsified pens containing insulin. Key points from the article and a link to the article will be included under the Devon Formulary section 6.1.2 (Antidiabetic drugs).

Nirmatrelvir, ritonavir (Paxlovid): be alert to the risk of drug interactions with ritonavir

Healthcare professionals are advised of the risk of potentially serious drug interactions with the ritonavir component of Paxlovid which is a CYP3A4 inhibitor. As many commonly used drugs are metabolised by CYP3A4, the risk of harmful drug interactions with Paxlovid is significant.

Additional resources highlighted in the article include the Specialist Pharmacy Service website, which was reviewed in the development of the formulary guidance for COVID-19 treatments, and the Liverpool COVID-19 drug interaction checker. The draft formulary guidance on COVID-19 treatments for non-hospitalised patients has been updated to reflect the advice on drug interactions from the article. Key points from the article and a weblink to the article will be included under the formulary drug entry for Paxlovid.

E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme

Key points from the article and a weblink to the article will be included under Devon Formulary section 4.10.2 (Nicotine dependence).

Oral isotretinoin: New safety measures following review into sexual and psychiatric adverse reactions

This was the subject of an article in the October Drug Safety Update, which is addressed earlier.

ACTION: Formulary Team to update the relevant Devon Formulary sections with recommendations for the MHRA Drug Safety Updates from September and November.

ACTION: Formulary Team to bring back October MHRA Drug Safety Update article on isotretinoin for discussion at 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
23/04	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