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

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 19th July 2023

Via Microsoft Teams

Present:

Name	Job Title	Organisation
Susie Harris (Chair)	Consultant Physician/Geriatrician	RDUH NHS FT
Glen Allaway	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Andy Craig	GP	NHS Devon ICB
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Rebecca Lowe	Joint Formulary Technician	NHS Devon ICB
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon ICB
Chris Sullivan	Deputy Chief Pharmacist	Devon Partnership NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

Guests:

Sarah Barrett	Senior Medicines Optimisation Pharmacist	NHS Devon ICB
Dr Claire Bethune	Immunology Consultant	UHP NHS Trust
Dr Alex Degan	Primary Care Medical Director	NHS Devon ICB
Emma Gitsham	Clinical Effectiveness Pharmacist – Specialist Medicines Service (SMS) Guidelines Lead	NHS Devon ICB
Dr David McGregor	Consultant Paediatrician	RDUH NHS FT
Natasha Moore	Senior Medicines Optimisation Pharmacist	NHS Devon ICB
Dr Ray Sheridan	Elderly Care Consultant	RDUH NHS FT

Observers:

Georgina Sharpe	Foundation Pharmacist	TS&D NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon ICB

1. Welcome and announcements

Meeting etiquette

Susie Harris explained the meeting etiquette.

Chairman's welcome

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

It was noted that Graham Simpole was stepping down from the group and that this would be his last meeting. The group thanked Graham for all his hard work and contributions to the FIG meetings over the last few years.

Apologies

NAME	JOB TITLE	ORGANISATION
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon ICB
Nicola Diffey	Pharmacist	Livewell Southwest
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB

Subsequent to the meeting apologies were received from Heidi Campbell, Pharmacist, NHS Kernow ICB.

Natasha Moore attended the meeting as deputy for Sarah Marner and as applicant for the addition of Avenor and Tiogiva.

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
Chronic Heart Failure • Dapagliflozin (Forxiga) • Empagliflozin (Jardiance) • Sacubitril valsartan (Entresto) • Various classes of drugs including diuretics, ACE inhibitors, adrenoreceptor blockers, beta-blockers, mineralocorticoid antagonists	Astra Zeneca UK Ltd Boehringer Ingelheim Ltd Novartis Pharmaceuticals UK Ltd Various manufacturers
Insulins • Insulin aspart (Novorapid & Fiasp) • Insulin aspart (Trurapi) • Insulin lispro (Admelog) • Insulin lispro (Humalog & Lyumjev) • Insulin glulisine (Apidra) • Various insulins	Novo Nordisk Ltd Sanofi Sanofi Eli Lilly and Company Ltd Sanofi Various manufacturers

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
Glucagon pre-filled pens: • Ogluo Alternative treatments: • GlucaGen HypoKit	Tetris Pharma Ltd Novo Nordisk Ltd
Drug interactions with hormonal contraception: • Barrier methods • Combined oral contraceptive pill (COC) • Copper intrauterine device (Cu-IUD) • Depot medroxyprogesterone acetate (DMPA) (Depo-Provera and Sayana Press) • Etonogestrel implant (Nexplanon) • Levonorgestrel-releasing intrauterine device (LNG-IUD) • Oral emergency contraception • Progestogen-only pill (POP) • Combined Hormonal contraceptive transdermal patch • Combined Hormonal contraceptive vaginal ring	 Various manufacturers Various manufacturers Various manufacturers Pfizer Ltd Organon Pharma (UK) Ltd Various manufacturers Various manufacturers Various manufacturers Various manufacturers Various manufacturers
Fluticasone propionate and salmeterol combination pMDIs: • Avenor **Alternatives:** • Seretide Evohaler • AirFluSal MDI Other fluticasone propionate and salmeterol combination pMDIs **Tiotropium DPIs:** • Tiogiva **Alternatives:** • Braltus Zonda • Other tiotropium DPIs	 Zentiva GlaxoSmithKline UK Sandox Limited Various manufacturers Glenmark Pharmaceuticals Europe Ltd TEVA UK Limited Various manufacturers
Lithium SMS guideline • Priadel 200mg, 400mg • Camcolit 400mg • Liskonum 450mg	 Essential Pharma M Essential Pharma Ltd Teofarma S.r.l.
COVID Treatments • Paxlovid (nirmatrelvir / ritonavir) • Molnupiravir (Lagevrio) • Remdesivir (Veklury) • Sotrovimab (Xejudy)	 Pfizer Ltd Merck, Sharpe and Dohme UK Ltd Gilead Sciences Ltd GlaxoSmithKline UK

Fidaxomicin for the treatment of *Clostridioides difficile* infection (including formulary guidance on the treatment of C. difficile infection) • Fidaxomicin (Dificlir) **Alternative treatments:** • Vancomycin • Metronidazole • Saccharomyces boulardii	 Tillotts Pharma UK Limited Various manufacturers Various manufacturers Various manufacturers
Jext adrenaline auto-injectors (AAI) for emergency treatment of acute anaphylaxis: • Jext AAI • Emerade AAI **Alternatives:** • EpiPen AAI • Other adrenaline auto-injectors	 ALK-Abello Ltd Bausch & Lomb U.K. Limited Mylan Various manufacturers

Name	Job Title	Declaration
Rebecca Lowe	Joint Formulary Pharmacy Technician	Other part time jobs - community pharmacy locum
Natasha Moore	Senior Medicines Optimisation Pharmacist	Secondary employment - locum community pharmacist.
Dr Alex Degan	Primary Care Medical Director, Devon Integrated Care	Work as paid advisor to manufacturing company/companies. I have presented on a Webinar for Pfizer with regard to COVID vaccines in 2020 and attended a workshop for GSK with regard to structure of the NHS in 2021 both of which I received payment for. I am also a GP partner in a dispensing practice in Mid Devon.
Dr Ray Sheridan	Elderly Care Consultant	Have taken part in a trial for drug(s)/device(s) - PI for RECOVERY trial - I don't receive any funding for this so no COI. Included in all COVID drugs in in-patient setting
Dr Claire Bethune	Immunology Consultant	Have taken part in a trial for drug(s)/device(s) - PI for RECOVERY trial - I don't receive any funding for this so no COI. Included in all COVID drugs in in-patient setting
Dr David McGregor	Consultant Paediatrician	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Novo Nordisk sponsored my attendance at BSPED 2022.

2. Minutes of the meeting held on 17th May 2023 and Actions/Matters Arising

Minutes of the meeting held on 17th May 2023

The minutes of the meeting held on 17th May 2023 were approved.

POST MEETING NOTE

The Formulary Team noted that subsequent to the discussion of Orobalin at the meeting on 17th May it had become apparent that the revised proposal presented by the specialists at the meeting takes the decision out of the remit of the FIG; prospective evidence collection for evaluation of efficacy in the absence of published evidence to support the proposed use should be approved through the hospital trust governance process. This will be handled internally by University Hospitals Plymouth. Orobalin will not be added to the Devon Formulary.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
22/61	Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin.	Formulary team	Ongoing
22/62	Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group.	Formulary team	Ongoing
22/76	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).* *Review NICE guidance for infected eczema and update formulary if required.* *NICE published updated guidance in June 2023, this has been added to the formulary team workplan*	 Formulary Team	 Complete Closed

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
22/89	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. ***Post meeting note****: These guidelines are affected by the outcome of discussions in respect of SMS guidelines for dexamfetamine for ADHD in children and young people aged 6 years and above (see action 22/104 & 22/105)*	Formulary Team	Complete
22/92	Report of e-FIG decisions: November 2022: Treatment of vaginal candidiasis - seek the views of specialists on the use of vaginal creams which require insertion using an applicator during pregnancy and bring revised guidance back to the FIG via the appropriate route.	Formulary Team	Ongoing
22/98	Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients.	Formulary Team	Ongoing
23/02	Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin – Proposed Formulary Entry to be amended in line with the discussion and added to the local formulary.	Formulary Team	Ongoing
23/04	4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.	Formulary Team	Ongoing
23/13	NICE guidance NG196: Atrial fibrillation – If accepted by specialists, publish formulary guidance for Atrial Fibrillation.	Formulary Team	Ongoing
23/27	Bevespi Aerosphere and Trixeo Aerosphere – ascertain from specialists which patient groups would benefit from a LABA/LAMA pMDI in preference to a LABA/LAMA SMI.	Formulary Team	Ongoing
23/28	Bevespi Aerosphere and Trixeo Aerosphere – bring back to FIG when specialists can attend.	Formulary Team	Ongoing
23/29	Metolazone 5mg tablets (Xaqua) – consult with heart failure and renal teams for metolazone 5mg tablets (Xaqua).	Formulary Team	Ongoing
23/31	Dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and young people aged 6 years and above – publish the guideline following remuneration negotiations with the LMC.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete

23/33	Solriamfetol for the treatment of excessive daytime sleepiness – publish the guideline following remuneration negotiations with the LMC.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/34	Solriamfetol for the treatment of excessive daytime sleepiness – publish the updated formulary entry (amber classification) once the SMS guideline has been published.	Formulary team	Complete
23/36	Western Locality Shared Care: Methotrexate, gastroenterology – folic acid update – publish updated guidelines following agreement with specialists.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/37	Lithium SMS Guidelines – update the guidelines in line with the discussion.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/38	Lithium SMS Guidelines – clarify thresholds for action (and action to be taken) for renal and thyroid function with specialists.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	On agenda
23/39	Dexamfetamine for ADHD, narcolepsy, and idiopathic hypersomnolence in adults – submit guideline to LMC for negotiation of remuneration with ICB Primary Care Team	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/40	Dexamfetamine for ADHD, narcolepsy, and idiopathic hypersomnolence in adults – publish the agreed guideline following negotiation or remuneration.	Clinical Effectiveness Pharmacist – SMS Guidelines Lead	Complete
23/41	Management of Hypertension (Update) – consult with specialist on proposed guidance.	Formulary team	Ongoing
23/42	Management of Hypertension (Update) – following consultation with specialists, bring draft guidance back to the FIG via the e-FIG process.	Formulary team	Ongoing
23/43	UrgoTul Silver Dressing – publish accepted formulary entry.	Formulary team	Complete
23/44	UrgoTul Silver Dressing – send epact data for non-formulary silver dressings to Devon Wound Management Group for awareness.	Formulary team	Complete
23/45	Harmonisation of preservative-free prostaglandin analogue / prostamide containing eye drops – publish the harmonised formulary entry.	Formulary team	Complete
23/46	Sodium zirconium cyclosilicate for treating hyperkalaemia: consideration of reclassification – work with specialists on the prescribing guidance.	Formulary team	Ongoing

23/47	Sodium zirconium cyclosilicate for treating hyperkalaemia: bring SZC back to FIG via the appropriate route.	Formulary team	Ongoing
23/48	MHRA Drug Safety Updates – April 2023: update the relevant formulary sections with recommendations from the MHRA Drug Safety Updates March 2023 and April 2023.	Formulary team	Ongoing
23/49	MHRA Drug Safety Updates – April 2023: write to MHRA to ask for clarification on frequency of monitoring for hepatic adverse reactions for patients receiving nitrofurantoin.	Formulary team	Ongoing

3. Report of e-FIG decisions

In May 2023 the Devon FIG was asked to consider the following items through the e-FIG process:

Fidaxomicin granules for oral suspension

Inclusion of fidaxomicin granules for oral suspension 40mg/ml in the Devon Formulary as amber (specialist input) for the treatment of *C. difficile* infection in adults and children with swallowing difficulties/enteral feeding requirements.

Responses received indicated acceptance of the proposed formulation and formulary entry. The Devon Formulary has been updated with the accepted formulary entry.

An additional note has been added to the *C. difficile* infection guidance page to include the oral suspension formulation.

Jext (adrenaline) auto-injectors and removal of Emerade auto-injectors

Inclusion of Jext (adrenaline) 150micrograms and 300micrograms auto-injectors in the Devon Formulary as a green (first line) option for emergency treatment of acute anaphylaxis and the removal of Emerade (adrenaline) auto-injectors.

Responses received indicated acceptance of the proposed formulation and formulary entry. The Devon Formulary has been updated with the accepted formulary entry.

A question was raised regarding the Emerade 500micrograms presentation, which is the preferred dosage of Emerade in adults for anaphylaxis. In response, it was highlighted that the NPSA alert noted “there is evidence to suggest that a single EpiPen (300 micrograms) or Jext (300 micrograms) pen will be a suitable replacement for a single Emerade 500 micrograms pen”. It was also mentioned that if Emerade were to return to the UK market, the FIG could consider reinstating it to the formulary.

Responses to both items were received from 13 FIG members. These were from 3 GPs, 1 secondary care consultant, 7 pharmacists, 1 nurse, and 1 pharmacy technician. The pharmacists were from the ICB and secondary care. No interests were reported.

4. Papers for information only

Report of COVID-19 related changes to the formulary (May 2023 to July 2023)

The FIG received an update of COVID-19 changes to the Formulary.

The Formulary Team has continued to support the development and dissemination of COVID-19 related guidance from various local and national groups.

COVID-19 is now managed in a similar way to other respiratory illnesses, through ongoing surveillance, vaccination programmes, and strong public health messaging.

The COVID-19 vaccine developed by SK Chemicals (SKYCovion) has been added to the formulary after it was given regulatory approval by the MHRA

NICE TA878: 'Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab, and tocilizumab for treating COVID-19' was published on 29th March 2023.

The formulary entries for nirmatrelvir plus ritonavir (Paxlovid), sotrovimab, and tocilizumab have been updated to incorporate the TA recommendations. Casirivimab plus imdevimab is not recommended for the treatment of COVID-19 under NICE TA878.

NHS England issued a national commissioning policy for molnupiravir and remdesivir for non-hospitalised patients at risk of progression to severe COVID in May 2023. The formulary entries for molnupiravir and remdesivir have been updated with the NHSE policy.

COVID-19 treatments for non-hospitalised patients and a proposal for the reclassification of the oral antivirals was included on the meeting agenda as a separate item.

Recent drug decisions within the formulary (including updates from NICE) – May 2023 to July 2023

The FIG received a report of recent drug decisions.

Devon FIG Annual Report (1st April 2022 – 31st March 2023)

The FIG received the annual report of activity and governance processes from 1st April 2022 to 31st March 2023. On 1st July 2022 NHS Devon CCG transitioned into NHS Devon Integrated Care Board (ICB).

The Devon FIG is the forum by which the ICB works with the provider trusts it commissions to incorporate national and local treatment choices and guidance into the Devon Formulary. The FIG is also responsible for deciding whether a medicine required formal "Shared Care" guidelines and for agreeing the clinical content of those guidelines.

During the period of the report, the FIG continued to deliver the Devon Formulary to promote prescribing that is safe, clinically appropriate and cost effective in both primary and secondary care by providing guidance on locally recommended drug and treatment choices.

The Devon Formulary is also the mechanism by which local commissioners and providers demonstrate that medicines and treatments recommended by NICE TA and HST guidance, and local commissioning policies are available for use, in consultation with the patient, and when recommended as part of their treatment.

Between 1st April 2022 and 31 March 2023 the Formulary and Referral website recorded over 2.5 million page views, an increase of over 17% over the previous year.

In January 2023 Dr Tawfique Daneshmend announced that he was stepping down as Chair of the Devon Formulary Group. Dr Daneshmend had supported the development of the Devon Formulary over the last 25 years.

Since March 2023 Dr Susie Harris, Consultant Representative (RDUH) has chaired the group.

Dr Jamie Smith, Consultant Representative (T&SD) and Samantha Smith, Pharmacist Representative (RDUH) stepped down from the group in August 2022, Dr William Nolan, GP Representative stepped down in October 2022. Dr Smith, Ms Smith and Dr Nolan had been committed FIG members over a number of years and made significant contributions to support the work of the group.

Becki Lowe, Joint Formulary Technician, NHS Devon ICB, joined the Group in October 2022.

There are four consultant representative vacancies and two GP representative vacancies on the Devon FIG. Work is ongoing to recruit additional consultant and GP representative members to the FIG.

The FIG thanked the ICB formulary team for all their work in preparing and presenting meeting papers and developing and maintaining the Formulary website.

The formulary team also thanked Susie Harris for her advice and support and for stepping into the role of Chair. The formulary team also thanked the FIG members for their ongoing support and commitment to the success of the Devon Formulary. The quality of FIG members' feedback on draft guidance and their involvement in detailed discussions were highlighted.

The FIG approved the Devon FIG Annual Report 2022-23. The report will be submitted to the Clinical Policy Recommendation Committee of the Integrated Care Board (ICB) for assurance.

ACTION: Devon FIG Annual Report to be submitted to the Clinical Policy Recommendation Committee.

5. Drug interactions with hormonal contraception

New guidance was published by the Specialised Pharmacy Services (SPS) on using contraception with enzyme-inducing medicines in February 2023. The Faculty of Sexual and Reproductive Healthcare (FSRH) has also updated its guidance on drug interactions and contraceptives.

The Formulary Team has reviewed and updated the current formulary guidance on drug interactions with hormonal contraception in consultation with specialists throughout Devon. Other contraception guidance has not been reviewed at this stage.

The guidance has been reformatted to provide specific recommendations in a clear and concise layout. It provides a summary of contraceptive methods affected and unaffected by cytochrome P450 drug interactions, and includes additional specific information on antibiotics, antiepileptic drugs, St John's Wort and contraceptive methods recommended in cases of diarrhoea and vomiting.

The FIG considered and accepted the proposed formulary entry without amendment.

ACTION: Formulary team to publish the updated formulary guidance for drug interactions with hormonal contraception.

6. Insulins

A proposal for two biosimilar insulins to be added to the formulary, namely Trurapi (insulin aspart) and Admelog (insulin lispro), was presented to the FIG. The Devon Formulary already includes a biosimilar insulin glargine and the use of biosimilar insulins is supported by NICE guidance for type 1 diabetes (NG17). An overview of Trurapi and Admelog was provided in the paper.

Trurapi and Admelog were proposed as green (first-line) for new patients on the basis that these are cost-saving compared with the current formulary options, Novorapid (insulin aspart) and Humalog (insulin lispro).

Novorapid and Humalog products would remain blue with a note that these are for existing patients and for patients who require the Novorapid or Humalog devices. It is envisaged that in the future there will be a transition to the biosimilar insulins. The initial focus will be on Trurapi, as Novorapid is more frequently prescribed than Humalog and the potential annual savings for Devon would be substantially higher.

If required in the future, the formulary entries can be updated to reflect the transition to biosimilar insulins for the wider population of patients. It was proposed that insulin glulisine will continue to be blue (second-line). Currently, there is no biosimilar insulin glulisine.

Evidence from the European Public Assessment Reports supporting the licensing of Trurapi and Admelog was presented in the meeting paper. Similarity was demonstrated for Trurapi compared with Novorapid and Admelog compared with Humalog.

In addition, a small number of other changes to the section on insulins were proposed. Since there is no longer a financial benefit in prescribing Abasaglar (biosimilar insulin glargine) over Lantus (insulin glargine), and Lantus remains the dominant insulin glargine product prescribed locally, it is proposed that Lantus is reclassified from second-line to first-line (green). The addition of insulin pens for cartridges to North & East Devon is proposed as for historical reasons, these are included in South & West Devon only.

The NHS Devon ICB Medicines Optimisation team have had conversations with several diabetes consultants with respect to biosimilar insulins. Full consultation with the specialist teams in respect of all proposed changes will be conducted by the Formulary team after the meeting and if a significant amendment to the proposed draft entries is raised, this will be brought back to the FIG through the appropriate route.

The FIG considered and accepted in principle the changes to insulins in the Devon Formulary subject to minor amendment and consultation with the MO team. Specifically, the FIG agreed:

- The addition of Trurapi (biosimilar insulin aspart) to the Devon Formulary as a green (first-line) option.
- The addition of Admelog (biosimilar insulin lispro) to the Devon Formulary as a green (first-line) option.
- The reclassification of Actrapid soluble insulin from green to blue (second-line).
- The reclassification of Lantus (insulin glargine) from blue to green (first-line).
- All pens for insulin cartridges included in South & West Devon to be included in North & East Devon.
- That the proposed updates to the insulin entries are clear and acceptable. For clarity, an amendment was agreed to note 1 of the entry for Trurapi and Admelog.

The discussion noted that Fiasp has amber status in the formulary at the request of specialists. The discussion noted that the MO team do not intend to bulk switch existing patients to the new formulary options. The initial plan is for any proposed changes to be discussed during routine patient reviews by the specialist diabetes teams.

ACTION: Formulary team to amend the proposed formulary entry for insulins in line with the discussion.

ACTION: Formulary team to undertake consultation with adult and paediatric specialists. Any significant changes will be brought back to the FIG via an appropriate route.

7. Glucagon 500micrograms and 1mg pre-filled pens (Ogluo)

Glucagon 500 micrograms and 1mg pre-filled pens (Ogluo) are licensed for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus. Ogluo is a ready-to-use auto-injector pen. The lower strength device is for use in children aged between 2 years and 6 years of age who weigh less than 25kg.

The paediatric diabetes teams at Royal Devon University Healthcare NHS Foundation Trust and Torbay & South Devon NHS Foundation Trust have requested the addition of Ogluo to the Devon Formulary. The current formulary option is GlucaGen Hypokit, which is only available in a 1mg strength. The Hypokit consists of a vial of powdered glucagon and a syringe containing water for injection; reconstitution and withdrawal of the correct dose into the syringe is required before administration. There is a risk of the injection not being given, an incomplete injection or injection of an incorrect dose. The proposal at the specialist team's request is for Ogluo to be considered as a green (first-line) option alongside GlucaGen Hypokit. A Consultant Paediatrician (RDUH) and a Senior Medicines Optimisation Pharmacist, NHS Devon ICB, were present for discussion of this item.

Clinical evidence from the European Public Assessment Report supporting the licensing of Ogluo was presented in the meeting paper. The pivotal study comparing Ogluo with GlucaGen Hypokit found that the time to achieve a positive plasma glucose response was on average 4 to 4.5 minutes longer for patients receiving Ogluo, and 92% of patients receiving Ogluo achieved glucose recovery in 20 minutes, compared to only 15 minutes for the entire study population for GlucaGen Hypokit,

with a small proportion taking longer than 20 minutes to recover. The SmPC indicates that patients should be advised that there may be a longer recovery time in some patients.

Feedback from the UHP specialist team was included in the meeting papers. The Formulary team received feedback from the Torbay and South Devon (T&SD) team after the meeting papers were distributed. The T&SD team were in agreement with the points made by the UHP team. In addition, the lead T&SD nurse had noted that there is currently a shortage of GlucaGen Hypokit so Ogluo is being prescribed when GlucaGen Hypokit is not available. The Formulary team reported that a recently updated Medicines Shortage Notice indicated that there will be only intermittent supplies of GlucaGen Hypokit until 2024.

The Formulary team estimated the cost impact of prescribing Ogluo in place of GlucaGen Hypokit for patients below 18 years of age in the community setting assuming normal stock levels of both drugs. The cost of an Ogluo pre-filled pen is £73 compared with £11.52 for a GlucaGen Hypokit.

The FIG was asked to take a decision in principle for the treatment of patients below 18 years of age. There is greater use of GlucaGen Hypokit in adult patients in the community. There would be a significant budget impact if Ogluo is prescribed in place of GlucaGen Hypokit in the adult population. The Formulary team has not received any requests from the adult diabetes specialist teams for Ogluo to be added to the Devon Formulary. The Formulary team will consult with the diabetes teams for adult patients and bring the results of the consultation to a future meeting. Secondary care pharmacists will be asked about the financial impact on the trusts.

The FIG was mindful of the costs for Ogluo. The FIG considered and supported in principle the proposal for Ogluo prefilled pens to be added to the Devon Formulary as a green (first-line) option alongside GlucaGen Hypokit for all paediatric patients. The FIG accepted the proposed formulary entry with minor amendment. However, it was recognised that there are different considerations for adult patients and further consultation is needed. Ogluo for adult patients will be brought back to the FIG.

Key points of the discussion noted:

- The consultant paediatrician present was clear that young children are at risk of hypoglycaemia and that severe hypoglycaemia can happen at any time. It is not possible to identify which patients are at the highest risk. Specialists support prescribing of Ogluo for all children. The reasons include that it is much easier for parents/carers to give when they are in a stressful situation.
- For a substantial group of patients this is a standby medicine which is renewed when it becomes out of date. It was agreed that each patient would be prescribed one device and that information on expiry dates be added to the Devon Formulary.
- Patients who can manage the GlucaGen Hypokit can be prescribed it. The 1mg dose is the correct dose for larger and older patients however incorrect reconstitution is a problem. Training by specialist teams is required.
- Drug shortages can cause pressure in the system.
- There has been an increase in use of real-time CGM monitors by patients. This may reduce the number of hypoglycaemia events experienced by patients.
- The Formulary team highlighted the response received from a consultant paediatrician on behalf of the UHP paediatric diabetes specialist team and the T&SD team.

ACTION: Formulary team to make minor amendments to the proposed formulary entry for Ogluo and proceed with consultation with adult specialists.

8. Chronic heart failure (including NICE TA902)

The Devon Formulary guidance for chronic heart failure (CHF) provides guidance on the pharmacological treatment of heart failure with reduced ejection fraction. NICE TA679 recommends dapagliflozin for CHF with reduced ejection fraction. The recent publication of NICE TA902 recommending dapagliflozin for symptomatic chronic heart failure (CHF) with mildly reduced or preserved ejection fraction has prompted the need to consider how CHF is addressed in the formulary and the appropriate formulary classification for dapagliflozin across the wider spectrum of CHF.

NICE TA902

NICE published TA902 on 21 June 2023. This left insufficient time for the routine review and consultation with the specialist teams before scheduling a discussion by the FIG to enable a decision to be taken on an update to the formulary entry for dapagliflozin and the formulary guidance for CHF at the July FIG meeting. In addition, an e-mail received from a GP practice indicated that there would be benefit in having an initial discussion with the FIG before consulting with the heart failure teams and bringing the TA to the September FIG meeting. The resource impact report for TA902 indicates the first prescription would be issued by secondary care and that prescribing would be continued by primary care. This appears to be related to the recommendation in TA679 for dapagliflozin for CHF with reduced ejection fraction to be started on the advice of a specialist and the NICE guidance NG106 recommendation for patients with suspected chronic heart failure to be referred to a specialist service for assessment and an echocardiography for diagnosis. However NICE Guideline NG28 (Type 2 diabetes in adults) supports primary care initiation of a SGLT2 inhibitor for CHF in a type 2 DM patient without seeking advice from a heart failure specialist.

The FIG had previously indicated that a pragmatic approach was required to the formulary classification for dapagliflozin for its NICE TA indications with advice from the specialist teams. The FIG was asked for an initial discussion on the formulary classification for dapagliflozin in CHF with preserved or mildly reduced ejection fraction noting that the heart failure teams had previously indicated that they would not have an objection to GP initiation of SGLT2 inhibitors for CHF with reduced ejection fraction. The FIG indicated that it would accept ‘green’ (first-line) for dapagliflozin in the formulary for CHF with mildly reduced or preserved ejection fraction if this classification is supported by the heart failure specialists.

It was noted that:

- a discrepancy exists between pieces of NICE guidance around how treatment with SGLT2 inhibitors is initiated.
- this is not a new drug; GPs have experience of its use in heart failure patients with reduced ejection fraction.

ACTION: Formulary Team to consult with heart failure specialists on NICE TA902 and bring formulary entry to September 2023 meeting

Formulary guidance for CHF

NICE has recently conducted an exceptional surveillance review of its NG106 guidance on CHF. The decision has been taken to update the pharmacological management section of NG106. Members of NICE's cardiovascular disease committee, and other topic experts, highlighted to NICE

that the recommendations on pharmacological treatments of heart failure with reduced ejection fraction in the NICE guideline are out of date when compared to 2021 European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure, and to current UK clinical practice. The ESC guidance recommends first-line positioning for ACE inhibitors/ARBs, beta blockers, mineralocorticoid antagonists and SGLT2 inhibitors in contrast to the sequencing of pharmacological treatments for heart failure with reduced ejection fraction currently recommended in the NICE guidance and TAs.

NICE has not given a publication date for the update to the guidance and a draft scope is not available for consultation.

The Formulary team was working on a draft update to the formulary guidance for CHF with reduced ejection fraction based on the ESC guidance when NICE issued the surveillance review. The draft formulary update incorporates ESC and British Heart Failure Society guidance for individual drugs. It is intended to continue with this review as the current formulary guidance is out of date and it could be some time before the update to the NICE guidance is published. When this happens, the Formulary team will review the formulary guidance in a timely manner.

Before consulting with the heart failure teams, the Formulary team asked the FIG whether it would support an approach to first-line treatments for CHF in line with the ESC guidance. The FIG indicated that this would be acceptable if the heart failure teams support this approach. Draft formulary guidance for CHF will be brought to the FIG for review at a future date following consultation with the heart failure teams.

9. Avenor (fluticasone propionate & salmeterol, pMDI) and Tiogiva (Tiotropium, DPI)

Applications have been received from the NHS Devon Medicines Optimisation team proposing the addition of two inhalers to the Devon Formulary. These are Avenor pressurised metered dose inhaler (pMDI), containing fluticasone propionate (FP) and salmeterol in a range of strengths and Tiogiva dry powder inhaler (DPI), containing tiotropium 18 microgram. The place in therapy for these products will be the same as the currently recommended products as they are considered direct replacements.

The Formulary team consulted with respiratory consultants and respiratory nurses in secondary care. Input was also sought from respiratory champions, primary care respiratory nurses and PCN pharmacists with an interest in respiratory medicines on proposed changes to the Devon Formulary. Consultant feedback focussed predominately on respiratory services in Devon, which is outside of the remit of the FIG. Responses from respiratory champions in primary care recognised the savings of the proposed inhalers. No particular issues were highlighted. Specialists requested that any switch programmes be introduced to patients in a multi-faceted fashion. This was backed by the NHS Devon MO team.

Avenor (pMDI)

Avenor 50/25 pMDIis licensed for asthma in children aged 4 years and over. Avenor 125/25 and Avenor 250/25 are licensed for asthma in patients aged 12 years and over. Use of an AeroChamber Plus spacer device with Avenor is recommended in patients who have, or are likely to have, difficulties in coordinating actuation with inspiration. In line with current formulary guidance on high

dose inhaled corticosteroid (ICS) via pMDI, a spacer device should also be used with Avenor 250/25 (high dose ICS).

It was proposed that Avenor 50/25 is added to the Devon Formulary as a blue (second line) option for asthma in children aged 4 years and over. Avenor 125/25 and Avenor 250/25 were also proposed to be added to the Devon Formulary as blue (second line) options for asthma in patients aged 12 years and over. It was proposed that current formulary FP/salmeterol pMDIs (Seretide 50/25 Evohaler, AirFluSal pMDI 125/25, and AirFluSal pMDI 250/25 are removed in favour of the Avenor pMDI brand.

The meeting paper presented clinical evidence from a Public Assessment Report for the licensing of Avenor pMDI published by the MHRA. The regulators were satisfied that equivalence was demonstrated compared to the reference product (Seretide Evohaler).

Avenor pMDIs offer cost savings of between £6.09 and £16.33 per inhaler versus the current Devon Formulary recommended FP/salmeterol pMDIs (Seretide 50 Evohaler and AirFluSal MDI). If 100% of primary care prescribing for FP/salmeterol pMDIs (including non-formulary products) were to switch to Avenor pMDI, there may be potential savings of approximately £460,000 per annum.

Data on inhaler carbon emissions provided in a PrescQipp bulletin indicate that the Avenor pMDIs are very similar to the current formulary recommended FP/salmeterol pMDIs in this respect.

Tiogiva

Tiogiva 18 microgram, inhalation powder, hard capsule is licensed as a maintenance bronchodilator treatment for patients with chronic obstructive airways disease (COPD). The recommended dose is inhalation of the contents of one capsule once daily with the dry powder inhaler, at the same time each day. To get a full dose, the patient must inhale a second time from the same capsule, in order to empty the capsule completely (this is also the case with the alternative tiotropium DPIs, Braltus Zonda and Spiriva HandiHaler).

It was proposed that Tiogiva 18 microgram, inhalation powder, hard capsules are added to the Devon Formulary as a green (first line) option for the maintenance treatment of COPD. It was also proposed that the current tiotropium DPI (Braltus Zonda 10 microgram, inhalation powder) is removed from the formulary in favour of Tiogiva.

Clinical evidence from a European Public Assessment Report (EPAR) for Tiogiva was presented in the meeting paper. The pivotal studies undertaken satisfied the regulators that Tiogiva was therapeutically equivalent to the reference product Spiriva, 18mcg, Inhalation powder, hard capsule, the benefits and risks were taken as being the same as those of the reference medicine.

Tiogiva 18 microgram, inhalation powder with device offers a cost saving of £8.51 versus the Braltus Zonda 10 microgram, inhalation powder with device. If 100% of prescribing (including non-formulary Spiriva devices and generic products) were to switch to the proposed Tiogiva, there may be potential savings of approximately £390,000 per annum.

Inhaler carbon emissions data suggest no difference between Tiogiva and Braltus, both of which have slightly lower emissions than Spiriva Respimat.

The FIG considered and accepted:

- the inclusion of Avenor 50/25 pMDI in the Devon Formulary as a blue (second line) option for asthma in children aged 4 years and over.
- the inclusion of Avenor 120/25 pMDI and Avenor 250/25 pMDI in the Devon Formulary as blue (second line) options for asthma in patients aged 12 years and over.
- the removal of Seretide Evohaler 50/25 pMDI, AirFluSal MDI 125/25, and AirFluSal MDI 250/25 from the Devon Formulary.
- the inclusion of the Tiogiva 18 microgram, inhalation powder with device in the Devon Formulary as a green (first line) option for the maintenance treatment of COPD.
- the removal of Braltus Zonda 10 microgram, inhalation powder with device from the Devon Formulary.

The discussion of Avenor pMDI and Tiogiva DPI noted:

- The potential cost savings and switching of existing patients. Switching patients to a DPI, where clinically appropriate, should be the first priority rather than switching to an alternative pMDI. The Medicines Optimisation team is expecting to start a programme in primary care later in the year.
- The FIG discussed the environmental impact of DPI and pMDI use.
- The frequency at which new devices are needed and the potential to reduce plastic waste. Tiogiva is available without a device.
- The lack of a dose counter on the Avenor device which could have cost implications.

ACTION: Formulary Team to update the Devon Formulary entry for inhalers in line with the agreement and discussion of Avenor (pMDI) and Tiogiva (DPI) together with additional relevant pages.

10. Priadel (lithium) update

The prescription of lithium in primary care in Devon is supported by an SMS Guideline, which defines the specialist, GP and patient responsibilities associated with “Shared Care”. The guideline also outlines monitoring requirements to support safe prescribing. The current Devon SMS guideline was published in 2018.

An update to the guideline was proposed during the May 2023 Devon FIG meeting to recommend six monthly calcium monitoring in line with NICE Guideline NG222 together with several additional updates in line with the 2022 NHS England national shared care protocol for lithium, and a number of house-keeping updates.

The FIG also requested that greater clarity be sought regarding the monitoring thresholds for action (and actions to be taken) for renal and thyroid function. It was agreed that further work would be undertaken, and an update would be brought to a future FIG meeting for final agreement.

Further work has been undertaken to review the monitoring guidance with Devon Partnership NHS Trust. Proposed updates were presented to the FIG, which included updated monitoring guidance for weight, renal failure, thyroid function, calcium and ECG – inclusion of thresholds for action and associated GP follow-up actions (the full list of changes was detailed in the FIG board pack).

The FIG reviewed the changes and accepted the updates for implementation in practice with two additional minor amendments:

- Addition of the word “ideally” to the following monitoring guidance “Blood samples should be taken ideally 12 hours post dose.”
- Addition of the following sentence: “If the dose is taken once daily in the evening – the level should be taken the following morning.”

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to update the SMS guidance as agreed by the FIG.

ACTION: Clinical Effectiveness Pharmacist – SMS Guidelines Lead to present the lithium guideline to the LMC for negotiation of remuneration.

11. COVID-19 treatments for non-hospitalised patients (NICE TA878)

NICE issued a technology appraisal (TA878) for COVID-19 therapeutics on 29th March 2023. Prior to the publication of NICE TA878, there was a national commissioning policy for COVID-19 treatments for non-hospitalised patients who are symptomatic with COVID-19 and at the highest risk of progression to severe COVID-19. The policy covered two oral antivirals (molnupiravir and nirmatrelvir/ritonavir [Paxlovid]), and two medicines given by intravenous infusion, remdesivir (antiviral) and sotrovimab (neutralising monoclonal antibody). These medicines are supplied by COVID Medicines Delivery Units (CMDU), which are based at acute trusts and were set up on an interim basis as part of the NHS pandemic response. The CMDU clinical leads for RDUH and UHP and the ICB service lead joined the discussion.

As the NHS moves from a pandemic to an endemic response to COVID-19 infections, ICBs have been given responsibility for providing timely access to COVID-19 treatments for their local population. Paxlovid and molnupiravir are now available for community pharmacies to order and may be prescribed in primary care on a FP10 prescription. The long-term ambition for the NHS is for access to COVID-19 therapeutics to become part of routine services.

Systems were expected to work towards routine provision of COVID treatments for non-hospitalised patients to coincide with the end of the implementation period for NICE TA878 (designated 26 June 2023 in NHS England communications). It is recognised that the preferred method of provision will vary between areas and may include primary and secondary care.

NICE TA878 recommends the use of Paxlovid and sotrovimab for non-hospitalised patients at risk of progression to severe COVID-19. Molnupiravir and remdesivir were not recommended in the appraisal consultation document issued prior to the final recommendations. NICE will address molnupiravir and remdesivir for non-hospitalised patients in a separate TA for which the expected date of publication is to be confirmed. Subsequently, NHS England issued a national commissioning policy for molnupiravir and remdesivir for non-hospitalised patients at risk of progression to severe COVID which applies until the TA for molnupiravir and remdesivir is published.

NICE TA878 and the NHS England commissioning policy for remdesivir and molnupiravir for non-hospitalised patients define the order in which COVID treatments are considered for patients who are symptomatic with COVID-19 confirmed through testing, at increased risk of progression to severe COVID, and do not require supplemental oxygen or hospitalisation for COVID. Patient

groups at increased risk of progression to severe COVID-19 are defined in the Independent Advisory Group report to the DOH. A list of these patient groups is included in TA878.

- **First-line**: **Paxlovid** (nirmatrelvir/ritonavir)
  - As per NICE TA878
- **Second-line**: **Sotrovimab**
  - When Paxlovid is contraindicated or unsuitable, as per NICE TA878.
- **Third-line**: **Remdesivir**
  - Where supply is available and treatment with both Paxlovid and sotrovimab are both contraindicated or not clinically suitable, as per NHSE policy.
- **Fourth-line**: **Molnupiravir**
  - Where treatment with both Paxlovid and sotrovimab are both contraindicated or not clinically suitable AND treatment with remdesivir is contraindicated, not clinically suitable or not available, as per NHSE policy.

Paxlovid and molnupiravir are given for 5 days. Treatment should commence within 5 days of the onset of COVID symptoms. Remdesivir is administered by intravenous infusion (three doses over three days), and sotrovimab is a single dose given by intravenous infusion. The oral antivirals are licensed for adults only. Remdesivir and sotrovimab are licensed from 12 years of age and if the patient weighs at least 40kg. Currently, the four medicines are included in the Devon Formulary as red (hospital-only) options.

Under the new national arrangements, patients at risk of progression to severe COVID-19 have been advised to contact their GP practice, NHS 111 or hospital specialist as soon as they test positive for COVID-19.

The meeting paper presented the treatment pathway, an overview of the clinical and cost effectiveness evidence supporting TA878 and the NHS England commissioning policy, prescribing information for Paxlovid and molnupiravir including the risk of clinically significant drug interactions with Paxlovid, and the number of referrals to the CMDU. The positioning of Paxlovid and molnupiravir in formularies in southwest England was included in the paper. The formulary position of Paxlovid and molnupiravir for formularies elsewhere in England was reported during the discussion. A draft Clinical Referral Guideline (CRG) with criteria for referral to a CMDU was included in the meeting papers.

The FIG was asked to consider whether it is clinically appropriate for Paxlovid to be reclassified in the Devon Formulary from red (hospital-only) to green (first-line) for initiation in primary care and for molnupiravir to be reclassified from red to amber (to be prescribed in primary care on the advice of a specialist). The FIG considered draft formulary guidance for COVID treatments for non-hospitalised patients which included the initial assessment of the patient, the treatment pathway, circumstances where Paxlovid is not appropriate requiring referral to the CMDU, and advice on determining whether there is a drug interaction with Paxlovid.

The discussion included:

- It was agreed that the formulary guidance on the initial assessment of patients was clear. However, it was noted that the patient groups recommended for treatment under NICE TA878 and the NHS England policy were in some cases defined by whether the patient had received a specialist treatment and the timing of this treatment. Some specialist teams are notifying GPs that patients are eligible for COVID-19 treatment, but this approach has not been adopted on a trust-wide basis.

- Some patients are contacting the specialist teams when they test positive for COVID-19 and prescribing is handled by the CMDU or the specialist team. The operation of CMDUs varies between the trusts and the degree to which specialist teams are involved in the provision of advice and the prescribing of treatments varies between specialities and trusts.
- The risk of clinically significant drug interactions with Paxlovid and the importance of having a complete drug history for the patient. The Liverpool COVID-19 Drug Interaction Checker was demonstrated. The extensive list of drug interactions and the clinical significance of these interactions was a key concern for the FIG. Primary care is not familiar with either Paxlovid or its individual constituents.
- The CMDU leads considered that managing the potential for a drug interaction becomes easier with experience and offered to provide training. A learning module on Paxlovid has been launched nationally. It was noted by the FIG that there are a relatively small number of patients in Devon estimated to meet criteria for treatment meaning that an individual GP may be required to take a decision on whether Paxlovid is an appropriate treatment for a patient infrequently.
- Paxlovid was a red (hospital-only) option in the majority of formularies in England which listed the oral antivirals for the treatment of COVID-19 and a green (first-line) option in a handful of formularies including the Cornwall & Isles of Scilly Formulary, the Dorset Formulary and the Somerset Formulary. It was acknowledged that discussions may be ongoing in other ICBs on the formulary position for Paxlovid following publication of TA878.
- The CMDU do not recommend treatment for all patients referred to the units. It was estimated by the specialists that around of 30% of patients referred to the CMDUs receive treatment. Some patients do not want treatment. Patients who are not receiving immunosuppressants, who have mild symptoms or are recovering may not be treated. The CMDU leads indicated that the patient groups at risk of progression to severe COVID-19 cover a broad spectrum ranging from patients with a mild form of a disease who are not receiving immunosuppressants to those who are not able to mount an immune response.
- Whether the level of support offered to primary care by the CMDU in the draft CRG would change in the future. The CMDU is seen as providing the specialist service for COVID-19. The draft CRG gives the GP the option of initiating Paxlovid if clinically appropriate or referring a patient to a CMDU for a decision on treatment. Assurance was given by the ICB service lead that CMDUs would continue. It was noted that CMDU are required because the second-line treatment is given by intravenous infusion and cannot be initiated in primary care. There appeared to be some questions over the future operation of the CMDU service for North and East Devon for the RDUH trust and ICB to resolve.
- Paxlovid and molnupiravir are not included on the Specialist Medicines Enhanced Service drug list for community pharmacies. The draft CRG includes arrangements for GPs to refer patients to the CMDU if the 5-day window to commence treatment may be breached. The trusts and the ICB lead have discussed arrangements for community pharmacies who are unable to fill a prescription for Paxlovid or molnupiravir within the 5-day treatment window.
- A busy GP who is not familiar with prescribing Paxlovid may interpret a green (first-line) position in the formulary to mean that Paxlovid can be prescribed without further checks. If first-line is agreed for Paxlovid, the formulary entry must make it clear that careful consideration and checking for interactions is required before Paxlovid is prescribed, with a cross-reference to the formulary guidance.
- The draft formulary guidance to be revised to emphasise the importance of timely assessment of patients and to indicate that GPs can seek advice and have the option of referring patients to a CMDU for a decision on prescribing.
- The FIG was undecided on whether it is clinically appropriate for Paxlovid to be reclassified in the Devon Formulary from red (hospital-only) to green (first-line) for initiation in primary care and for molnupiravir to be reclassified from red to amber (to be prescribed in primary care on the

advice of a specialist). It was considered that a decision would need to be taken in the context of the service provided by the CMDUs. If reclassification of Paxlovid and molnupiravir was considered appropriate and the level of support provided by the CMDU changed, the FIG would reconsider its decision.

It was agreed that the Formulary team would update the draft guidance and drug entries in line with the discussion. A further discussion to be scheduled at a future meeting.

12. MHRA Drug Safety Updates

May 2023

Direct-acting oral anticoagulants (DAOCs): paediatric formulations: remainder of dose adjustments in patients with renal impairment: Risk minimisation materials have been made available to support paediatric use of DOACs. The Devon Formulary has guidance for anticoagulation for adults. Anticoagulation for paediatric patients is a specialist area. The article reminds healthcare professionals that renal function in adults should be assessed by calculating creatinine clearance (CrCl) using the Cockcroft-Gault formula. This advice is included in the formulary guidance on anticoagulation, pulmonary embolism / deep vein thrombosis and 'Prescribing medicines in renal impairment'. The formulary entries for DOACs include dosing recommendations in renal impairment for indications where treatment is initiated in primary care or continued long term in primary care. A link to the Drug Safety Update will be included in the introductory text above the DOAC entries in the formulary.

Glucose solutions: recommendations to minimise the risks associated with the accidental use of glucose solutions instead of instead of saline solutions in arterial lines: No update to the formulary is planned. The advice is considered to be more relevant to acute trust guidance and procedures.

Febuxostat: updated advice for the treatment of patients with a history of major cardiovascular disease: This article replaces previous advice on the use of febuxostat in the treatment of gout. In July 2019, advice was issued to avoid febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina), unless no other therapy options were appropriate. Following a further trial on the cardiovascular safety of febuxostat, the product information has been updated to advise that treatment of patients with pre-existing major cardiovascular diseases should be exercised cautiously, in particular in those initiating urate lowering therapy or with high urate crystal and tophi burden. The article notes that the NICE guidance for gout (NG219) which was issued after the results of the FAST study recommends that allopurinol should be offered as first-line treatment for people with gout who have major cardiovascular disease. The formulary entry for allopurinol will be updated to replace the link to the 2019 Drug Safety Update on febuxostat with the key points and a link to the current article. The NICE guidance for gout has been reviewed and an update to the formulary guidance is planned.

Letters sent to healthcare professionals and drug alerts in February 2023

Recall of Emerade 500 micrograms and Emerade 300 micrograms autoinjectors, due to the potential for device failure: A National Patient Safety Alert was issued to support the recall of Emerade 500 micrograms and 300 micrograms autoinjectors. A decision was taken by e-FIG to remove Emerade autoinjectors from the Devon Formulary.

Caprelsa (vandetanib): Restriction of indication: The communication refers to an indication for which vandetanib is not recommended under NICE TA550. No update to the formulary is required as a result of this communication.

Naseptin Nasal Cream: Caution advised when prescribing and dispensing due to reformulation to remove allergen: The formulary entry for chlorhexidine hydrochloride with neomycin sulphate nasal cream has been updated with information from the communication.

June 2023

Calcium chloride, calcium gluconate: potential risk of underdosing with calcium gluconate in severe hyperkalaemia: A National Patient Safety Alert has been issued on this subject. Calcium salts (either calcium chloride or calcium gluconate) are used to stabilise the myocardium and prevent cardiac arrest in patients experiencing severe hyperkalaemia. However, the two salts are not equivalent in terms of calcium dose. There is a risk of inadvertent underdosing if calcium gluconate is used instead of calcium chloride. The Devon Formulary includes calcium chloride and calcium gluconate injection as red (hospital-only) options. A link to the Drug Safety Update and the NPSA alert will be added to the entries. The Formulary does not include guidance on the management of acute severe hyperkalaemia. It is expected that this would be the subject of guidance issued by acute trusts.

Non-steroidal anti-inflammatory drugs (NSAIDs): potential risks following prolonged use after 20 weeks of pregnancy: Healthcare professionals are reminded that use of systemic (oral and injectable) NSAIDs such as ibuprofen, naproxen, and diclofenac is contraindicated in the last trimester of pregnancy (after 28 weeks of pregnancy). A review of data from a 2022 study has identified that prolonged use of NSAIDs from week 20 of pregnancy onwards may be associated with an increased risk of oligohydramnios and foetal renal dysfunction. Advice is given on prescribing and additional neonatal monitoring if use of a systemic NSAID after week 20 of pregnancy is considered necessary. The formulary page 'Prescribing advice for NSAIDs and COX-2 inhibitors' will be updated with the key points and a link to the article.

Adrenaline auto-injectors (AAIs): new guidance and resources for safe use: The formulary entry for adrenaline autoinjectors was updated recently to add Jext and remove Emerade following the NPSA to recall Emerade. A link to the manufacturers' educational material for the formulary brands of auto-injector was added to the entry. A link to the Drug Safety Update article and the MHRA resources will also be added to the formulary entry. The current formulary entry includes advice to carry two in-date autoinjectors at all times.

Letters sent to healthcare professionals and drug alerts in May 2023

Clexane (enoxaparin sodium) device – Important information regarding differences between PREVENTIS and ERIS needle guard safety systems: This communication indicates that minor changes have been made to a previous communication on this subject. No changes are required to the formulary entry for enoxaparin.

Levothyroxine containing products: Biotin interference with laboratory tests – Important Safety Information: The communication will be reviewed, and consideration given to its relevance to formulary guidance.

ACTION: Formulary Team to update the relevant formulary sections with recommendations from MHRS Drug Safety Updates May and June 2023.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
22/61	Formulary team to liaise with the Chair on writing to the Pathology Optimisation Group to ask the group to discuss the MHRA recommendations for vitamin B12 testing for patients receiving metformin.	Formulary team	Ongoing
22/62	Update formulary with a link to MHRA Drug Safety Update and note regarding Pathology Optimisation Group after correspondence is sent to the group.	Formulary team	Ongoing
22/80	Pharmacological treatment for type 2 diabetes (NICE NG28): bring the formulary guidance for the pharmacological treatment of Type 2 diabetes to a future meeting.	Formulary Team	Ongoing
22/92	Report of e-FIG decisions: November 2022: Treatment of vaginal candidiasis - seek the views of specialists on the use of vaginal creams which require insertion using an applicator during pregnancy and bring revised guidance back to the FIG via the appropriate route.	Formulary Team	Ongoing
22/98	Undertake further work on Ryeqo SmPC recommendation for DXA scan at 12 months for all patients.	Formulary Team	Ongoing
23/02	Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin – Proposed Formulary Entry to be amended in line with the discussion and added to the local formulary.	Formulary Team	Ongoing
23/04	4.10.2 Nicotine dependence – undertake further consultation and bring the proposed formulary entry back to FIG via an appropriate route.	Formulary Team	Ongoing
23/13	NICE guidance NG196: Atrial fibrillation – If accepted by specialists, publish formulary guidance for Atrial Fibrillation.	Formulary Team	Ongoing
23/27	Bevespi Aerosphere and Trixeo Aerosphere – ascertain from specialists which patient groups would benefit from a LABA/LAMA pMDI in preference to a LABA/LAMA SMI.	Formulary Team	Ongoing
23/28	Bevespi Aerosphere and Trixeo Aerosphere – bring back to FIG when specialists can attend.	Formulary Team	Ongoing
23/29	Metolazone 5mg tablets (Xaqua) – consult with heart failure and renal teams for metolazone 5mg tablets (Xaqua).	Formulary Team	Ongoing
23/41	Management of Hypertension (Update) – consult with specialist on proposed guidance.	Formulary team	Ongoing

23/42	Management of Hypertension (Update) – following consultation with specialists, bring draft guidance back to the FIG via the e-FIG process.	Formulary team	Ongoing
23/46	Sodium zirconium cyclosilicate for treating hyperkalaemia: consideration of reclassification – work with specialists on the prescribing guidance.	Formulary team	Ongoing
23/47	Sodium zirconium cyclosilicate for treating hyperkalaemia: bring SZC back to FIG via the appropriate route.	Formulary team	Ongoing
23/48	MHRA Drug Safety Updates – April 2023: update the relevant formulary sections with recommendations from the MHRA Drug Safety Updates March 2023 and April 2023.	Formulary team	Ongoing
23/49	MHRA Drug Safety Updates – April 2023: write to MHRA to ask for clarification on frequency of monitoring for hepatic adverse reactions for patients receiving nitrofurantoin.	Formulary team	Ongoing
23/50	Devon FIG Annual Report to be submitted to the Clinical Policy Recommendation Committee	Formulary team	Complete
23/51	Drug Interactions with Hormonal Contraceptives – publish the updated formulary guidance.	Formulary team	Complete
23/52	Insulins – amend proposed formulary entry for insulins in line with the discussion.	Formulary team	Complete
23/53	Insulins undertake consultation with adult and paediatric specialists. Any significant changes will be brought back to the FIG via an appropriate route.	Formulary team	Ongoing
23/54	Glucagon 500micrograms and 1mg pre-filled pens (Ogluo) – make minor amendments to the proposed formulary entry and proceed with consultation with adult specialists.	Formulary team	Ongoing
23/55	Chronic heart failure (including NICE TA902) - Consult with heart failure specialists.	Formulary team	Ongoing
23/56	Avenor (fluticasone propionate & salmeterol, pMDI) and Tiogiva (Tiotropium, DPI) - Update the Devon Formulary entry for inhalers in line with the agreement and discussion of Avenor (pMDI) and Tiogiva (DPI) together with additional relevant pages.	Formulary team	Complete
23/57	Priadel (lithium) update - update the SMS guidance as agreed by the FIG.	SMS Guidelines Lead	Complete
23/58	Priadel (lithium) update – present the lithium guideline to the LMC for negotiation of remuneration.	SMS Guidelines Lead	Ongoing
23/59	Update the relevant formulary sections with recommendations from MHRS Drug Safety Updates May and June 2023.	Formulary team	Ongoing