Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 22 June, 2022

Via Microsoft Teams

Present:

Tawfique Daneshmend (Chair)	Consultant Gastroenterologist	RDUH NHS FT
Glen Allaway	GP	NHS Devon CCG
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Ailene Barclay	Pharmacist	UHP NHS Trust
Heidi Campbell	Pharmacist	NHS Kernow CCG
Andy Craig	GP	NHS Devon CCG
Susie Harris	Consultant (Elderly Care)	RDUH NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Tom Kallis	Community Pharmacist	
Nick Keysell	GP	NHS Devon CCG
Carole Knight	Formulary Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Bill Nolan	GP	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Christopher Sullivan	Deputy Chief Pharmacist - Clinical Services	DP NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

James Benzimra	Consultant Ophthalmologist	RDUH NHS FT
Emma Gitsham	Clinical Effectiveness Pharmacist	NHS Devon CCG
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon CCG

Observers:

Yeonwoo Jee	Pharmacist	RDUH NHS FT
Tran Nguyen	Pre-registration Pharmacist	RDUH NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

Chairman's welcome

Tawfique Daneshmend welcomed attendees to the meeting of the Devon Formulary Interface Group.

Apologies

Nicola Diffey	Pharmacist	Livewell Southwest
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Jamie Smith	Consultant in Diabetes and Endocrinology	T&SD NHS FT
Sam Smith	Interim Chief Pharmacist	NDDH

Declarations of Interest

The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Tirbanibulin (Kylisyri®) for actinic keratosis	Almirall Limited
Alternative treatments: • 5-Fluorouracil 5% cream (Efudix®) • Imiquimod 5% cream (Aldara®) • Methyl-5-aminolevulinate cream (Metvix®) with Photodynamic therapy (PDT) • Fluorouracil (.05%) with salicylic acid 100mg/g (10%) cutaneous solution (Actikerall®)	Mylan Meda Pharmaceuticals Galderma (U.K) Ltd Almirall Limited
Lipid guidance ▪ Various statins ▪ Ezetimibe ▪ Bempedoic acid (Nilemdo, Nustendi) ▪ Inclisiran (Leqvio) ▪ Alirocumab (Praluent) ▪ Evolocumab (Repatha)	 Various manufacturers Various manufacturers Daiichi Sankyo UK Ltd Novartis Sanofi Amgen Limited

Intermittent catheters: ▪ HydroSil GO ▪ Actreen Hi-Lite, Actreen Glys, ▪ SpeediCath Compact, SpeediCath Flex Pocket, SpeediCath Compact Eve ▪ Infyna Chic, Infyna Plus, VaPro Pocket, VaPro Plus Pocket ▪ LoFric Primo, LoFric Origo, LoFric Sense, LoFric Hydro-Kit **Alternatives**: ▪ Various intermittent catheters	 Bard Ltd B.Braun Medical Ltd Coloplast Ltd Hollister Wellspect Healthcare Various manufacturers
Atrial fibrillation • Beta-blockers • Calcium channel antagonists • Digoxin • Amiodarone • Dronedarone • Anticoagulants including warfarin and DOACs	 Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers
Hypertension in adults Various classes of drugs including ACE inhibitors, angiotensin II receptor blockers (ARBs), calcium channel blockers, thiazide diuretics, alpha-blocker, beta-blocker • Indapamide • Spironolactone	 Various manufacturers Various manufacturers Various manufacturers
Type 2 diabetes in adults • Metformin • Various classes of drugs including sulfonylureas, DPP-4 inhibitors, GLP-1 agonists and SGLT2 inhibitors • Insulin	 Various manufacturers Various manufacturers Various manufacturers
Allergic rhinitis / antihistamines ▪ Various antihistamines ▪ Various nasal and topical corticosteroids	 Various manufacturers Various manufacturers

Ciclosporin eye drops (Verkazia) for vernal keratoconjunctivitis Verkazia eye drops for paediatric patients **Alternative treatment:** Ikveris eye drops	 Santen UK Ltd Santen UK Ltd
Ilube (acetylcysteine) 5% w/v eye drops: Ilube 5% eye drops Acetylcysteine 5% eye drops preservative free (*unlicensed)*	 Rayner Various manufacturers
Testosterone for hypoactive sexual desire disorder in women Testosterone products used off-label.	 Various manufacturers
Transdermal oestrogens for HRT Estradiol transdermal patch (Evorel) **Alternative treatments:** 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

e-FIG Item	Company
Levetiracetam continuous subcutaneous infusion for palliative care Desitrend Keppra **Alternative treatments:** Midazolam solution for infusion	 Desitin Pharma Ltd UCB Pharma Ltd Various manufacturers

Name	Role	Declaration
Tom Kallis	Community Pharmacist	May or may not be included under 'various manufacturers.' I have participated in a paid advisory board for Daiichi-Sankyo in 2021

2. Minutes of the meeting held on Wednesday 6th April 2022 and Matters Arising

Minutes of the meeting held on Wednesday 6th April 2022

The minutes of the meeting held on Wednesday 6th April 2022 were approved.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
21/46	Palliative care: Levetiracetam 100mg/ml concentrate solution for intravenous infusion - circulate the final draft of the proposed formulary entry via the e-FIG process or bring the item back to a future meeting. This is now with nurses and will be circulated to the FIG for final agreement.	Formulary Team	Complete
21/54	Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement. *Post meeting note: RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*	Formulary Team	Ongoing
21/72	Osteoporosis – liaise with specialists and bring final draft to a future FIG meeting. *Post-meeting note: The National Osteoporosis Guideline Group (NOGG) issued updated guidance for osteoporosis in April 2021. A draft update to the formulary guidance based on the new guidance from NOGG has been sent to specialists for review and will be scheduled for discussion at a future FIG meeting.*	Formulary Team	Ongoing
21/84	Undertake further consultation with specialists on the Management of Epilepsy.	Formulary Team	Complete
21/86	Osteoporosis – Check the MHRA and Dental Association websites for patient information on bisphosphonates and osteonecrosis of the jaw and add to the formulary if appropriate.	Formulary Team	Complete
22/09	Vaginal micronised progesterone (Utrogestan) for threatened miscarriage - Following consultation with consultants seek FIG agreement to the proposed formulary entry via the e-FIG process.	Formulary Team	Complete

22/12	NICE TA753: Cenobamate for treating focal onset seizures in epilepsy - Following consultation with consultants Formulary team to seek FIG agreement to the proposed formulary entry via the e-FIG process.	Formulary Team	Complete
22/13	7.3.2 Progesterone-only contraceptives: update and harmonisation - seek clarity on the route for safe disposal of domestic hazardous (cytotoxic / cytostatic) clinical waste in Devon. *Post meeting note: Domestic clinical waste disposal is the responsibility of local district, city or borough councils; arrangements between the 8 councils in Devon. Clinicians / patients may therefore need to contact their local council on an individual basis for advice on local arrangements.*	Formulary Team	Complete
22/17	Sacubitril Valsartan: partial review – work with heart failure teams to develop draft prescribing guidance for sacubitril valsartan and submit to FIG for discussion.	Formulary Team	Ongoing
22/18	Lipid guidance – Confirm that the necessary financial arrangements have been agreed.	Medicines Optimisation	Ongoing
22/19	Circulate the final changes to the formulary guidance for the management of lipids to FIG members for agreement via the e-FIG process.	Formulary Team	On agenda
22/20	NICE TA753: Cenobamate for treating focal onset seizures in epilepsy - liaise with tertiary care specialist to confirm agreement with the formulary entry.	Formulary Team	Complete
22/21	NICE TA753: Cenobamate for treating focal onset seizures in epilepsy - liaise with Medicines Optimisation team regarding a pop-up message for GP prescribing systems.	Formulary Team	Complete
22/22	Formulary team to update the formulary with the approved formulary entry for NICE TA753: Cenobamate for treading focal onset seizures in epilepsy.	Formulary Team	Complete
22/23	NICE TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction – consult with heart failure teams over clarification to draft update to empagliflozin.	Formulary Team	Complete
22/24	NICE TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction – update the formulary entry for empagliflozin under section 2.12 (antidiabetic Drugs) with the accepted formulary entry.	Formulary Team	Complete

22/25	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) – Feedback to specialists on the discussion to understand the frequency of potassium monitoring required.	Formulary Team	Ongoing
22/26	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) look at TA599 evaluations to determine if potassium threshold of 5.5mmol/L has been considered for patients with heart failure.	Formulary Team	Ongoing
22/27	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) - update the proposed formulary entry and bring back to a future FIG meeting.	Formulary Team	Ongoing
22/28	NICE TA775: Dapagliflozin for treating chronic kidney disease – consult with the renal specialists over clarification to draft update to dapagliflozin entry	Formulary Team	Complete
22/29	NICE TA775: Dapagliflozin for treating chronic kidney disease – update the formulary entry with the accepted formulary entry for Dapagliflozin.	Formulary Team	Complete
22/30	Octasa (mesalazine) 1g suppositories add the accepted formulary entry to the local formulary.	Formulary Team	Complete
22/31	Octasa (mesalazine) 1g suppositories - consider Scriptswitch message to remind clinicians to prescribe mesalazine enemas and suppositories by brand.	MO Team	Ongoing
22/32	Anoro Ellipta (umeclidinium bromide/vilanterol) Dry Powder Inhaler – add the accepted entry for Anoro Ellipta dry powder inhaler to the Devon Formulary.	Formulary Team	Complete
22/33	Add the accepted formulary entry for Vaginal micronised progesterone (Utrogestan) for threatened miscarriage and section 6.4.1 text to the local formulary.	Formulary Team	Complete
22/34	Riluzole for the treatment of individuals with the amyotrophic lateral sclerosis form of motor neurone disease – minor amendment to the monitoring text as detailed above.	Formulary Team	Complete
22/35	Riluzole for the treatment of individuals with the amyotrophic lateral sclerosis form of motor neurone disease – progress the SMS share care guideline through the Local Medical Committee	Formulary Team	Complete
22/36	Riluzole oral suspension – publish the SMS North and East Devon entry for riluzole oral suspension.	Formulary Team	Complete

22/37	MHRA Drug Safety Update - Cladribine (Mavenclad): new advice to minimise risk of serious liver injury – Update formulary entry for cladribine (section 8.1.5 Antimetabolite drugs) to be updated with a link to the Drug Safety Update.	Formulary Team	Complete
22/38	Following further consultation with specialists. Progress the formulary entry for Amiodarone (Cordarone X): via the e-FIG process, or a short discussion at the next FIG meeting.	Formulary Team	Ongoing

Report of e-FIG decisions – June 2022

In May 2022 an e-FIG was circulated in which Devon FIG members were asked to consider two items:

- Denosumab (Prolia) for the prevention of osteoporotic fractures in postmenopausal women – proposal to extend existing SMS guideline to south Devon
- Levetiracetam concentrate for intravenous infusion for palliative care: proposed updates to the levetiracetam formulary entry.

Responses for both items indicated acceptance of the proposals. The Formulary will be updated.

It was noted that a palliative care specialist at T&SDFT had developed supporting guidance for the formulary entry for Levetiracetam. The Devon FIG noted their thanks to the specialist.

Report of COVID-19 related changes to the formulary (May 2022 to June 2022)

Since the last Devon FIG meeting (6th April) the Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

The temporary Devon Formulary page, “COVID-19 Updates” has been updated with important information related specifically to the COVID-19 pandemic.

The UK commissioning policies for nMABs and anti-virals for patients with hospital-onset COVID-19 and non-hospitalised patients with COVID-19 have been updated. The links to the commissioning policies in the formulary page for nMABs and anti-virals will be refreshed to link to the updated policies.

Valneva COVID-19 vaccine has been added to the formulary following regulatory approval by the MHRA.

Baricitinib is recommended to be available as a treatment option through routine commissioning for adults and children (aged 2 years and over) hospitalised with COVID-19 in accordance with the criteria set out in the commissioning policy.

Details of the national commissioning policy will be added to the baricitinib drug entry.

3. Tirbanibulin for actinic keratosis

At its meeting on 18th May 2022 the Clinical Policy Committee made a recommendation for the routine commissioning of tirbanibulin (Klisyri) for actinic keratosis for the treatment of mild to moderate (non-hyperkeratotic, non-hypertrophic) keratosis of the face or scalp in adults.

The FIG was asked to consider the proposed formulary entry in principle subject to the ratification of the CPC recommendation through the CCG's governance processes.

The FIG considered and accepted the proposed formulary entry for tirbanibulin for actinic keratosis.

ACTION: Formulary team to add the accepted formulary entry for tirbanibulin to the Formulary. (Pending publication of the policy)

The inclusion of tirbanibulin as a blue (second line) treatment option has implications for the existing Devon Formulary guidance for the field treatment of mild to moderate actinic keratosis. Dermatology specialists across Devon were asked to provide comments on proposed changes to the formulary guidance pages to accommodate tirbanibulin. In addition, a number of areas where further harmonisation between the S&W and N&E Devon guidance could be achieved were noted.

The FIG agreed that the traffic light classification for fluorouracil 0.5% with salicylic acid 10% cutaneous solution (Actikerall) be harmonised to a 'blue' second line treatment across Devon.

The FIG accepted the draft advice on the management of adverse skin reactions from fluorouracil 5% cream and that this should be harmonised across Devon.

ACTION: The Formulary team to update the guidance for AK and entries for Actikerall and fluorouracil 5% cream in line with the discussion.

The FIG accepted the inclusion of imiquimod cream 5% (Aldara) as an option for the field treatment of moderate to severe AKs for N&E Devon and indicated a preference for harmonisation of the classification across Devon. Specialist feedback from N&E Devon recommended a blue classification. However, feedback had not been received from S&W Devon where this is currently listed as amber.

ACTION: The Formulary team will consult with specialists in S&W Devon to see if a Devon-wide harmonisation of the classification for imiquimod 5% cream (Aldara) is acceptable.

FIG members requested additional guidance on the time interval between a first and second course of 5-fluorouracil cream in the event that the first course has not been effective.

ACTION: The Formulary team to seek specialist advice from dermatologists regarding the interval between first and second treatment courses using 5-fluorouracil cream.

4. Devon Formulary Interface Group Annual report 2021-2022

The Devon FIG Annual Report was presented to the group.

The report provides an overview of the work undertaken by the Devon FIG from 24th February 2021 to 31st March 2022. It is the first Annual Report since the merger of the N&E Devon FIG and the S&W Devon FIG to form the Devon FIG.

The creation of a single FIG provides greater opportunity for Devon wide recommendations to be agreed. In year, the focus of the Devon FIG has been to build on the work of its predecessors. It has continued to develop and review the Devon formulary with consideration being given to opportunities to harmonise recommendations across both presentations of the formulary. However, there are times, when to allow for differences in specialist opinion, services provided or existing financial arrangements, recommendations may differ between areas.

In addition, the Devon Formulary continued to support the production of SMS guidelines as well as the development and dissemination of COVID-19 related guidance from various local and national groups.

The FIG has also considered the environmental impact of recommendations; where possible taking steps to promote options with a lower carbon footprint, or which may reduce waste.

Between 24th February 2021 and 31st March 2022, the Formulary and Referral website recorded almost 2.5 million page views, an increase of 20% over the previous year. A new website is being constructed, which will support the development of the formulary into the future.

The Formulary Team thanked Tawfique Daneshmend for his advice and support and for continuing to Chair meetings of the Devon FIG. FIG members were also thanked for their considerable input into the process of developing formulary guidance.

The FIG thanked the Formulary Team for all their work in producing papers for the FIG meetings and for developing and maintaining the Formulary website.

The group approved the Devon Formulary Annual Report for 2021-2022. The report will be submitted to the Clinical Policy Recommendation Committee (CPRC) of the Integrated Care Board (ICB) for assurance on how the CCG promotes prescribing which is safe, clinically appropriate and cost-effective in both primary and secondary care by providing guidance on locally recommended drug treatment choices.

ACTION: Devon FIG Annual report to be submitted to the CPRC of the ICB.

The Terms of Reference of the Devon FIG be reviewed following the establishment of the ICB. It was noted that the Devon FIG and Devon Formulary was an effective model that will continue.

ACTION: Terms of Reference of the Devon FIG to be reviewed following the establishment of the ICB.

5. Management of blood lipids and lipid-regulating drugs

Management of blood lipids

The formulary guidance had been discussed at the FIG meeting on Wednesday 6th April. The FIG members proposed a small number of amendments, and it was agreed that these changes would be reviewed by the FIG before taking a final decision on the guidance.

A consultation has taken place with specialists. The proposed amendments to the guidance were presented to the FIG for review and a final decision. Amendments included:

- the section on monitoring has been reviewed and amended to provide clarity on when monitoring is required;
- information has been included on referral if inclisiran is ineffective;
- the text has been clarified in a small number of additional areas.

The FIG considered and accepted the proposed updates to the guidance and the replacement of the existing guidance in its entirety.

ACTION: The Formulary team to update the guidance on Management of blood lipids in line with the discussion.

Lipid-regulating drugs

Formulary section 2.12 has been reviewed. A consultation has taken place with specialists. Proposed updates were presented to the FIG.

The FIG accepted the proposed updates including:

- The addition of the indications "familial hypercholesterolaemia" and "mixed dyslipidaemia" to the entry for rosuvastatin to offer an alternative high intensity statin if atorvastatin is not tolerated or not appropriate.
- The addition of rosuvastatin hard capsules for patients with swallowing difficulties or a nasogastric tube. Currently, there is no formulary option for these patient groups. Rosuvastatin is cost saving at equivalent intensity to atorvastatin chewable tablets, which have been the subject of frequent supply shortages.
- The addition of a note to the rosuvastatin entry for the 40mg dose. There are contraindications specific to this dose. The SmPC recommends specialist initiation for the 40mg dose due to the increased reporting rate of adverse reactions at this dose. It was noted that neither the AAC pathway nor NICE Clinical Knowledge Summaries indicate that specialist advice should be sought if a daily dose of 20mg rosuvastatin is not effective. Specialists support the 40mg dose remaining blue (second-line), in keeping with the lower doses of rosuvastatin, and its use for the prevention of cardiovascular disease for patients who are unable to reach their target on rosuvastatin 20mg/day if it is clinically appropriate for patients to receive the higher dose. The proposed update indicates that specialists may be contacted for advice if necessary.
- The removal of nicotinic acid from the Devon Formulary in line with NICE CG181 guidance. There is no prescribing of nicotinic acid in primary care in Devon. NICE guidance CG181 indicates that nicotinic acid should not be routinely recommended due to no evidence of health benefits and common occurrence of side effects. Nicotinic acid is included for S&W Devon only.

ACTION: MO team to add a Scriptswitch message to atorvastatin chewable tablets to advise recommending rosuvastatin hard capsules.

ACTION: Formulary Team to update section 2.12 Lipid-regulating drugs in line with the discussion.

6. NICE guidance NG136: Hypertension in adults

NICE guidance for hypertension in adults (NG136) was first issued in August 2019 and updated in March 2022 following a review of evidence on blood pressure targets for people with cardiovascular disease and a reassessment of antihypertensive drug treatment.

An update to the Devon Formulary guidance for hypertension is planned. As hypertension is a condition managed by primary care, the update to the guidance has been reviewed to determine whether there are any potential implications for managing patients in the primary care setting before consulting with specialists.

A paper highlighting the key changes to the NICE guidance relevant to the Devon formulary was presented to the group for a preliminary discussion. Points noted by the group were regarding:

- NICE guidance recommends starting antihypertensive therapy should be discussed with specific patient groups including “renal disease”. Clarification was requested on which patients with renal disease should be offered treatment.
- that not all GPs are aware of the blood pressure@ home scheme for patients monitoring their blood pressure at home.

It was also noted that the Pathology Group has been looking at malignant hypertension.

7. NICE guidance NG196: Atrial fibrillation

NICE issued updated guidance for atrial fibrillation (NG196) in April 2021. The formulary guidance for atrial fibrillation (AF) has been updated to include a statement alerting the reader to the new NICE guidance and that there is a new assessment for bleeding risk. The current formulary guidance is almost identical in N&E Devon and S&W Devon.

The proposed update to the formulary guidance for atrial fibrillation was brought to the FIG for an initial discussion before consultation with specialists.

The FIG considered the proposed update. There was discussion about:

- adding that a single lead ECG was not satisfactory to confirm AF to reinforce the NICE recommendation that a 12-lead ECG should be used;
- prescribing DOACs in primary care;
- the recommendation for switching from warfarin to a DOAC and availability of practical advice.

It was agreed that the Formulary team will consult with specialists on the anticoagulation guidance.

ACTION: Formulary team to consult with specialists on the anticoagulation guidance.

The Chair thanked the Formulary team for all the work that had been put into developing the draft guidance.

8. Intermittent catheters

Formulary recommendations for intermittent catheters have been reviewed with specialist teams with the intention to harmonise the two formulary presentations.

Specialists have indicated that prescribing is currently wholly undertaken in primary care; inclusion of the proposed guidance is not expected to significantly increase expenditure, but rather to support GPs who are asked to prescribe these products.

A number of proposals were considered and accepted by the FIG, including:

- bringing the designated product page for intermittent catheters in line with current formulary format;
- the harmonisation of the introductory guidance text in the North & East Devon and South & West Devon formulary presentations;
- removal of HydroSil Silicone intermittent catheters, and addition of HydroSil GO;
- the reclassification of Actreen Hi-Lite intermittent catheters from blue to green and LoFric Primo intermittent catheters from green to blue;
- removal of VaPro Hydrophilic anti-infective catheters, and addition of VaPro Pocket Hydrophilic anti-infective catheters;
- removal of HydroSil Gripper and LoFric Origo Tiemann intermittent catheters, and addition of SpeediCath Flex Pocket;
- the reclassification of LoFric Origo intermittent catheters from green to blue
- removal of HydroSil Rose intermittent catheters, and addition of Infyna Chic intermittent catheters;
- the reclassification of LoFric Sense intermittent catheters from green to blue;
- addition of Actreen Glys Set and Infyna Plus all-in-one intermittent catheters
- addition of VaPro Plus Pocket all-in-one reduced infection catheters.

ACTION: Formulary team to update the formulary with the accepted formulary guidance.

9. NICE guidance NG28: Type 2 diabetes in adults

NICE guidance (NG28) for type 2 diabetes was updated in February and March 2022. The update included the section on pharmacological treatments. An overview of the key changes and a copy of the NICE treatment pathway was included in the meeting paper.

It was noted the updated NICE guidance includes treatment recommendations specifically for patients with cardiovascular disease, chronic heart failure or risk factors for cardiovascular disease. The current formulary guidance on treatment options is laid out

according to whether metformin is tolerated. Examples of how the update to the NICE guidance may be laid out in the formulary were presented on screen to the FIG.

The FIG was asked to consider which layout would be the most pragmatic and user-friendly option.

The FIG considered and agreed that the most user-friendly layout would be for the formulary guidance to mirror the four possible patient groups based on the presence of chronic heart failure or cardiovascular disease/ risk factors and whether metformin is tolerated.

The was discussion about risk factors. It was agreed that the formulary team will continue to include a reasonable level of risk factor information in the Formulary guidance.

10. Allergic rhinitis and antihistamines

An update was provided, work is in progress.

11. Ciclosporin eye drops (Verkazia) for vernal keratoconjunctivitis

The Formulary team has received an application for the inclusion of ciclosporin 1mg/1ml emulsion eye drops (Verkazia) from a consultant ophthalmologist, Royal Devon University Healthcare NHS Foundation Trust. Verkazia is indicated for severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents. VKC is a rare form of ocular allergy characterised by an inflammation of the conjunctivitis with corneal involvement and tissue remodelling including papillae formation. Chronic and severe forms of VKC have an increased risk of sight threatening complications. Ciclosporin eye drops are considered if inflammation cannot be controlled sustainably with dual-acting agents with activity against H1 receptors and mast cell degradation. Short-tapered courses of corticosteroid eyedrops are used in moderate/severe disease to treat recurrences.

Unlicensed or off-label ciclosporin eye drops are considered to be an established treatment for VKC. The licensing of Verkazia was supported by a pivotal clinical trial in children and adolescents which found consistent effects on measures of corneal damage and improvement in the four main symptoms of VKC together with a reduction in rescue topical steroid medication. Local specialists report that Ikervis is being used off-label to treat children and adolescents with severe VKC. Ikervis eye drops are the same composition and strength as Verkazia. Ikervis is included the Devon Formulary as amber in line with NICE TA369 for the treatment of dry eye disease in adults. Verkazia and Ikervis are cost-neutral when given at the same dosing frequency.

The applicant has requested an amber classification. Most patients are able to discontinue treatment after the summer months. Examination of the eye is required every three to six months in patients who use Verkazia for more than 12 months; this fits in with monitoring of the condition.

The applicant joined the meeting for discussion of the item.

The Devon FIG considered and accepted the inclusion of Verkazia in the Devon Formulary with an amber (specialist) classification.

The Formulary team shared on screen the proposed update to the formulary entry for ciclosporin (Anti-inflammatory agents, Chapter 11 Eye).

The Devon FIG considered and accepted the proposed update. The entry will be published when the extent of prescribing of Ikervis for VKC in secondary care has been ascertained and the impact on the primary care drug budget of transferring prescribing to primary care has been discussed with the CCG's Head of Medicines Optimisation.

ACTION: Formulary team to contact trust pharmacies to ascertain the level of prescribing of Ikervis for children and adolescents.

ACTION: The Formulary team will discuss the impact of the amber classification on prescribing in primary care with the Head of Medicines Optimisation.

ACTION: Formulary team to update the Devon formulary as agreed by the Devon FIG.

12. Reclassification of Ilube (acetylcysteine) 5% w/v eye drops from red to amber

Ilube eye drops are artificial tears with mucolytic and lubricant properties. They contain acetylcysteine, a mucolytic agent which helps to breakdown excessive mucin associated with ocular surface inflammatory conditions such as dry eye disease. Ilube also contains hypromellose to assist with lubrication of the eye. Ilube is licensed for the relief of dry eye syndromes associated with deficient tear secretion, impaired or abnormal mucus production.

Ilube 5% eye drops are currently listed as red (hospital only) in the South & West Devon formulary presentation and are non-formulary in North & East Devon.

An application has been received from a Consultant Ophthalmic Surgeon, University Hospitals Plymouth NHS Trust, for the reclassification of Ilube 5% eye drops in the Devon Formulary from red (hospital only) to amber (specialist input), in line with its licensed indications. A consultant ophthalmologist from Royal Devon University Healthcare NHS Foundation Trust joined the meeting for discussion of the item.

Currently the South & West Devon formulary presentation does not include management guidelines for the treatment of dry eye, but the referral side of the website and the North & East formulary presentation include guidance and information on dry eyes. Formulary product recommendations differ between the areas, and it is the intention of the Formulary team to review and provide Devon-wide guidance at a future meeting.

The application suggests that Ilube eye drops are currently used in very few selected cases. It is a well-established drop used for licensed indications usually over many months and patients attend hospital for reviews when stable at six to twelve months. Meanwhile patients

need repeat prescriptions. Ilube is currently a 'red' hospital only drug in the formulary. The hospital pharmacy gives only a two-month supply.

Therefore, it is proposed that Ilube 5% eye drops are reclassified in the Devon Formulary as an amber (specialist input) option for the relief of dry eye syndromes associated with deficient tear secretion, impaired or abnormal mucus production. Where Ilube is considered appropriate, it would be initiated in secondary care with the first prescription supplied by the outpatient pharmacy, then subsequent prescriptions to be undertaken by GPs in primary care with a specialist review every 6-12 months, where patients are established stable and prescribing can be continued, or prescribing is discontinued.

Local specialists generally support the reclassification of Ilube 5% eye drops in the South & West and their inclusion in the North & East for use in line with its licensed indications.

The Devon FIG considered and accepted the reclassification/inclusion of Ilube 5% eye drops from 'red' hospital only to 'amber' specialist input in the Devon Formulary.

In terms of harmonisation of the formulary presentations the FIG accepted the addition of unlicensed preservative free acetylcysteine 5% eye drops to the North & East presentation of the formulary as red (hospital only).

The discussion noted that:

- there are many patients with dry eyes. Ilube is for a particular type of dry eye, patients need to be diagnosed in secondary care. To reduce the possibility of inappropriate initiation of treatment in primary care for other types of dry eye, it was agreed that information be added to the formulary entry to state that this treatment is for patients with mucus strands who are diagnosed in secondary care,
- that the first prescription will be written in secondary care,
- it must be made clear who is considered a specialist in the context of diagnosis of dry eye syndromes associated with deficient tear secretion, impaired or abnormal mucous production. The FIG agreed the wording 'secondary care eye specialist' be included.

ACTION: Formulary Team to update the formulary entry in line with the discussion.

13. Testosterone for low sexual desire in menopausal women

Testosterone supplementation for low sexual desire is recommended in NICE guidance (NG23) Menopause: diagnosis and management (issued 2015). The recommendation is to 'Consider testosterone supplementation for menopausal women with low sexual desire if HRT alone is not effective'. The NICE guidance notes that it is an off-label use of testosterone. There is no testosterone product licensed for low sexual desire in menopausal women in the UK.

Testosterone supplementation for the treatment of low sexual desire in menopausal women is not included in the Devon Formulary. There is significant interest in the use of testosterone for this indication. The Formulary team has received enquiries on this subject.

NICE has published a scoping document for the update to NICE guidance (NG23) 'Menopause: diagnosis and management', which is due to be published in August 2023. It is reported that no substantive new evidence was identified for testosterone for altered sexual desire and the existing recommendation would be maintained.

The FIG received a paper providing an overview of guidance on testosterone for menopausal women from specialist organisations and organisations providing guidance for primary care. Points covered by this guidance included: the treatment pathway; baseline tests; who should initiate treatment; off-label testosterone preparations; measures of effectiveness; a trial period; and long-term prescribing and monitoring. The formulary position of testosterone for menopausal women in other formularies in South West England was presented during the discussion.

There was discussion about:

- Low sexual desire is a multi-factorial condition; possible causes should be explored with the patient before considering testosterone. The importance of the woman being fully oestrogenised before treatment with testosterone was considered. Prescribing of testosterone for menopausal women is off-label. Baseline tests and parameters to be monitored on long-term treatment vary between guidance.
- Prescribing of testosterone should be evidence-based with an awareness of the risks.
- The position of testosterone for low sexual desire in menopausal women in the six other formularies in south west England was presented. Two formularies do not include testosterone for this indication. A third formulary indicates the pathway for HRT is under development; in the meantime, patients should be referred to secondary care. The approach taken by the remaining formularies include initiation by a secondary care specialist with continued prescribing in primary care under a shared care arrangement in one formulary, and initiation by a specialist which may include a GP with additional training in menopause and HRT in two formularies.
- There is no specifically commissioned specialist menopause service in Devon. The GPs' experience is that secondary care services are not providing advice on HRT and are not accepting referrals for menopause. Initiation of testosterone for menopausal women on the recommendation of a secondary care specialist would not be a pragmatic position in Devon.
- The Dorset Formulary and the Somerset Formulary have adopted the approach of initiation on the advice of a specialist which may include a GP with additional training in menopause or HRT. It was noted that additional training was not defined in the formularies or accompanying prescribing guidance. The FIG noted that currently there is no system which would enable a practice without a GP with a specialist interest in menopause to refer patients or seek advice on the treatment of patients from a GP with a specialist interest at another practice. Development of a primary care menopause service led by GPs with a specialist interest would overcome this.
- The consensus view was that a formulary position of green (first-line) for initiation by a GP would not be a preferred approach. It was acknowledged that there are GPs who are prescribing testosterone for this indication.
- Several GPs indicated there had been discussions within their practices on the prescribing of testosterone for menopausal women in response to requests from patients. The practices have taken the decision not to prescribe testosterone for low sexual desire in menopausal women over concerns about the evidence base and the absence of a menopause service and support for prescribing.

- The consensus view was that the development of a primary care menopause service led by GPs with additional training / specialist interest in menopause is the preferred approach to provide advice to GPs on HRT and for referral of patients for consideration of treatments, such as testosterone.
- The FIG agreed that it would like to see an evidence review of testosterone for low sexual desire at a future meeting. It would not be appropriate to take a decision on the inclusion of testosterone in the Devon Formulary without an appropriate medical support service for primary care in place which will need to include provision for initiation of unlicensed specialist treatments.

Post-meeting note: The CCG's commissioning team were informed of the preference for a primary care menopause service led by GPs with additional training / specialist interest in menopause.

14. Transdermal oestrogens for HRT

The Devon Formulary guidance for menopause is based on NICE guidance NG23 'Menopause: Diagnosis and Management'. The formulary guidance includes the advice to consider transdermal rather than oral hormone replacement therapy (HRT) for women who are at increased risk of venous thromboembolism (VTE). This recommendation is not included in section 6.4.1 'Female sex hormones and their modulators' which includes the individual drug entries for the formulary HRT preparations. The Formulary team has received several enquiries on transdermal oestrogen for patients with risk factors for venous thromboembolisation (VTE). The team proposed that advice on considering transdermal rather than oral HRT for women at increased risk of VTE be added to section 6.4.1 Female sex hormones and their modulators of the formulary and the relevant drug entries.

The Formulary Team is undertaking a review of transdermal oestrogen products for HRT for discussion at a future meeting. Several points relevant to this review were brought to the attention of the FIG. These included:

- There continue to be supply shortages of transdermal oestrogen gels (Oestrogel, Sandrena) and spray (Lenzetto). The formulary transdermal oestrogen is available (Evorel patch). Generally, the FIG would not take a decision on an application for a product where there is a frequent shortage of supply because this causes difficulties for both the patient and the GP, however, it is recognised there is considerable interest in this area.
- The Royal College of General Practitioners, the Royal College of Obstetrics and Gynaecology and the British Menopause Society has recently issued a position statement on the menopause including the following statement: "For women at higher risk of VTE transdermal products are preferred, but it is important to remember that oral medication is appropriate for many women where VTE risk is not a significant concern".
- The scope for the update to NICE guideline NG23 has been published. The update will include the section on long-term risks and benefits of HRT. NICE highlighted the detailed and complex analysis in studies of the risk of breast cancer with HRT in their surveillance review to identify new evidence. The expected date of publication for the updated NICE guidance is August 2023.

The FIG considered and accepted the proposed updates to the formulary section 6.4.1 Female sex hormones and their modulators.

ACTION: Formulary team to update the Formulary with the agreed formulary entry.

15. Service transitions for young people with an existing ADHD diagnosis

Young people in Devon with ADHD may be referred to the Devon adult ADHD service by either child health teams, Child and Adolescent Mental Health Services (CAMHS) or GPs. Previously the service accepted referrals when the young person was 17.5 years old but delayed the first appointment until closer to their eighteenth birthday.

The Devon Adult Autism & ADHD (DAANA) Service have indicated that they are willing to offer transition appointments for patients aged 17.5 years. At the appointment the clinician would formulate a treatment plan collaboratively with the young person, which might involve changing their ADHD medication. The adult ADHD service would take over specialist responsibility of the young person after the transition appointment with a revised shared care agreement with the GP which supports the change in specialist service provider.

DAANA has piloted a transitions pathway with paediatric specialists in Torbay over the last year with positive feedback from young people and their families. DAANA has also reached out to paediatric specialists in Exeter who are keen to adopt a similar practice. It is hoped north Devon and CAMHS will be keen to support the process also.

In order to support the smooth transition of patients between paediatric and adult services it is proposed that changes are made to the Specialised Medicines Service (SMS) adult ADHD prescribing guidelines for methylphenidate, lisdexamfetamine and atomoxetine.

Currently the guidelines are explicit in covering the management of adults aged 18 years and over and contain little information regarding the service transition process.

In addition, some updates are proposed to align with the paediatric ADHD SMS prescribing guidelines which are currently being reviewed and some minor changes are proposed to improve reading and useability of the document.

The FIG considered and accepted the proposed amendments to the Specialised Medicines Service (SMS) adult ADHD prescribing guidelines for methylphenidate, lisdexamfetamine and atomoxetine without amendment.

ACTION: Formulary team to update the Devon Formulary with the accepted Specialised Medicines Service (SMS) adult ADHD prescribing guidelines for methylphenidate, lisdexamfetamine and atomoxetine without amendment.

16. MHRA Drug Safety Updates (Apr 22 to May 22)

April 2022

Pregabalin (Lyrica): findings of safety study on risks during pregnancy

The MHRA has updated the SmPC for pregabalin following the publication of an observational study and European review of the findings. The product information continues to advise that effective contraception should be used during treatment and use in pregnancy avoided unless clearly necessary.

A summary of the advice and weblinks to the Drug Safety Update and patient information developed by the MHRA is included in the formulary guidance on the Management of epilepsy and under the entry for pregabalin in section 4.8.1 Control of the epilepsies.

May 2022

Denosumab 60mg (Prolia): should not be used in patients under 18 years due to risk of serious hypercalcaemia

Denosumab 60mg (Prolia) is included in the Devon Formulary as amber for the treatment of osteoporosis in post-menopausal women in line with a NICE TA and a Specialist Medicine Service (SMS) "Shared Care" guideline.

The formulary entry for Prolia will be updated to include a weblink to the Drug Safety Update.

ACTION: Formulary entry for Prolia to be updated to include a weblink to the Drug Safety Update.

17. Recent drug decisions (including NICE)

The FIG received a report of recent drug decisions. These include:

- the discontinuation and removal of Hydrosorb comfort dressings
- the removal of Sukkarto (metformin M/R tablets) as a MO Team preferred brand.

Amendments included the removal of two NICE Technology Appraisals (TAs) from the Devon Formulary. These were NICE TA332 and NICE TA532. There is no change to formulary drugs as the TAs indicated that the drugs under evaluation were not recommended by NICE for the TA indication.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
21/54	Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement. *Post meeting note: RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*	Formulary Team	Ongoing
21/72	Osteoporosis – liaise with specialists and bring final draft to a future FIG meeting. *Post-meeting note: The National Osteoporosis Guideline Group (NOGG) issued updated guidance for osteoporosis in April 2021. A draft update to the formulary guidance based on the new guidance from NOGG has been sent to specialists for review and will be scheduled for discussion at a future FIG meeting.*	Formulary Team	On agenda
22/17	Sacubitril Valsartan: partial review – work with heart failure teams to develop draft prescribing guidance for sacubitril valsartan and submit to FIG for discussion.	Formulary Team	Ongoing
22/18	Lipid guidance – Confirm that the necessary financial arrangements have been agreed.	Medicines Optimisation	Complete
22/19	Circulate the final changes to the formulary guidance for the management of lipids to FIG members for agreement via the e-FIG process. This was added to the agenda of the meeting held on 22nd June 2022.	Formulary Team	Complete
22/25	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) – Feedback to specialists on the discussion to understand the frequency of potassium monitoring required.	Formulary Team	Ongoing

22/26	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) look at TA599 evaluations to determine if potassium threshold of 5.5mmol/L has been considered for patients with heart failure.	Formulary Team	Ongoing
22/27	NICE TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update to TA599 and consideration of reclassification from red to amber) - update the proposed formulary entry and bring back to a future FIG meeting.	Formulary Team	Ongoing
22/31	Octasa (mesalazine) 1g suppositories - consider Scriptswitch message to remind clinicians to prescribe mesalazine enemas and suppositories by brand.	MO Team	Ongoing
22/38	Following further consultation with specialists. Progress the formulary entry for Amiodarone (Cordarone X): via the e-FIG process, or a short discussion at the next FIG meeting.	Formulary Team	On agenda
22/39	Add accepted formulary entry for Tirbanibulin to the formulary. (Pending publication of the policy)	Formulary Team	Ongoing
22/40	Tirbanibulin for actinic keratosis – Update guidance for AK and entries for Actikerall and fluorouracil 5% cream in line with the discussion.	Formulary Team	Ongoing
22/41	Tirbanibulin for actinic keratosis - consult with specialists in SW Devon to see if a Devon wide harmonisation of the classification for imiquimod 5% cream (Aldara) is acceptable.	Formulary Team	Ongoing
22/42	Seek specialist advice from dermatologists regarding the interval between first and second treatment courses using 5-fluorouracil cream.	Formulary Team	Ongoing
22/43	Submit Devon FIG Annual Report for CPRC of the ICB.	Formulary Team	Complete
22/44	Terms of Reference of the Devon FIG to be reviewed following the establishment of the ICB.	Formulary Team	On agenda
22/45	Lipid guidance – Update the guidance on the Management of blood lipids in line with the discussion.	Formulary Team	Complete
22/46	Lipid Guidance - add a Scriptswitch message to atorvastatin chewable tablets to advise recommending rosuvastatin hard capsules.	MO Team	Complete
22/47	Lipid Guidance update section 2.12 Lipid-regulating drugs in line with the discussion.	Formulary Team	Complete
22/48	NICE guidance NG196 – Atrial fibrillation: consult with specialists on the anticoagulation guidance.	Formulary Team	Ongoing
22/49	Intermittent Catheters: Update the formulary with the accepted formulary guidance.	Formulary Team	Complete

22/50	Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis - Contact trust pharmacies to ascertain the level of prescribing for Ikervis for children and adolescents.	Formulary Team	Complete
22/51	Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – discuss the impact of the amber classification on prescribing in primary care with the Head of Medicines Optimisation	Formulary Team	Ongoing
22/52	Ciclosporin eye drops (Verkazia for vernal Keratoconjunctivitis – Update Devon formulary as agreed by the Devon FIG.	Formulary Team	Ongoing
22/53	Reclassification of Ilube (acetylcysteine) 5% w/v eye drops from red to amber – update the formulary entry in line with the discussion.	Formulary Team	Complete
22/54	Transdermal oestrogens for HRT – update the formulary with the agreed formulary entry.	Formulary Team	Complete
22/55	Serviced transitions for young people with an existing ADHD diagnosis - update the Devon Formulary with the accepted Specialised Medicines Service (SMS) adult ADHD prescribing guidelines for methylphenidate, lisdexamfetamine and atomoxetine without amendment.	Formulary Team	Complete
22/56	MHRA Drug Safety Update – May 2022: Formulary entry for Prolia to be updated to include weblink to the Drug Safety Update.	Formulary Team	Complete