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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 12 October 2022

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Matt Howard (Chair)	Clinical Evidence Manager	NHS Devon ICB
Glen Allaway	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
Andy Craig	GP	NHS Devon ICB
Tawfique Daneshmend	Consultant Gastroenterologist	RDUH NHS FT
Susie Harris	Consultant Physician/Geriatrician	RDUH NHS FT
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 Pharmacy Technician	NHS Devon ICB
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Charlie Thomas	Senior Medicines Optimisation Pharmacist	NHS Devon ICB
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Hannah Bishop	Programme Manager – diabetes	NHS Devon ICB
Patrick English	Consultant Physician	UHP NHS Trust
Emma Gitsham	Clinical Effectiveness Pharmacist – Specialised Medicines Service (SMS) Guidelines Lead	NHS Devon ICB
Jonathan Graham	Consultant	T&SD NHS FT
Neil Walker	Consultant	RDUH NHS FT

Observers:

Grace McMahon	Clinical Effectiveness Support Officer	NHS Devon ICB
Carys Shepley	Medicines Optimisation Technician	NHS Devon ICB

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Dr Daneshmend was unable to Chair the meeting. The FIG agreed that Matt Howard would Chair the meeting on this occasion.

Chairman's welcome

Matt Howard welcomed attendees to the meeting of the Devon Formulary Interface Group.

Apologies

NAME	JOB TITLE	ORGANISATION
Nicola Diffey	Pharmacist	Livewell Southwest
Tom Kallis	Community Pharmacist	
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB
Bill Nolan	GP	NHS Devon ICB
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon ICB

The Chair noted that Dr Bill Nolan and Dr Jamie Smith had recently stepped down from the group. The group expressed their thanks to Bill and Jamie for their contributions to the success of the Devon Formulary.

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
Continuous glucose monitoring in diabetes	Manufacturers of glucose monitoring systems for diabetes, such as Abbott, Dexcom, GlucoRx, Medtronic, Medtrum Ltd, Senseonics Inc, Ypsomed Ltd (list not exhaustive)
Type 2 diabetes mellitus • Metformin • Pioglitazone • Various classes of drugs including sulfonylureas, DPP-4 inhibitors, GLP-1 agonists and SGLT2 inhibitors • Insulin	 Various manufacturers Various manufacturers Various manufacturers Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Stoma care Stoma accessories Stoma appliances	 Includes, but is not limited to: C D Medical, CliniMed, Coloplast, ConvaTec, Dansac, Hollister, Medicareplus International, Oakmed, Opus Healthcare, Pelican Healthcare, ProSys International, Respond Healthcare, Rhodes Pharma, Salts Healthcare, Trio Healthcare. Various manufacturers
Vaginal candidiasis (pregnancy) Clotrimazole vaginal cream and pessaries (Canestan) Miconazole vaginal cream (Gyno-Daktarin vaginal cream)	 Various manufacturers Bayer PLC Janssen-Cilag Limited
Icosapent ethyl (Vazkepa) **Alternatives:** Statins Ezetimibe	Amarin Pharmaceuticals Ireland Limited Various manufacturers Various manufacturers
Morphine orodispersible tablets: Actimorph **Alternatives:** Morphine sulfate oral solution	Ethypharm UK Ltd Various manufacturers
Ethinylestradiol with etonogestrel contraceptive vaginal ring: SyreniRing **Alternatives:** NuvaRing **Ethinylestradiol with norelgestronmin contraceptive transdermal patch:** Evra Other contraceptive transdermal patches	 Crescent Pharma Organon Pharma (UK) Limited Gedeon Richter (UK) Ltd Various manufacturers
Child and adolescent ADHD Methylphenidate (both modified release and immediate release formulations) Atomoxetine Lisdexamfetamine: Elvanse Adult hard capsules and Elvanse hard capsules	 Various manufacturers Various manufacturers Takeda UK Ltd

e-FIG ITEM	PHARMACEUTICAL COMPANY/ MANUFACTURER
Edoxaban **Alternative direct-acting oral anticoagulants:** Rivaroxaban (Xarelto) Apixaban (Eliquis) Dabigatran (Pradaxa)	Daiichi Sanko UK Limited Bayer plc Bristol-Myers Squibb-Pfizer Boehringer Ingelheim Limited
Potassium permanganate Permitabs **Alternative**: Hydrogen peroxide solution Various antiseptic products	Alliance Pharmaceuticals Limited Various manufacturers Various manufacturers
Sevodyne transdermal patches **Alternative**: Butec transdermal patches Buprenorphine transdermal patches	Aspire Pharma Limited Qdem Pharmaceuticals Limited Various manufacturers

Name	Job Title	Declaration
Patrick English	Consultant Physician	Have taken part in trial for the above drug(s)/devices(s) Lecture Fees from Chairing Astra Zeneca (x2), Tetris Pharma (advisory board meeting) and Sanofi (x1) in last 12 months.
Rebecca Lowe	Joint Formulary Pharmacy Technician	Any other interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) under consideration. Please refer to 'types of conflict of interest'. I have a second job as a Bank Pharmacy Technician at HMP Channings Wood.
Neil Walker	Consultant	In receipt of lecture fees in the last year from above manufacturing company - Work shop facilitator for conference supported by CGMS companies.

2. Minutes of the meeting held on Wednesday 17th August 2022 and Actions/Matters Arising

Minutes of the meeting held on Wednesday 17th August 2022

The minutes of the meeting held on Wednesday 17th August 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
21/54	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
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
22/40	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
22/48	NICE guidance NG196 – Atrial fibrillation: consult with specialists on the anticoagulation guidance.	Formulary Team	Ongoing
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
22/61	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
22/63	MHRA Drug Safety Update: June 2022 – add a time-limited link from the formulary entry for Novorapid Pumpcart to the NPSA alert	Formulary Team	Ongoing
22/64	MHRA Drug Safety Update: July 2022 – update the formulary section on migraine, epilepsy and the topiramate entry.	Formulary Team	Ongoing
22/65	Asymptomatic bacteriuria screening in pregnancy – liaise with local specialists/Local Maternity Network and bring views and formulary guidance back to the FIG either via the e-FIG process or to a meeting.	Formulary Team	Ongoing
22/66	FIG Terms of Reference to be updated to reflect organisational and membership changes.	Formulary Team	Ongoing
22/67	Solriamfetol for the treatment of excessive daytime sleepiness – circulate the proposed formulary entry and amended guideline to specialists for comment.	SMS pharmacist	Ongoing
22/68	Solriamfetol for the treatment of excessive daytime sleepiness – bring SMS prescribing guideline back to the FIG via the appropriate route.	SMS pharmacist	Ongoing
22/69	Update the proposed formulary guidance for osteoporosis and undertake further consultation with specialists.	Formulary Team	Ongoing
22/70	Following further consultation with specialists bring formulary guidance for osteoporosis and drug entries back to the FIG via the appropriate route.	Formulary Team	Ongoing
22/73	Potassium permanganate – communicate publication of new formulary entry for potassium permanganate to specialist teams and primary care.	Formulary Team	Ongoing
22/74	Potassium permanganate – notify LPC (via MOCC LPC representative) of new formulary entry for potassium permanganate when published.	Formulary Team	Ongoing

22/75	Schedule the formulary entry for potassium permanganate for review by the FIG at an appropriate time in the future	Formulary Team	Ongoing
22/76	Remove potassium permanganate from the South & West Devon guidance for infected eczema and review formulary guidance for infected eczema and bring to FIG for discussion following specialist consultation.	Formulary Team	Ongoing
22/77	Liaise with Wound Management Group over alternatives to potassium permanganate for highlighting in the formulary.	Formulary Team	Ongoing
22/78	Iron deficiency anaemia – Forward draft formulary entry to specialists for final comment.	Formulary Team	Ongoing
22/79	Iron deficiency anaemia – following consultation with specialists update the formulary entry with the accepted entry or bring back to a future FIG meeting for discussion or pursue through the e-FIG process.	Formulary Team	Ongoing

Report of e-FIG decisions July and September 2022

In July 2022 the Devon FIG was asked to consider two items through the e-FIG process:

- The 2nd paper for Edoxaban for atrial fibrillation in patients with high (good) creatinine clearance.
- Venlafaxine formulary entry: removal of a note.

In September 2022 the Devon FIG was asked to consider two items through the e-FIG process:

- Potassium permanganate.
- Sevodyne transdermal patches.

All four of the proposals were accepted. The Devon Formulary had been updated in line with each of the proposals.

Report of COVID-19 related changes to the formulary (August 22 to October 22)

Since the last Devon FIG meeting (17th August) 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 Moderna and Pfizer/BioNTech bivalent COVID-19 booster vaccines have been added to the Devon Formulary.

3. Continuous glucose monitoring (CGM) in diabetes

Consultants from UPH and RDUH joined the meeting for discussion of this item together with NHS Devon’s Programme Manager for diabetes.

At its meeting on 21st September 2022 the Clinical Policy Recommendation Committee made a recommendation for the routine commissioning of CGM for diabetes. The recommendation is awaiting sign-off from the ICB Executive Committee.

Real time continuous glucose monitors (rtCGM) measure interstitial glucose levels using a sensor which has a small filament sitting under the skin. They are an alternative to “finger prick” self-monitoring blood glucose (SMBG) testing for people with diabetes. Measurements are generally taken every few minutes and are wirelessly transmitted to a receiver. A range of rtCGM devices is available. Most systems will provide alerts to users if their glucose levels fall outside of a pre-defined glucose range. More advanced systems can provide predictive alerts for hypoglycaemia and may also be used in conjunction with other devices such as insulin pumps.

Like rtCGM, intermittently scanned continuous glucose monitors (isCGM) measure interstitial glucose levels. However, unlike rtCGM, isCGM devices require the user to bring their receiver in close proximity of the sensor to take a reading. This means that many of the automated rtCGM features are not available on isCGM devices.

NHS Devon has two existing commissioning policies relating to CGM. These cover the provision of real time and intermittently scanned CGM, providing eligibility criteria for each form of the technology. In February 2022, NICE released updated national guidelines NG17, NG18 and NG28. These national guidelines cover the diagnosis and management of type 1 and 2 diabetes in adults, children and young people. The 2022 revisions of NG17 and NG18 recommend that all adults, children and young people with type 1 diabetes should be offered a rtCGM device to monitor their glucose levels. NG28 recommends that a small defined group of adult patients with type 2 diabetes who are treated with insulin should be offered isCGM. These recommendations represented a large increase in the use of these technologies compared with the provision made under the existing NHS Devon commissioning policies.

NICE found rtCGM to be a cost-effective option compared to SMBG in patients with type 1 diabetes, meaning that the greater cost associated with the technology are considered, on average, good value for the health benefits gained. There is a large variation in the cost of rtCGM systems, therefore it is expected that if multiple devices meet the needs and preferences of a patient, clinicians will only offer the device with the lowest cost.

Routine funding of secondary care procured (non GP prescribable) rtCGM for all patients with type 1 diabetes would have a significant financial impact. The proposed commissioning policy supports access to rtCGM for all patients with type 1 diabetes; it provides clarity regarding the circumstances under which secondary care procured rtCGM devices may be made available, with the aim of achieving equitable outcomes from the use of CGM devices in patients with diabetes, within the finite resources available to the NHS in Devon.

At the September CPRC meeting it was proposed, and supported by specialists during the discussion, that CGM monitoring devices should be classified as ‘amber’ (specialist input) in the Devon Formulary. This proposal was included in an initial draft formulary entry for these technologies. Following wider circulation of the draft entry, comments were received from specialists indicating that they could not support the ‘amber’ classification. These comments were included in an additional board paper and circulated to the FIG ahead of the meeting.

The FIG were asked to make a decision “in principle” on the Devon Formulary classification of GP prescribable rtCGM and isCGM devices, pending approval and subsequent publication of the final policy position.

The FIG considered the proposed formulary entry for CGM in diabetes. There was discussion about:

- Specialists had indicated that a proportion of patients with Type 1 diabetes are not routinely seen in secondary care. Specialist teams felt they do not have the capacity to initiate all patients onto CGM.
- These devices can collect more detailed data than traditional SMBG. GPs are not used to reviewing this level of information. Specialists present indicated that the additional data would be considered during specialist reviews. GPs would not be expected to review the detailed data available from these devices, but to consider the broad trends when reviewing patients.
- GPs and other primary care clinicians do not currently have experience of initiating this technology. Upskilling and support are required to ensure that the potential benefits offered by CGM are realised in practice. These benefits are expected to accrue when an informed discussion between patient and clinician can identify the most appropriate device, when the patient is sufficiently knowledgeable to respond appropriately to the device readings / alarms, and when clinicians are able to review and act on the available data collected. Primary care initiation ('green' or 'blue' formulary classification) is therefore not appropriate at this stage.
- Prescribers need to understand the differences between the available devices to be able to discuss the range of options with patients.
- Simply prescribing the sensors and directing patients to a manufacturer's website for information on initiation is not acceptable to GPs as patients experiencing difficulty would return to their GP with questions they may feel ill equipped to answer.
- Some companies will supply reader devices for patients without compatible smart phones; these may be free, or charged for, or in some cases free only to specific patient groups. These devices cannot be prescribed in primary care.
- A lot of practical implications need to be considered.
- There are likely to be different challenges to implementation in different parts of Devon. Specialist nurse led clinics may be possible in Plymouth. Other approaches including GPs, nurses and pharmacists (at practice or PCN level) may be suitable, with appropriate training. Manufacturer support may also be an option but should be considered carefully and in line with relevant local policies on working with industry.

The Committee was unable to make a recommendation on the traffic light classification of CGM because:

- The knowledge and skills to initiate patients onto devices are not currently available in primary care.
- Feedback from specialists is that 'amber' is not appropriate as they lack the capacity to support the expected number of patients.
- A range of approaches may need to be developed across Devon to support implementation.

The Devon Diabetes Delivery Group are to be asked to work with specialists and GP representatives to develop a plan to support implementation. Once an implementation support plan is in place, the FIG can reconsider formulary classification of CGM.

4. Pharmacological treatment for type 2 diabetes (NICE NG28)

Consultants from UPH and RDUH were present for the discussion of this item.

Following discussion of NICE Guideline NG28 at the June 2022 FIG meeting the Formulary team drew up four pathways for the pharmacological treatment for type 2 diabetes in line with the request from the FIG. A small group of diabetes specialists had offered to assist by reviewing draft guidance and answering clinical questions. Specialists proposed that the formulary guidance be simplified and suggested a layout like that in the Exeter Handbook of Diabetes.

The meeting paper included the Exeter Handbook of Diabetes simplified summary of NG28 and relevant text. The Formulary team shared a proposed layout for a formulary pathway on screen during the FIG meeting discussion. The FIG agreed that a single formulary pathway would be easier to follow than the four pathways previously requested.

ACTION **Formulary team to bring the formulary guidance for the pharmacological treatment of Type 2 diabetes to a future meeting.**

The FIG also considered the NG28 recommendation for SGLT2 inhibitors for patients with chronic heart failure. It was noted that the NICE TAs for dapagliflozin and empaglifozin for chronic heart failure include a recommendation for treatment to be started on the advice of a heart failure specialist, whereas the NG28 recommendation for a SGLT2 inhibitor for chronic heart failure did not stipulate that specialist advice was required before initiation of treatment. A discussion took place, it was agreed that the formulary guidance for SGLT2 inhibitors should be pragmatic. It was noted that there is no titration schedule for initiating treatment with a SGLT2 inhibitor for chronic heart failure and that GPs are familiar with prescribing SGLT2 inhibitors for type 2 diabetes. The GPs present did not have concerns about initiating an SGLT2 inhibitor for chronic heart failure if there was guidance in place and the heart failure teams considered this to be acceptable.

A consultant from UHP had produced some guidance for the UHP heart failure team on the initiation of SGLT2 inhibitors for chronic heart failure in patients with type 2 diabetes which will be shared with the Formulary Team. The Formulary Team will liaise with Heart Failure Teams to seek their views on GP initiation of SGLT2 inhibitors for patients with chronic heart failure (with or without type 2 diabetes) without first seeking advice from a heart failure specialist.

ACTION **Formulary team to liaise with Heart Failure Teams over GP initiation of SGLT2 inhibitors for chronic heart failure.**

5. Stoma care: guidance and product recommendations review

The draft formulary entry is currently with specialists. Due to time constraints, consideration of the Stoma care: guidance and product recommendation review was deferred to a future meeting.

ACTION: **Formulary team to bring Stoma care: guidance and product recommendations review to a future meeting.**

6. Vaginal candidiasis in pregnancy

An update to the British Association of Sexual Health and HIV guidance (BASHH) for the treatment of vulvovaginal candidiasis in 2019 includes longer topical antifungal treatment regimens of 7 days for acute vaginal candidiasis in pregnancy.

NICE Clinical Knowledge Summaries have recently adopted the 1st and 2nd line recommendations from BASHH except for the 100mg clotrimazole pessaries. The British National Formulary (BNF) indicates that longer treatment durations may be required in pregnancy without being specific to formulations or strengths. The basis of the longer treatment duration is an analysis of two studies comparing 4 days and 7 days of miconazole 2% vaginal cream reported in a 2001 Cochrane report which found that a 4 day course was significantly less effective, however, miconazole vaginal cream is licensed for 7 days in the UK. The BASHH guidance states 'The studies included in the systematic review used lower dose formulations of topical imidazoles. In theory, a full seven-day course of the higher dose formulations (clotrimazole 500 mg pessary or 10% cream, miconazole 1200 mg) is unlikely to be clinically necessary but there is insufficient evidence to make a more specific recommendation'.

The Formulary team received a request from a GP for clarity on the appropriate treatment option in pregnancy.

The Formulary team consulted with specialists in sexually transmitted infections and consultants in obstetrics and gynaecology.

The FIG considered the proposed formulary entry, a discussion took place:

- The inclusion of multiple strengths of clotrimazole pessaries from the BASHH guidance is potentially confusing, the clinician may not know which option to choose.
- The GPs noted that the BASHH recommendation for a 7-day course with single use products was a significant change in the treatment of patients.
- Only clotrimazole 100mg pessaries are licensed for a treatment duration (6-days) which is similar to the 7-day course recommended by the BASHH. The formulary guidance should indicate the BASHH guidance includes additional treatment options for vaginal candidiasis in pregnancy and include a weblink to the BASHH guidance. It was recognised that a 7-day course is off-label for all strengths of clotrimazole pessaries.
- It was noted that the BASHH guidance and NICE CKS include clotrimazole 10% vaginal cream and miconazole 2% vaginal cream for vaginal candidiasis during pregnancy, despite the SmPC for clotrimazole 10% vaginal cream stating that the pessary should be used in pregnancy as these can be inserted without an applicator. The GPs present and a specialist indicated that they would not prescribe vaginal cream which requires insertion with an applicator during pregnancy.

ACTION: **Formulary team to update the proposed formulary guidance and entries taking account of the discussion and bring back to FIG via the most appropriate route.**

7. NICE TA805: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides

Technology Appraisal 805 was issued by NICE in July 2022. To meet the mandatory timeline for publishing the TA in the Devon Formulary the FIG was asked to consider the proposed new formulary entry.

Icosapent ethyl contains eicosapentaenoic acid (EPA), a constituent of omega-3 products licensed for the treatment of hypertriglyceridaemia. Icosapent is licensed to reduce the risk of cardiovascular events in statin-treated patients with a fasting elevated triglyceride level. The TA recommendation is for its use in secondary prevention of cardiovascular disease in line with the specified criteria.

NICE has updated clinical guidance CG181 'Cardiovascular disease: risk assessment and reduction' to indicate that existing statements on omega-3 fatty acids do not apply to icosapent when used in line with TA805.

Icosapent ethyl was licensed by the MHRA in April 2021 on the basis of authorisation by the European Medicines Agency. The European Public Assessment Report (EPAR) and the NICE TA were reviewed for the meeting paper.

The formulary guidance for the management of blood lipids is based on the AAC summary of national lipid guidance. The AAC summary guidance had not been updated to incorporate the TA for icosapent at the time of writing this paper. An NHS Devon Senior MO Pharmacist and NICE Medicines and Prescribing Associate has contacted the AAC and NICE to enquire whether the AAC summary guidance would be updated to incorporate icosapent. NICE responded that an update to the summary guidance is under review by the AAC. No response had been received from the AAC at the time of writing the meeting paper.

A consultation on the formulary entry for icosapent ethyl was held with the lipid specialists, cardiologists and diabetes specialists in Devon.

The FIG considered the proposed formulary entry for icosapent and the proposed amendments to incorporate the update to NICE guidance CG181. The discussion noted:

- Comments from a cardiologist were discussed and minor amendments to the formulary entry for icosapent were agreed.
- The GPs present indicated that GPs will not want to initiate treatment without specialist advice as they will require clarity on the monitoring requirements for individual patients.
- The FIG accepted icosapent with amber 'specialist input' classification.

ACTION: Formulary Team to add NICE TA805 to the Devon Formulary in line with the ICB's statutory responsibilities.

8. Consideration of SyreniRing 0.120mg/0.015mg per 24 hours, vaginal delivery system

Due to time constraints consideration of the SyreniRing 0.120mg/0.015mg per 24hours, vaginal delivery system was deferred. This item will now be progressed at a future meeting or via the e-FIG process.

ACTION: **Formulary team to progress consideration of SyreniRing 0.120mg/0.015mg per 24 hours, vaginal delivery system through a future meeting or via the e-FIG process.**

9. Consideration of Actimorph (morphine sulfate) orodispersible tablets

Actimorph is an immediate-release orodispersible formulation of morphine sulfate available in 1mg, 2.5mg, 5mg, 10mg, 20mg and 30mg strengths. The tablets are indicated for severe pain which can be adequately managed only with opioids and are licensed for use in adults and children aged 6 months and older.

The basis of the proposal follows discussions between the NHS Devon ICB Medicines Optimisation Team, primary care practices, and the NHSE Southwest Controlled Drugs Accountable Officer (CDAO) about improving the safety of morphine prescribing for breakthrough pain, in light of a recent national investigation on the unintentional overdose of morphine sulfate oral solution by the Healthcare Safety Investigation Branch (HSIB). It has been suggested that use of the orodispersible tablet could make it easier for patients to accurately administer a dose, reducing the risk of accidental under or overdosing when measuring the oral solution.

The orodispersible tablets have been proposed as a green (first-line) formulary option as an alternative to morphine sulfate oral solution, which will remain in the formulary. The tablets may be a safer method of achieving the correct dose than the oral solution which is currently a first-line option.

Financial comparisons between immediate release oral morphine products are complicated as they are not all available in the same range of strengths and are not all priced on a “cost per mg” basis. In addition, the daily dose required by each patient may vary over time, and the oral solution is likely to be dispensed in multiples of whole bottles (100ml or 300ml), which may result in wastage. Since the difference in costs is dependent on the dose required for the patient, it has not been possible to provide a credible estimate of the likely impact of prescribing Actimorph in preference to morphine sulfate oral solution 10mg/5ml, although it seems plausible that costs would increase. Medicines Optimisation colleagues have indicated that they do not expect any increases to be significant and support the inclusion of Actimorph in the Devon Formulary. Local specialists in pain medicine and palliative medicine support the inclusion of Actimorph in the Devon Formulary.

The FIG considered and accepted the inclusion of morphine sulfate orodispersible tablets (Actimorph) in the Devon Formulary as a green (first line) option for severe pain which can be adequately managed only with opioids in adults and children aged 6 months and older.

The FIG noted the potential safety role of the orodispersible tablets which are easier to administer and may reduce the risk of patients accidently under dosing or overdosing when measuring morphine sulfate solution.

ACTION: **Formulary Team to add morphine sulfate orodispersible tablet (Actimorph) to the Devon Formulary as a green (first line) treatment.**

10. MHRA Drug Safety Updates (August 2022 – September 2022)

The two MHRA Drug safety updates issued since the last meeting of the Devon FIG were noted:

August 2022

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists.

Use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates.

It is recommended that any use of home nebulisers to deliver rescue treatments for acute asthma in children and adolescents should be initiated and clinically managed by a specialist such as a respiratory specialist paediatrician.

Salbutamol and terbutaline nebuliser solutions are amber (specialist-input) formulary options. The notes to the entries include a cross-reference to the formulary 'Nebulisation guidance' which indicates that children requiring long-term nebulised therapy should be under the care of a consultant paediatrician.

A link to the Drug Safety Update will be included under the formulary entries for salbutamol and terbutaline and under the formulary guidance on nebulisation.

ACTION: Formulary entries for salbutamol and terbutaline and formulary nebulisation guidance to be updated to include a link to the Drug Safety Update.

September 2022

Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to difference in formulations.

The formulary entry for methylphenidate modified release (MR) and the SMS guidelines for methylphenidate for ADHD recommend brand prescribing and include a table illustrating the formulation characteristics, release profiles and duration of action of the MR products.

A reference and link to the Drug Safety Update will be included in the formulary entry for methylphenidate MR.

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

Rucaparib (Rubraca): withdrawal of third-line treatment indication.

Rucaparib is included in the formulary in line with NICE TA611. NICE has not made any amendments to this TA as a result of the withdrawal of this indication.

11. Methylphenidate, lisdexamfetamine and atomoxetine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above

A consultant from Torbay and South Devon NHS Foundation Trust joined the meeting for discussion of this item.

There are currently three ADHD “Shared Care” / SMS prescribing guidelines in Devon for methylphenidate, lisdexamfetamine and atomoxetine which apply to children and adolescents aged 6 years to 18 years. The guidelines were last updated in 2016 (excluding any temporary COVID-19 arrangements).

Updates to the formulary guidelines, which included recommendations from NICE guideline NG97 (2018) were first considered by FIG in April 2021. The FIG requested several formatting amendments and clarifications.

Following a pause to the development of the child and adolescent guidelines to support the commissioning of adult services and the SMS funding allocation, the Devon FIG was asked to consider revised guidelines. The guidelines are a result of feedback received form the FIG in 2021 and specialists in 2021 and 2022.

The FIG considered the proposed formulary guidelines: The discussion included:

- Minor amendments to support monitoring requirements were agreed.
- Pulse and finding arrythmia - it was agreed to remove “or arrythmia measured on 2 occasions” as GPs indicated that arrhythmia in a child would likely warrant further investigation if detected on a single occasion.
- Addition of a note to recognise the availability of smartphone apps which may help aid calculation of growth centiles, and a link to the RCPCH website for UK-WHO growth charts.

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

12. Recent Drug decisions (including NICE)

Due to time constraints the review of recent drug decisions (including NICE) from August 2022 to October 2022 was deferred until the next 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
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
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
22/40	Tirbanibulin for actinic keratosis – Update guidance for AK and entries for Actikerall and fluorouracil 5% cream in line with the discussion.	Formulary Team	Complete
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	Complete
22/48	NICE guidance NG196 – Atrial fibrillation: consult with specialists on the anticoagulation guidance.	Formulary Team	Ongoing
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

22/61	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
22/63	MHRA Drug Safety Update: June 2022 – add a time-limited link from the formulary entry for Novorapid Pumpcart to the NPSA alert	Formulary Team	Complete
22/64	MHRA Drug Safety Update: July 2022 – update the formulary section on migraine, epilepsy and the topiramate entry.	Formulary Team	Ongoing
22/65	Asymptomatic bacteriuria screening in pregnancy – liaise with local specialists/Local Maternity Network and bring views and formulary guidance back to the FIG either via the e-FIG process or to a meeting.	Formulary Team	Ongoing
22/66	FIG Terms of Reference to be updated to reflect organisational and membership changes.	Formulary Team	Complete
22/67	Solriamfetol for the treatment of excessive daytime sleepiness – circulate the proposed formulary entry and amended guideline to specialists for comment.	SMS pharmacist	Complete
22/68	Solriamfetol for the treatment of excessive daytime sleepiness – bring SMS prescribing guideline back to the FIG via the appropriate route.	SMS pharmacist	On agenda
22/69	Update the proposed formulary guidance for osteoporosis and undertake further consultation with specialists.	Formulary Team	Complete
22/70	Following further consultation with specialists bring formulary guidance for osteoporosis and drug entries back to the FIG via the appropriate route.	Formulary Team	Ongoing
22/73	Potassium permanganate – communicate publication of new formulary entry for potassium permanganate to specialist teams and primary care.	Formulary Team	Complete
22/74	Potassium permanganate – notify LPC (via MOCC LPC representative) of new formulary entry for potassium permanganate when published.	Formulary Team	Ongoing
22/75	Schedule the formulary entry for potassium permanganate for review by the FIG at an appropriate time in the future.	Formulary Team	Ongoing
22/76	Remove potassium permanganate from the South & West Devon guidance for infected eczema and review formulary guidance for infected eczema and bring to FIG for discussion following specialist consultation. ***Post meeting note**: Potassium permanganate removed from South & West guidance for infected eczema (3rd Nov 2022)*	Formulary Team	Ongoing
22/77	Liaise with Wound Management Group over alternatives to potassium permanganate for highlighting in the formulary.	Formulary Team	Ongoing
22/78	Iron deficiency anaemia – Forward draft formulary entry to specialists for final comment.	Formulary Team	Complete

22/79	Iron deficiency anaemia – following consultation with specialists update the formulary entry with the accepted entry or bring back to a future FIG meeting for discussion or pursue through the e-FIG process.	Formulary Team	Complete
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	Ongoing
22/81	Pharmacological treatment for type 2 diabetes (NICE NG28): liaise with Heart Failure Teams over GP initiation of SGLT2 inhibitors for chronic heart failure	Formulary Team	Complete
22/82	Stoma care: guidance and product recommendations review: bring review to a future meeting.	Formulary Team	On agenda
22/83	Vaginal candidiasis in pregnancy: update the proposed formulary entry taking account of the discussion and bring back to the FIG via the most appropriate route.	Formulary Team	Complete
22/84	NICE TA805: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides: Add NICE TA805 to the Devon Formulary in line with the ICB's statutory responsibilities.	Formulary Team	Complete
22/85	Consideration of SyreniRing 0.120mg/0.015mg per 24 hours, vaginal delivery system: progress through a future meeting or via the e-FIG process.	Formulary Team	On agenda
22/86	Consideration of Actimorph (morphine sulfate) orodispersible tablets: add to the formulary as a 'Green' first line treatment.	Formulary Team	Complete
22/87	Formulary entries for salbutamol and terbutaline and formulary nebulisation guidance to be updated to include a link to the Drug Safety Update.	Formulary Team	Ongoing
22/87	Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to difference in formulations: Formulary entry for methylphenidate MR to be updated to include a weblink to the Drug Safety Update.	Formulary Team	Ongoing
22/88	SMS Guidelines: Methylphenidate, lisdexamfetamine and atomoxetine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above: Update the guidelines in line with discussion.	Formulary Team	Ongoing