NHS
Devon
Clinical Commissioning Group

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 25th August 2021

Via Microsoft Teams

Present:

Tawfique Daneshmend (Chair)	Consultant Gastroenterologist	RD&E NHS FT
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Heidi Campbell	Pharmacist	NHS Kernow CCG
Andy Craig	GP	NHS Devon CCG
Nicola Diffey	Pharmacist	Livewell Southwest
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Tom Kallis	Community Pharmacist	
Nick Keysell	GP	NHS Devon CCG
James Leavy	Medicines Information Pharmacist	RD&E NHS FT
Bill Nolan	GP	NHS Devon CCG
Graham Parsons	Lead Pharmacist (Clinical Commissioning and Medicines Optimisation Lead)	UHP NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Samantha Smith	Interim Chief Pharmacist	NDHT
Christopher Sullivan	Deputy Chief Pharmacist - Clinical Services	DP NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

Jill Ashcroft	Medicines Optimisation Pharmacist	NHS Devon CCG
Liz Fleming	Specialist Medicines Optimisation Dietitian	NHS Devon CCG
Dr Jenny Hayes	Medical Lead Consultant	Exeter Hospiscare
Charlie Thomas	Medicines Optimisation Practice Pharmacist	NHS Devon CCG

Observers:

Richard Croker	Deputy Director for Medicines Optimisation & Lead for Pathology Optimisation	NHS Devon CCG
Sam Stephenson	Head of Medicines Optimisation - Secondary Care in hospital Commissioning	NHS Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

Chairman's welcome

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

Vivek Soni has stepped down from the group. Graham Parsons joined the group as pharmacy representative for University Hospitals Plymouth NHS Trust.

Register of participants

All expected attendees were present.

Apologies

Glen Allaway	GP	NHS Devon CCG
Susie Harris	Consultant (Elderly Care)	RD&E NHS FT
Carole Knight	Formulary Pharmacist	NDHT
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG
Jamie Smith	Consultant in Diabetes and Endocrinology	T&SD NHS FT

Declarations of Interest

Declarations of Interest were collected. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. All declarations are reported in the minutes.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Budesonide orodispersible tablet for induction of eosinophilic oesophagitis (TA708)	
Jorzeva® orodispersible tablets	Dr Falk Pharma, UK, Ltd
Alternative treatments:	
Budesonide nebuliser liquid (generic)	Various manufacturers
Alternative brand: Pulmicort®	Astra Zeneca UK Ltd
Flixotide® nebules	GlaxoSmithKline UK

Levetiracetam for palliative care:	
Levetiracetam 100mg/ml concentrated solution for IV infusion	
Desitrend®	Desitin Pharma Ltd
Keppra®	UCB Pharma Ltd
Alternative treatments:	
Midazolam solution for infusion	Various manufacturers
Eye infections - Conjunctivitis	
Chloramphenicol 0.5% eye drops	Various manufacturers
Chloramphenicol eye ointment	Various manufacturers
Fusidic acid 1% eye drops	Advanz Pharma
Alternative treatments:	
Various antibiotic eye drops	Various manufacturers
Oral Nutritional Supplements	
Any branded or generic oral nutritional supplements	Various manufacturers
Management of lower urinary tract symptoms (LUTS) in men/incontinence in women/nocturia	
Temporary containment products:	
Various pads / collecting devices	Various manufacturers
Catheters:	
Various devices	Various manufacturers
Medicines:	
Alpha blockers – various medicines	Various manufacturers
Antimuscarinics - various medicines	Various manufacturers
Mirabegron (Betmiga®)	Astellas Pharma Ltd
Finasteride (generic)	Various manufacturers
Duloxetine (generic)	Various manufacturers
Furosemide (generic)	Various manufacturers
Desmopressin oral lyophilisates (Noqdirna®)	Ferring Pharmaceuticals Ltd
Surgery for BPH / LUTS in men and/or urinary incontinence in women	Would benefit from private provision of surgery for BHP/LUTS in men and /or urinary incontinence in women.

CNS stimulants and drugs for ADHD:	
Methylphenidate modified release (Xenidate XL, Concerta XL, Medikinet XL, Equasym XL)	Mylan, Janssen-Cilag Ltd, Flynn Pharma Ltd, Shire Pharmaceuticals Ltd/Takeda UK Ltd
Alternative brands: (Delmosart XL, Matoride XL, Xaggitin XL, Ritalin XL)	Janssen-Cilag, Sandoz Ltd, Ethylpharm UK Ltd
Methylphenidate immediate release (generic)	Various manufacturers
Lisdexamfetamine (Elvanse, Elvanse Adult)	Takeda UK Ltd
Atomoxetine (generic)	Various manufacturers
Alternative brands: (Strattera)	Eli Lilly and Company Limited
Dexamfetamine (generic)	Various manufacturers
Alternative brand: (Amfexa)	Flynn Pharma Ltd
Modafinil	Various manufacturers
Hepatitis B vaccination for patients with chronic kidney disease	
Engerix B® HBvaxPRO40® Fendrix®	GlaxoSmithKline UK Merck, Sharpe & Dohme (UK) Ltd GlaxoSmithKline UK
Methotrexate / Folic acid dose clarification	
Folic acid 5mg tablets (generic)	Various manufacturers
Denosumab SMS guideline	
Prolia®	Amgen Ltd
Alternative treatments: Aclasta solution for infusion Zoledronic acid solution for infusion (generic)	 Novartis Pharmaceuticals UK Ltd Various manufacturers

e-FIG Item	Company
Prescribing for Alzheimer's disease, section 4.11 Drugs for Dementia Donepezil, Galantamine, Memantine, Rivastigmine	Various manufacturers

Name of attendee	Role	Declaration
Liz Fleming	Specialist Medicines Optimisation Dietitian	**General / financial:** I also work on a self-employed basis for (i) Sentinel Healthcare South West CIC as Diabetes Dietitian Educator and (ii) as a freelance dietitian offering online dietetic consultations for various clinical conditions and general healthy eating advice.

2. Minutes of the meeting held on Wednesday 23rd June 2021 and Matters Arising

Minutes of the meeting held on Wednesday 23rd June 2021 and Matters Arising

The minutes of the meeting held on Wednesday 23rd June 2021 were approved.

Summary of actions			
	Action	**Lead**	**Status**
21/18	Medicines for attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults - Methylphenidate, Lisdexamfetamine and Atomoxetine: Circulate final draft to FIG members via the e-FIG process for agreement.	Emma Gitsham	Complete
21/19	Prescribing for Alzheimer's disease: progress guidance through the e-FIG process.	Formulary team	Complete
21/21	Behavioural and Psychological Symptoms of Dementia – add accepted entry for BPSD and amendment to risperidone entry to the formulary.	Formulary Team	Complete
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Outstanding
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Outstanding
21/29	Oral nutritional supplements - update the proposed ONS guidance in line with the discussion at the FIG meeting and further feedback from specialists.	Liz Fleming	Complete
21/30	Oral nutritional supplements - bring updated proposed formulary ONS guidance back to a future meeting for final agreement.	Liz Fleming	Complete

21/32	Reclassification of acamprosate (N&E FIG) – contact Head of CCG's Medicines Optimisation Team regarding the communication from the Public Health Commissioner and reimbursement for acamprosate prescribing in primary care.	Formulary Team	Complete
21/33	Lisdexamfetamine for the management of ADHD - publish the accepted formulary entry for lisdexamfetamine for the treatment of ADHD in adults subject to ratification of the policy decision by the CCGs Commissioning Committee.	Formulary Team	Complete
21/34	Lixisenatide for the treatment of type 2 diabetes – remove lixisenatide from the formulary subject to ratification of the policy withdrawal by the CCG's Commissioning Committee.	Formulary Team	Complete
21/35	Talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy.	Nicola Diffey	Outstanding
21/36	Larval Therapy – feedback the outcome of the discussion to the specialists.	Formulary Team	Outstanding
21/37	Levetiracetam in a syringe pump for palliative care: Formulary team to feedback outcome of discussion to consultants and undertake further work in this area.	Formulary team	Complete
21/38	Levetiracetam in a syringe pump for palliative care: Respond to questions from the Formulary team on availability from community pharmacies.	Tom Kallis	Complete
21/39	Update the formulary entry for Helicobacter Pylori (*H. Pylori*) retesting for Dyspepsia and Gastro-oesophageal reflux disease (GORD) in line with the discussion.	Formulary Team	Complete
21/40	ADHD in adults. Clinical Effectiveness to feed back to mental health commissioners on the need to ensure that the commissioned service is suitably resourced to provide the level of follow up required in the SMS guidelines.	Formulary Team	Complete
21/41	ADHD in adults. Update proposed guidelines in line with the discussion, to be forwarded for negotiation of remuneration with the Local Medical Committee.	Emma Gitsham	Complete
21/42	Publish the formulary entry for Bempedoic acid with ezetimibe for treating hypercholesterolaemia or mixed dyslipidaemia within 3 months of publication of NICE TA694.	Formulary Team	Complete

Matters Arising

- E-mail from CCG mental health commissioner

  In June 2021 the Devon FIG discussed and agreed three new Devon-wide "shared care" type Specialised Medicines Service (SMS) prescribing guidelines for attention deficit hyperactivity disorder (ADHD) in adults.

To support the timeframe for the introduction of newly commissioned Devon-wide specialist services for adults with ADHD and meet the CCG's deadline it was necessary to conclude the discussions at the June FIG meeting with specialist representatives from Devon Partnership NHS Trust and Devon LMC present.

A message subsequently received from the Interim Head of Mental Health Commissioning (CYP and Adults), NHS Devon CCG was presented to the FIG. The message expressed the commissioner's thanks to the FIG and others involved for allowing time for a facilitated discussion and recognised the flexibility of the group in enabling the discussion together with the impact this had on other agenda items.

- Report of e-FIG decisions:

  - Prescribing for Alzheimer's disease, section 4.11 Drugs for Dementia (August 2021) Proposed updates to the formulary guidance for prescribing for Alzheimer's disease and section 4.11 drugs for dementia had been discussed at the predecessor FIGs and by the Devon FIG. The final draft guidance and update to section 4.11 incorporated the outcomes of these discussions.

    The FIG was asked to consider acceptance of the final draft guidance and updates to section 4.11 through the e-FIG process.

    Responses received indicated acceptance of the proposed formulary entry. Comments received were detailed in the meeting papers together with responses provided by the Formulary Team.

    The formulary will be updated.

ACTION: Formulary guidance for prescribing for Alzheimer's disease and section 4.11 drugs for dementia to be updated as agreed through the e-FIG process.

- Reformatting of section 8.1.5 Other antineoplastic drugs

  Following an IT issue affecting the Devon Formulary App (caused by limitations on App page memory capacity) earlier this year, it was noted that this was some sections of the formulary have become particularly large and risk becoming cumbersome and unwieldly. It was suggested that these could be refreshed and reformatted to allow ease of reading and to alleviate any potential future storage IT issues.

  One such section is 8.1.5 other antineoplastic drugs; this page is very long, currently containing 91 drug monographs. This section will be split into separate pages by drug class. Entries will be reviewed and updated to reflect the current standard format for formulary drug monographs; supporting information such as NICE TAs, MHRA Drug Safety Updates, and commissioning policies will be checked for completeness, and updated for factual accuracy if necessary.

  The formulary team will be completing this work over the coming months and will inform the FIG when it has been completed.

- Report of COVID-19 related changes to the formulary (June to August 2021)

  Since the last Devon FIG meeting (23rd June) 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", remains relevant to the current pandemic status and has been updated with important information related specifically to the COVID- 19 pandemic.

  The commissioning policy for remdesivir in the treatment of COVID-19 has been updated in line with the policy document published in June 2021.

  New information has been added on the management of oral retinoid medicines during the COVID-19 pandemic, which covers the Pregnancy Prevention Programme, monitoring for psychiatric disorders, blood tests and clinical monitoring, advice for prescribers to provide to patients, and reporting side effects to oral retinoid medicines. This is based on temporary advice published by the MHRA in June 2021.

3. Budesonide orodispersible tablet for induction of eosinophilic oesophagitis (NICE TA708)

The proposed formulary entry for NICE Technology Appraisal 708: Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis was presented to the FIG, this included an overview of the clinical trial supporting the licensing of budesonide 1mg tablets and the rationale for the NICE TA recommendations.

In addition, it was proposed that the formulary entries for budesonide preparations for gastrointestinal disorders are aligned between the two formulary areas of Devon. Entocort CR 3mg capsules are currently included for South and West Devon only. Entocort CR capsules are now the same cost as Budenofalk 3mg capsules. The gastroenterologists from the RD&E have asked for Entocort CR capsules to be included for North and East Devon.

This was the only opportunity for the FIG to discuss the proposed entry for budesonide 1mg tablets "face to face" in order to comply with the mandatory timeline for the addition of the TA to the Devon formulary.

Budesonide 1mg orodispersible tablet is the only medicine licensed for the treatment of eosinophilic oesophagitis. The NICE website indicates that budesonide 1mg orodispersible tablets are commissioned by CCGs and the providers are NHS hospital trusts.

Tawfique Daneshmend provided some background on eosinophilic oesophagitis and discussed his experience in treating this condition. An increase in cases in children has been reported. It was noted that budesonide 1mg orodispersible tablets are licensed for use in adults only. Dr Daneshmend indicated that eosinophilic oesophagitis is a long-term condition, and that remission is unlikely.

The FIG took a decision in principle to accept the proposed formulary entry for budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis pending a further

consultation with the specialists. The FIG also considered and accepted the addition of Entocort CR 3mg capsules for North and East Devon. The discussion included:

- Orodispersible tablets 1mg were accepted as a 'Red' (hospital only) drug.
- No brand of rectal foam has been included in the proposed entry as there is no clinical reason to specify a brand.
- It was noted that no responses were received from the gastroenterologists on the proposed formulary entry for budesonide 1mg orodispersible tablets during the first consultation. A second consultation will be held with the specialists. The specialists will be informed the FIG have agreed to the inclusion of Entocort CR 3mg capsules for North and East Devon and have agreed in principle to the addition of budesonide 1mg orodispersible tablets as a red drug to the Devon Formulary.

ACTION: Formulary Team to conduct a second consultation with gastroenterologists on the proposed entry for budesonide 1mg orodispersible tablets.

ACTION: Formulary Team to publish accepted formulary entry.

4. Palliative care: Levetiracetam 100mg/ml concentrate solution for intravenous infusion

Jenny Hayes, consultant in palliative medicine, Exeter Hospiscare and Jill Ashcroft, NHS Devon CCG medicines optimisation pharmacist and their team lead for end of life care joined the meeting for this discussion.

During the June FIG meeting, there was discussion of a proposal from the palliative care consultants for levetiracetam 100mg/ml for infusion to be an amber formulary option for use in the community setting as a continuous subcutaneous infusion for patients with a primary or secondary brain tumour who are no longer able to take oral levetiracetam and have an ongoing risk of seizures. Levetiracetam 100mg/ml solution is licensed for intravenous use and is used off-label as a subcutaneous infusion. This is supported by the Scottish Palliative Care guidelines.

The FIG members were supportive of an amber classification subject to the following areas being addressed satisfactorily:

- Availability of levetiracetam from community pharmacies
- Identification of patients and planning of care
- Support for GPs
- Practical areas concerning administration in the community, including education and support for community nurses

A paper was presented to the FIG which included feedback from the palliative care consultants on these points together with further information obtained since the previous meeting and draft formulary guidance for levetiracetam for infusion for inclusion in the palliative care chapter.

It was proposed that the formulary guidance could be published only when the standard operating procedure (SOP) for community teams has been signed off. This SOP should include information on the availability of syringe drivers and compatibility with other medicines if appropriate. A link could be included from the formulary entry to the SOP and vice versa.

The FIG considered the proposed formulary entry for Levetiracetam 100mg/ml concentrate solution for use as a subcutaneous infusion for palliative care. There was discussion about:

- Availability of levetiracetam 100mg/ml solution for infusion. It was noted that early discussion with the community pharmacist is important to ensure availability when a prescription is issued. Levetiracetam 100mg/ml solution for infusion is available to order from community pharmacies but is not routinely held in stock by community pharmacies.
- Community nurses are encouraged to have discussions at an early stage about the options available for their patients. It was noted that anticipatory prescribing of levetiracetam 100mg/ml is not recommended by the consultants.
- The diluent for levetiracetam 100mg/ml should be included in the formulary entry. Levetiracetam 100mg/ml is available in vials or ampoules. Consideration should be given to whether there are any differences between the two formulations with regard to safe use in the community setting.
- Due to annual leave, the consultants had not had an opportunity to discuss the proposed formulary guidance as a team before the FIG meeting. The FIG did not feel that there were any outstanding areas of concern from previous discussions.
- The FIG accepted the formulary classification of amber (specialist-initiated) for levetiracetam 100mg/ml solution for use as a subcutaneous infusion in palliative care subject to agreement of the final draft formulary guidance and the community nursing teams agreeing a SOP for use in the community.

A final draft of the proposed formulary entry will be either circulated via the e-FIG process or brought to a future FIG meeting.

ACTION: Formulary Team to circulate the final draft of the proposed formulary entry via the e-FIG process or bring the item back to a future meeting.

5. Eye Infections: update

An update to the formulary guidance for conjunctivitis was included in the June 2021 board pack following a change to the Summary of Product Characteristics (SPCs) for chloramphenicol 0.5% eye drops to include a contraindication for children under 2 years of age which occurred as the result of European Medicines Agency guidance on boron used as an excipient. The item was not discussed in June due to time constraints.

Shortly after the June meeting, the MHRA issued a Drug Safety Update for chloramphenicol eye drops advising that following a review of the evidence for the maximum daily limit for boron for children younger than 2 years, the MHRA had concluded chloramphenicol eye drops can be safely administered to children aged 0 to 2 years. The contraindication for this age group will be removed from UK SPCs and patient information leaflets for chloramphenicol eye drops in due course. The formulary guidance for conjunctivitis and the entries for chloramphenicol eye drops were updated with the key points from the Drug Safety Update at the time it was published.

Alignment of the North and East Devon and South and West Devon formulary guidance for Eye Infections and the entries for chloramphenicol ophthalmic products and fusidic acid eye drops under section 11.3.1 was proposed. Clarifications have been added for neonatal conjunctivitis and strengthened wording for fusidic acid eye drops for both formulary areas.

Specialists were asked for their views on the proposed changes to the guidance and drug entries. In addition, specialists in South and West Devon were asked for their views on two further questions:

- Should the formulary classification for fusidic acid drops be updated from 'Red' (hospital only) to 'Amber' (GP may prescribe on specialist advice) in line with North and East Devon? The South and West Devon specialists supported a move from red to amber classification.

- Do specialists agree with the proposal to update the South and West Devon formulary classification for single dose chloramphenicol 0.5% eye drops from 'Green' first line to 'Amber' (specialist input) in line with North and East Devon? Feedback from both areas was that any chloramphenicol preparation should remain green to avoid unnecessary contact with specialists.

The FIG considered and accepted the proposed formulary entries. It was agreed that corneal abrasion should be retained under indications. There was discussion about:

- Unilateral and bilateral infection. It was agreed the description of conjunctivitis from the College of Optometrists would be used in the formulary guidance.
- Preservative free eye drops should only be used for patients with a known allergy to preservatives. This should be included on the entry page but not included in the guidance.
- No further information on ocular trauma was requested. It was agreed the brief text on corneal abrasion included in North and East Devon formulary guidance should be removed.

ACTION: Formulary Team to publish the formulary entry for Eye infections and the updates to the formulary entries for chloramphenicol ophthalmic products and fusidic acid eye drops in line with the discussion.

6. Oral Nutritional Supplements (ONS)

Liz Fleming, Specialist Medicines Optimisation Dietitian and Charlie Thomas, Senior Medicines Optimisation Pharmacist, NHS Devon CCG joined the meeting for this item.

In April 2021, a draft paper was presented to the Devon FIG to gather early input on the development of this guidance section. At the same time the proposed guidance was circulated to local dietitian specialists Devon-wide for additional feedback.

Liz Fleming has liaised with dietitian specialists, and with support from Darren Wright, work has been undertaken to update and harmonise the formulary ONS guidance taking into account feedback received from specialists and the FIG.

At the meeting in April the FIG considered and accepted the following:

- Proposed changes to formulary products (subject to specialist feedback and subsequent recommendations).
- More than one formulary option to be available in most instances.
- Product sections should include supporting information to inform appropriate selection.
- Product nutritional content should be included in a table format.

Revised guidance (including additional product recommendations) in line with the feedback from dietitian specialists and the FIG was presented.

The FIG considered and accepted the proposed ONS guidance. There was discussion about:

- It is estimated that £400,000 savings may be made from the primary care prescribing budget.
- It was noted that where supplements are mixed with fruit juice the nutritional content will depend on the juice used.
- A conversation with a dietitian may be needed when giving Altrajuce as it has a higher sugar and lower protein content than the alternatives.
- Include the statement "Powder milkshakes are not suitable for patients with severe or end stage kidney failure (CKD Stage 4-5), or for patients with Stage 3B CKD who are hyperkalaemic or have hyperphosphataemia" at the top of every slider where powder milkshakes are mentioned.

ACTION: Liz Fleming to update the proposed guidance in line with the discussion.

ACTION: Once updated Formulary Team to publish the ONS guidance.

7. Management of urinary incontinence in women / Management of nocturia

Due to illness this item was deferred to a future meeting.

8. MHRA Drug Safety Updates June to July 2021

The MHRA Drug Safety Updates for June and July were noted.

June Safety Update

<u>CDK4/6 inhibitors (abemaciclib, palbociclib, ribociclib): reports of interstitial lung disease and pneumonitis, including severe cases</u>

- Reports of interstitial lung disease and pneumonitis with CDK4 inhibitors which are red (hospital) formulary drugs used to treat a variety of cancers. The formulary entries have been updated to include advice for healthcare professionals, a reference and link to the drug safety update.

Atezolizumab (Tecentriq) and other immune-stimulatory anti-cancer drugs: risk of severe cutaneous adverse reactions (SCARs)

- Severe cutaneous skin reactions are now an identified risk for atezolizumab which is a red (hospital) drug used for various cancers. The formulary entry has been updated with a reference and link to the safety update with advice for patients.

Letters sent to healthcare professionals:

No updates to the formulary were required.

July Safety Update

Chloramphenicol eye drops containing borax or boric acid buffer: use in children younger than 2 years

- The FIG was provided with an overview of the rationale for the decision by the MHRA to overturn the contraindication imposed by the European Medicines Agency for children under 2 years of age. A summary of the key points was included in the formulary guidance for eye infections and the formulary entries for chloramphenicol eye drops at the time the safety update was published.

Herbal and homeopathic medicines: reminder to be vigilant for suspected adverse drug reactions and to report them to the Yellow Card Scheme

- This is a general reminder for clinicians to remember to ask about the use of herbal or homeopathic medicines for patients with suspected adverse drug reactions. No update to the formulary is required.

Oral retinoid medicines (isotretinoin, alitretinoin, and acitretin): temporary monitoring advice during coronavirus (COVID-19 pandemic)

- Advice has been issued on the use of oral retinoids during the pandemic. including discussions at initiation, implementation of pregnancy prevention programmes and monitoring for psychiatric and other adverse events through remote consultations. Isotretinoin, alitretinoin and acitretin are included in the Devon Formulary as red (hospital) drugs. The formulary entries have been updated and in addition, a link has been added to the drug safety update and key points added to the temporary Covid-19 update page.

Letters sent to healthcare professionals:

- Updated advice on tumour lysis syndrome which is a known effect of venetoclax, a red (hospital) drug for treatment of various cancers. This letter has not been referenced in the formulary as it is a known effect and the specialists were provided with patient alert cards.

- Inrebic (fedratinib) 100mg hard capsules: Potential interaction with grapefruit or grapefruit juice. Fedratinib is not included in the Devon Formulary.

9. 4.4 CNS stimulants and drugs for attention deficit hyperactivity disorder (ADHD)

Discussion of CNS stimulants and drugs for ADHD was deferred from the June FIG meeting to allow time for discussion of the SMS prescribing guidelines for adult ADHD.

An updated paper which included a subsequent consultation with paediatric ADHD specialists was presented to the FIG. The updated entries harmonise the existing formulary pages for N&E and S&W Devon, reflect the changes in commissioning status of lisdexamfetamine, the new SMS guidelines, and provide information to support the safe use of these medicines. There were two specific points for consideration, firstly on Concerta XL and secondly on dexamfetamine.

Concerta XL brand of methylphenidate modified release tablets:

- Specialists were consulted on three different options to achieve a Devon wide approach to Concerta XL. Responses received from specialists were mixed on Concerta XL with some keen to ensure that Concerta XL is available for current patients, others noted previous experience with switching to other brands, social issues for medication failure were also raised.

Dexamfetamine:

- A proposal that the indications and associated notes from the S&W Devon dexamfetamine entry are adopted into the N&E Devon entry.

The FIG considered the proposed formulary entry. There was discussion about the preferred approach to the inclusion of the Concerta XL.

- The FIG accepted the use of Concerta XL for existing patients across Devon and agreed that it is not recommended for new initiations due to its higher cost.
- The FIG agreed that Xenidate XL should be the first line option for patients unable to tolerate other formulations of methylphenidate MR products. Concerta would be a second line option for these patients, to be considered after Xenidate XL.
- The FIG did not wish to merge the formulary entries for methylphenidate modified release and immediate release preparations into a single, larger methylphenidate entry (as had been suggested in specialist feedback). It was felt clearer to keep the two entries separate in the formulary.
- Torbay Hospital paediatric specialists were noted to not be in favour of any particular brand of methylphenidate MR tablets. The pharmacy representative from Torbay will increase local awareness that Xenidate XL is the preferred option for new initiations.
- The FIG accepted the addition of refractory ADHD and the associated notes to the N&E Devon entry for dexamfetamine.

It was recognised that whilst Xenidate XL is the 1st line option, there are significant capacity constraints preventing review and switching of all patients currently prescribed Concerta XL.

The Formulary Team will draft additional notes to reflect the agreed position of Xenidate XL and Concerta XL, and circulate for agreement via e-FIG.

ACTION: The Formulary Team will draft an e-FIG in line with the discussion for agreement of the final wording of the formulary guidance in respect of Xenidate XL and Concerta XL.

ACTION: Following agreement of the final wording of the formulary guidance in respect of Xenidate XL and Concerta XL. Formulary Team to update the Formulary in line with the discussion.

10. Hepatitis B vaccination for patients with chronic kidney disease

In March 2018, the NHS England (NHSE) General Medical Services Contract commissioning intentions set out the plan to make clear the responsibility to deliver Hepatitis B vaccinations to renal patients rests with the renal service and not with general practice, unless there are locally agreed arrangements in place to deliver this service.

As of 1st July 2019, commissioning responsibility and associated funding for Hepatitis B vaccination for patients with chronic kidney disease has transferred from Primary Care Commissioning to Specialised Commissioning.

Following the changes in responsibility, the Devon Formulary section relevant to hepatitis B vaccinations has been reviewed to ensure the changes are reflected appropriately, and that consistent information is maintained.

Renal specialists have been consulted on the changes to information represented in the Devon Formulary and have offered advice and feedback, which has been incorporated in the proposed changes to the Devon Formulary entry.

The Devon Formulary Team has not been involved in any discussions regarding locally agreed arrangements but has been made aware that provisional arrangements are being made. It is understood that longer-term plans are being discussed. When longer-term local arrangements are agreed, the Devon Formulary section may need to be updated again to reflect this.

The FIG were asked to consider the proposed amendments to the hepatitis B vaccination section of Chapter 14 Immunological products and vaccinations and the reclassification of hepatitis B vaccines to red (hospital only) for renal indications.

The FIG considered and accepted the proposed changes without amendment.

ACTION: Formulary Team to update the formulary entry for Hepatitis B vaccination for patients with chronic kidney disease with the accepted amendments.

11. Methotrexate/Folic acid dose scheduling clarification

“Off-label” prescribing of folic acid is routinely recommended for the prevention of methotrexate-induced side-effects. The use of folic acid in this way is recommended in the Devon Formulary entries for methotrexate and folic acid, and local “shared care” guidelines for methotrexate.

Following an enquiry from a GP regarding the specific dose of folic acid to be prescribed, the Formulary Team has reviewed the existing formulary entries, the advice in each local "shared care" guideline, and national guidance (NICE, BNF, Specialist Pharmacy Service, etc.) in order to provide greater clarity in the formulary entries.

Currently there are nine different "shared care" type prescribing guidelines for methotrexate in Devon, depending on locality and speciality. They primarily cover use in gastroenterology, rheumatology and dermatology conditions; in South Devon only there are also guidelines covering ophthalmology and respiratory conditions. Although the guidelines differ, they are broadly similar in their recommendations: all guidelines recommend co-prescription of folic acid 5mg at least once weekly at least 24 hours after taking methotrexate. A number of the guidelines indicate that the specific folic acid regimen will depend on the side effects of methotrexate. Other specific variations are that:

A. The north and east Devon rheumatology guideline, and all the south Devon guidelines provide additional dosing advice, stating that the usual recommended dose is 5mg once daily on the six days of the week that the patient does not take methotrexate.
B. The west Devon gastroenterology guideline is less definitive, stating "folic acid is often prescribed with methotrexate; these are taken daily…" and also "In patients who experience mucosal or gastro-intestinal side effects with methotrexate, folic acid 5mg each week may be given. It may be routinely given to help reduce the frequency of such side effects."

It was proposed that point A will be followed up with specialists during the next routine review of these guidelines, and that point B will be addressed earlier by contacting gastroenterology specialists at University Hospitals Plymouth NHS Trust to discuss a more specific, definitive recommendation.

The FIG considered the proposed updates to the formulary entries.

- GPs present indicated that they were happy with the wording proposed to clarify the methotrexate/folic acid dosing schedule.

ACTION: Formulary Team to publish accepted clarification to the methotrexate/folic acid dosing schedule.

- It was noted that the north and east Devon rheumatology guideline, and all the south Devon guidelines provide additional dosing advice, stating that the usual recommended dose is 5mg once daily on the six days of the week that the patient does not take methotrexate. The Torbay hospital pharmacy representative reported this was considered to be sensible and easier for patients as they know that they have to take something every day. The FIG agreed that follow up with specialists at the next review of the guidelines would be appropriate.
- The West Devon gastroenterology guideline was noted to be less definitive in the recommendation on folic acid. The FIG agreed this should be addressed earlier by contacting gastroenterology specialists at UHP NHS Trust to discuss a more specific, definitive recommendation.

ACTION **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.**

12. North, East and West Devon: Denosumab (Prolia®)

Denosumab for osteoporosis is an amber (specialist input) drug in North, East and West Devon where there is a SMS (Specialised Medicines Service) guideline in place. Denosumab for osteoporosis is provided by the specialist service at Torbay Hospital.

Following publication of an MHRA Drug Safety update in August 2020, which reported increased risk of multiple vertebral fractures within 18 months of stopping or delaying ongoing treatment with denosumab 60mg, the Formulary entry was updated. Updates to the SMS guideline were delayed pending publication of a new technology appraisal by NICE which would incorporate denosumab. NICE have since suspended the TA.

It was noted that treatment with denosumab should not stop without specialist review as there is usually a need for alternative therapy to be prescribed. The Formulary Team sought the views of local specialists. The specialists indicated that GPs should seek advice from a specialist if discontinuation of denosumab is being considered.

The specialists did not wish to make any changes to the patient groups identified for treatment with denosumab in the SMS guideline.

The FIG considered and accepted the amendments to the SMS prescribing guideline subject to a further consultation with the RD&E consultant rheumatologists. Previous contact had not resulted in a response. If no queries are raised, the update to the guideline will be taken through the routine process for publication.

ACTION: James Leavy to ascertain the name of the consultant rheumatologist responsible for osteoporosis at RD&E.

ACTION: If no queries are raised by consultant rheumatologists at RD&E, the routine process should be followed for publishing the update to the guideline.

13. Recent drug decisions (including NICE)

The recent drug decisions were noted.

14. Future FIG meeting dates (2022)

The 2022 FIG meeting dates were included in the board pack. Microsoft Teams meeting invitations will be circulated to FIG members.

The formulary team suggested that due to the volume of work to be undertaken, FIG members may be consulted on a proposal to extend the duration of FIG meetings.

There was discussion about the range of work likely to be brought to FIG meetings over the coming months. This includes work to harmonise drug entries and increase consistency in guidance across Devon, consideration of new drug applications, new and updated guidance pages in response to national guidance eg NICE etc, and Drug Safety Updates.

ACTION: Calendar invitations for 2022 FIG meetings to be circulated to FIG members.

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	Outstanding
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Outstanding
21/35	Talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy.	Nicola Diffey	Outstanding
21/36	Larval Therapy – feedback the outcome of the discussion to the specialists.	Formulary Team	Complete
21/43	Formulary guidance for prescribing for Alzheimer's disease and section 4.11 drugs for dementia to be updated as agreed through the e-FIG process.	Formulary Team	Outstanding
21/44	Budesonide orodispersible tablet for induction of eosinophilic oesophagitis (NICE TA708) – conduct a second consultation on proposed entry and to let specialists know that Entocort CR capsules have been accepted as 'Red' in the North and East. Post meeting note: The Gastroenterology Clinical Director responded to confirm acceptance of the proposed entry by the Torbay and South Devon team. No response was received from the teams at NDHT, RD&E and UHP.	Formulary Team	Complete
21/45	Budesonide orodispersible tablet for induction of eosinophilic oesophagitis (NICE TA708) – publish accepted formulary entry.	Formulary Team	Complete
21/46	Palliative care: Levetiracetam 100mg/ml concentrate solution for intravenous infusion - circulate the final draft of the proposed formulary entry via the e-FIG process or bring the item back to a future meeting.	Formulary Team	Outstanding
21/47	Eye infections: Update - publish the formulary entry for Eye infections in line with the discussion.	Formulary Team	Complete
21/48	Oral Nutritional Supplements (ONS) update the proposed guidance in line with the discussion	Liz Fleming	Complete
21/49	Oral Nutritional Supplements (ONS) – once updated by Liz Fleming publish ONS guidance.	Formulary Team	Complete
21/50	4.4 CNS stimulants and drugs for attention deficit hyperactivity disorder (ADHD) – draft an e-FIG in line with the discussion for agreement of the final wording of the formulary guidance in respect of Xenidate XL and Concerta XL	Formulary Team	Complete
21/51	Following agreement of the final wording of the formulary guidance in respect of Xenidate XL and Concerta XL. Formulary Team to update the Formulary in line with the discussion.	Formulary Team	Outstanding

21/52	Hepatitis B vaccination for patients with chronic kidney disease - update the formulary entry for Hepatitis B vaccination for patients with chronic kidney disease with the accepted amendments.	Formulary Team	Complete
21/53	Methotrexate/folic acid dose scheduling clarification - publish accepted clarification to the methotrexate/folic acid dosing schedule.	Formulary Team	Complete
21/54	Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement. *Post meeting note: RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*	Formulary Team	Ongoing
21/55	North, East and West Devon: Denosumab (Prolia®) – ascertain names of consultant rheumatologists responsible for osteoporosis at RD&E.	James Leavy	Outstanding
21/56	North, East and West Devon: Denosumab (Prolia®) – If no queries raised by consultant rheumatologists at RD&E, the update to the SMS guideline to be taken through the routine process for publication	Formulary Team	Outstanding
21/57	Calendar invitations for 2022 FIG meetings to be circulated to FIG members.	Fiona Dyroff	Complete