NHS
Devon
Clinical Commissioning Group

Meeting of the Devon Formulary Interface Group

Minutes

Wednesday 8th December 2021
Via Microsoft Teams

Present:		
Tawfique Daneshmend (Chair)	Consultant Gastroenterologist	RD&E NHS FT
Glen Allaway	GP	NHS Devon CCG
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon CCG
Ailene Barclay	Pharmacist	UHP NHS Trust
Heidi Campbell	Pharmacist	NHS Kernow CCG
Andy Craig	GP	NHS Devon CCG
Susie Harris	Consultant (Elderly Care)	RD&E NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Tom Kallis	Community Pharmacist	
James Leavy	Medicines Information Pharmacist	RD&E NHS FT
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	MO Pharmacist	NHS Devon CCG
Jamie Smith	Consultant in Diabetes and Endocrinology	T&SD NHS FT
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:		
Natasha Moore	Senior MO Pharmacist	NHS Devon CCG
Yin Ki (Albe) Ng	Senior MO Pharmacist - Secondary Care	NHS Devon CCG
Tony Avades	Consultant Chemical Pathologist	UHP NHS Trust
Observers:		
Fern Bamford-Elsdon	Pre-reg Pharmacist	RD&E NHS Trust
Niclas Caradine	Pre-reg Pharmacist	RD&E NHS Trust
Laura Faulkner	GPST4 Leadership and Excellence Trainee	DRSS
In attendance:		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

New members, observers and guests

New members, observers and guests present were welcomed to the meeting.

- Ailene Barclay, Pharmacist, UHP NHS Trust joined the group. Graham Parsons, Pharmacist, UHP NHS Trust had stepped down from the Devon FIG.

The new members, observers and guests present introduced themselves to the group.

Apologies

Nicola Diffey	Pharmacist	Livewell Southwest
Nick Keysell	GP	NHS Devon CCG
Carole Knight	Formulary Pharmacist	NDHT
Sam Smith	Interim Chief Pharmacist	NDHT

Declarations of Interest

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

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Alirocumab 300mg injection: application Alirocumab (Praluent) **Alternative treatments**: Evolocumab (Repatha)	Sanofi Amgen Ltd
Alirocumab and evolocumab: formulary classification Alirocumab (Praluent) Evolocumab (Repatha)	 Sanofi Amgen Ltd
Luforbec (BDP extrafine / formoterol) metered dose inhaler for asthma and COPD Luforbec (BDP extrafine 100mcg / formoterol 6mcg) MDI **Alternative treatments:** Fostair 100/6 MDI or NEXThaler	 Lupin Healthcare (UK) Ltd Chiesi Limited

Proposal to add various Easyhaler Dry Powder inhalers and Trimbow NEXThaler	
Easyhaler budesonide, Formoterol Easyhaler, Fobumix Easyhaler, Fusacomb Easyhaler	Orion Pharma (UK) Limited
Trimbow NEXThaler	Chiesi Limited
Alternative treatments:	
Pulmicort Turbohaler, Oxis Turbohaler, Symbicort Turbohaler	AstraZeneca UK Limited
Kelhale	Cipla EU Ltd
Qvar	Teva UK Limited
Clenil Modulite, Atimos Modulite, Fostair / Fostair NEXThaler, Trimbow	Chiesi Limited
Flixotide Accuhaler / Evohaler, Seretide Accuhaler / Evohaler, Trelegy Ellipta	GlaxoSmithKline UK
Luforbec	Lupin Healthcare (UK) Ltd
Duoresp Spiromax	Teva Pharma B.V.
AirFluSal / AirFluSal Forspiro	Sandoz Limited
Sacubitril/valsartan: formulary entry	
Entresto	Novartis Pharmaceuticals Ltd
Alternative treatments:	
Dapagliflozin (Forxiga)	Astra Zeneca UK Ltd
Ivabradine, Hydralazine, Isosorbide dinitrate/mononitrate	Various manufacturers
Consideration of Inhixa (enoxaparin) for addition to the formulary	
Inhixa	Techdow Pharma
Alternative treatments:	
Clexane	Sanofi
Enoxaparin, Dalteparin, Tinzaparin	Various manufacturers
Lyumjev insulin lispro: application	
Lyumjev	Eli Lilly and Company Ltd
Alternative treatments:	
Insulin lispro (Humalog)	Eli Lilly and Company Ltd
Insulin lispro	Sanofi
Insulin aspart	Novo Nordisk Ltd, Sanofi
Fiasp insulin aspart	Novo Nordisk Ltd
Insulin glulisine (Apidra)	Sanofi
Treatment of *Clostridioides difficile* (*C. difficile)*	
Fidaxomicin (Dificlir)	Tillotts Pharma UK Limited
Alternative treatments:	
Vancomycin, Metronidazole	Various manufacturers

Giardiasis: Tinidazole (Fasigyn) discontinuation Fasigyn **Alternative treatments:** Tinidazole, Metronidazole	 Pfizer Various manufacturers
Management of Epilepsy Various medicines	Various manufacturers
9.4.1 Foods for special diets: Gluten-free update Fresh bread, long-life bread, and mixes	 Genius, Glutafin, Juvela, Various manufacturers
Osteoporosis Various medicines	Various manufacturers
Inclisiran: RCGP and BMA statement Inclisiran (Leqvio) **Alternative treatments:** Various statins Ezetimibe Bempedoic acid (Nilemdo, Nustendi) Alirocumab Evolocumab	 Novartis Pharmaceuticals UK Ltd Various manufacturers Various manufacturers Daiichi Sankyo UK Limited Sanofi Amgen Ltd

Name	Role	Declaration
Yin Ki (Albe) Ng	Senior Medicines Optimisation Pharmacist (secondary care)	Indirect interest – partner is a stroke physician at Musgrove Park Hospital
Tony Avades	Consultant Chemical Pathologist	In receipt of lecture fees in the last year from manufacturing company – I have presented talks to GPs and Hospital Consultants
Patrick English (not present at meeting)	Supporting consultant for Lyumjev Application Consultant diabetologist UHP NHS Trust	Has been paid for services to Eli Lilly for the production of a video demonstrating the use and utility of the PARM tool developed in conjunction between NEW Devon CCG and Eli Lilly with Patrick English as an advisor. Most of the advisory role was considered work as part of the community diabetes role and payment was only received for the production of the video and the delivery of national teaching events. Patrick English has also been in receipt of honoraria from Novo Nordisk and Napp within the last 3 years for the delivery of teaching to Medical colleagues in primary and secondary care.

Tom Kallis	Clinical Pharmacist Locality Lead	Sponsorship by Chiesi for PNC Clinical Pharmacist Training Event
Peter Kelly (not present at meeting)	Applicant for Lyumjev Lead Diabetes Specialist Nurse UHP NHS Trust	Historically I have provided diabetes education sessions for the above company and have x 2 planned lecture for Sept/Oct 2021.
Jamie Smith	Consultant Physician	In receipt of speaker fees from Amgen, Novo-Nordisk, Lilly, Astra Zeneca within last 2 yrs. Previously PI for clinical trial for praluent in odyssey programme within last 3 yrs.

2. Minutes of the meeting held on 20th October 2021 and Matters Arising

Minutes of the meeting held on 20th October 2021

The minutes of the meeting held on 20th October 2021 were approved.

COVID-19 related changes to the formulary

Since the Devon FIG meeting held on 20th October 2021 the Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

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

NICE Guideline NG191: managing COVID-19, has been updated to bring together existing NICE recommendations on managing COVID-19, and new recommendations on therapeutics into one place, so information can be found more easily. As such the formulary COVID updates page will be refreshed to provide the most up-to-date links to the appropriate sections within the guidance.

Additionally, with the regulatory approval of the current COVID-19 vaccines, and the recent UK commissioning policy for Ronapreve, new drug entries will be added to the Devon Formulary, alongside appropriate links to NG191.

ACTION: New drug entries for COVID-19 vaccines and Ronapreve to be added to the local 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
21/35	Talk to colleagues at Livewell regarding their difficulties in prescribing larval therapy. The Formulary Team has contacted Nicola Diffey to take this forward.		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	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. This is now with nurses and will be circulated to the FIG for final agreement.	Formulary Team	Ongoing
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 decision.	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. The Formulary team has been informed of the name of the relevant specialist	James Leavy	Closed

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	Ongoing
21/58	Matters arising: Report of e-FIG decisions – Update the Devon Formulary with the accepted formulary entry for Concerta XL.	Formulary Team	Complete
21/59	Fidaxomicin for the treatment of *Clostridioides difficile* infection (including formulary guidance on the treatment of *C. difficile* infection) - Ascertain whether Vancomycin 125mg capsules are included on the Enhanced Service for the Availability of Specialist Medicines in Plymouth.	Formulary Team	Complete
21/60	Fidaxomicin for the treatment of *Clostridioides difficile* infection (including formulary guidance on the treatment of *C. difficile* infection) - revise in line with the discussion and circulate to specialists for comment.	Formulary Team	Complete
21/61	Fidaxomicin for the treatment of *Clostridioides difficile* infection (including formulary guidance on the treatment of *C. difficile* infection) - circulate final draft guidance for consideration via e-FIG. Post meeting note: paper was discussed at December FIG meeting. The policy and guidance have since been published.	Formulary Team	Complete
21/62	8.3.4.1 Breast cancer (incl. Raloxifene): update and harmonisation – update the formulary with the accepted entries for 8.1.4.1 Breast cancer and 6.4.1 Female sex hormones and their modulators in line with the discussion.	Formulary Team	Complete
21/63	Diagnostic and monitoring devices for diabetes mellitus. Contact lancet company reps regarding the environmental impact and waste where a new lancet device is supplied with each box of lancets.	Medicines Optimisation team technician	Complete
21/64	Diagnostic and monitoring devices for diabetes mellitus – update the formulary entry for diagnostic and monitoring devices for diabetes mellitus with the approved formulary entry.	Formulary Team	Complete
21/65	Anal Irrigation Systems – update the formulary entry for anal irrigation systems in line with the discussion.	Formulary Team	Outstanding
21/66	Anal Irrigation Systems – contact Heidi Campbell at Kernow CCG regarding supplies in Cornwall.	Formulary Team	Complete
21/67	Luforbec (BDP extra/formoterol) metered dose inhaler for asthma and COPD – Formulary team to update the proposed formulary entry in line with the discussion and carry out a further consultation with specialists.	Formulary Team	Complete

21/68	Luforbec (BDP extra/formoterol) metered dose inhaler for asthma and COPD – Subject to the responses from specialists the formulary team will undertake an e-FIG process prior to updating the formulary. Post meeting note: Consultation with the specialists was discussed with the FIG at the December meeting. Proposed amendments to the formulary were agreed.	Formulary Team	Complete
21/69	Reducing the carbon footprint for inhaler prescribing in Devon: proposal to add further dry powder inhalers to the Devon Formulary. Trimbow NEXThaler undertake further consultation with respiratory specialists. Undertake further consultation with respiratory specialists.	Formulary Team	Complete
21/70	Reducing the carbon footprint for inhaler prescribing in Devon: proposal to add further dry powder inhalers to the Devon Formulary – Trimbow NEXThaler – subject to responses from specialists the formulary team will undertake an e-FIG process prior to updating the formulary. Post meeting note: Consultation with the specialists was discussed with the FIG at the December meeting. Proposed amendments to the formulary were agreed.	Formulary Team	Complete
21/71	NICE Technology Appraisal (TA)733: Inclisiran for primary hypercholesterolaemia or mixed dyslipidaemia – publish the accepted formulary entry.	Formulary Team	Complete
21/72	Osteoporosis – liaise with specialists and bring final draft to a future FIG meeting.	Formulary Team	Ongoing

3. Alirocumab 300mg injection

Alirocumab is a monoclonal antibody lipid-modifying agent and PCSK9 inhibitor. The 75mg and 150mg injection are included in the Formulary as red (hospital only) options in line with NICE TA 393 which was issued in 2016.

An application has been received from, a lipid specialist for Torbay and South Devon NHS Foundation Trust supported by a lipid specialist for University Hospitals Plymouth NHS Trust to consider the addition of alirocumab 300mg injection to the formulary.

The 300mg dosing regimen was licensed after the TA and a 300mg injection device was not marketed until 2021. A local decision on the 300mg injection is required as the NICE TA has been moved to the static list. The specialists and the CCG Senior Medicines Optimisation Pharmacist for secondary care were present for the discussion of this item.

The licensing of the 300mg every four weeks dosing regimen was based on the CHOICE-1 study. The European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) concluded that the 300mg every four weeks dosing regimen is generally safe and effective on the basis of this trial. This dosing regimen offers the benefit of fewer injections for patients whose LDL-C levels are stabilised on this regimen.

Cardiovascular outcome data was not available from the alirocumab clinical trials when the cost effectiveness analysis was undertaken for NICE TA393. In the absence of this data, the cost effectiveness analysis was based on the magnitude of LDL-C reduction for alirocumab compared with alternative therapies.

The FIG considered the clinical trial data and financial impact of alirocumab 300mg injection. and accepted the inclusion of alirocumab 300mg injection into the Formulary without amendment.

There was discussion about the tolerability of 2ml subcutaneous injections.

ACTION: Formulary team to update the formulary with the accepted entry for Alirocumab 300mg/2ml solution for injection, pre-filled pen.

4. Alirocumab and evolocumab: formulary classification

Alirocumab and evolocumab injections are lipid-modifying PCSK9 inhibitors which are included in the Devon Formulary in line with their respective NICE TAs as red (hospital only) drugs. The injections are available as pre-filled syringes for subcutaneous administration. With training, the injection can be administered by a patient or carer.

A request for the reclassification of alirocumab and evolocumab from red (hospital only) to amber (specialist) options has been received from the lipid specialists for University Hospital Plymouth NHS Trust and Torbay and South Devon NHS Foundation Trust. The specialists and the CCG Senior Medicines Optimisation Pharmacist for secondary care were present for the discussion. There are capacity pressures in both lipid services and the number of alirocumab and evolocumab patients has increased since the NICE TAs were published.

The proposal applies only to patients who are able to self-administer injections. Patients would be taught how to self-administer injections in secondary care. The specialist would counsel patients, initiate and stabilise treatment before considering the appropriateness of patients for continuation of prescribing in primary care.

This was an initial discussion of the proposal from the specialists. The FIG was asked to consider:

- The clinical appropriateness and practicality of asking GPs to prescribe alirocumab and evolocumab.
- The letter to GPs and supplementary prescribing guidance developed by the lipid specialists.
- If there are any circumstances in which it would not be appropriate to ask a GP to prescribe alirocumab and evolocumab (the request for an amber classification is for patients who can self-administer injections).

The FIG agreed in principle with the proposal for lipid specialists to ask GPs to take on the continued prescribing of alirocumab and evolocumab under the circumstances outlined in the letter to GPs and the supporting guidance. The patient groups considered to be appropriate for prescribing in primary care will need to be defined and agreed on before the FIG can take a final decision on the proposal for formulary reclassification.

The FIG considered the proposed letter and supporting information developed by the lipid specialists to be broadly acceptable.

The FIG considered the monitoring of patients receiving alirocumab or evolocumab was within the current annual lipid review recommended for patients receiving other lipid-modifying drugs

The FIG did not consider the request to be non-commissioned work, however, the FIG acknowledged that some GPs may consider the request to continue the prescribing of alirocumab or evolocumab in primary care to be additional work as this is currently undertaken in secondary care.

The views of cardiologists who may prescribe alirocumab and evolocumab were not available at the time of the meeting. The FIG has yet to consider a proposal for cardiologists to request GPs continue the prescribing of alirocumab or evolocumab in primary care.

It was noted in the discussion that cardiovascular outcome data is available from clinical trials for alirocumab and evolocumab whereas this data is not available for inclisiran, which can be initiated by GPs with the support of the NICE committee for the inclisiran TA.

A final decision on the formulary classification of alirocumab and evolocumab will not be taken until all the required information is available and the trust/primary care prescribing budget for PCSK9 inhibitors is resolved.

5. Inclisiran: Royal College of General Practitioners and BMA statement

NICE technology appraisal (TA) 733: Inclisiran for the treatment of primary hypercholesterolemia and mixed dyslipidaemia was discussed at the October 2021 FIG meeting after NICE brought the implementation period forward from 90 days to 30 days. The FIG agreed inclisiran would be a blue (second-line) option in the Devon Formulary in line with the TA criteria and enabling initiation in primary care which was supported by the NICE committee for TA733.

The Royal College of General Practitioners (RCGP) and the British Medical Association (BMA) issued a statement on inclisiran on 3rd December 2021. The RCGP and BMA have discussed the proposed roll out of inclisiran within primary care with NHS England and Improvement (NHSEI) following concerns raised by members and then subsequently a British Medical Journal (BMJ) editorial asking for the drug's approval to be reconsidered (Bryan et al, 2021). The RCGP and the BMA have indicated they will continue to work with NHSEI to understand more about the proposals and information from the trials and will communicate an update to their members once they have further details.

The lipid specialists for Torbay and South Devon NHS Foundation Trust and University Hospital Plymouth NHS Trust and the CCG Senior Medicines Optimisation Pharmacist for secondary care were present for the discussion of this item.

The RCGP and BMA statement includes recommendations for GPs on the prescribing of inclisiran. The FIG was asked whether it accepts the proposed update to the inclisiran entry to include a link to the statement from the RCGP and the BMA.

The FIG considered and accepted the proposed update to the formulary entry 2.12 lipid-regulating drugs. This is an interim position and a link out to the statement is adequate.

A discussion took place. This included that:

- telling patients there is no data on cardiovascular outcomes may make inclisiran less desirable for some patients who may prefer a more established drug,
- GPs may be less keen to prescribe inclisiran based on the RCPP and BMA statement,
- Lipid specialists are intending to develop local guidance once NHSE and the AAC have updated their guidance on lipid management to incorporate inclisiran.

ACTION: Formulary team to update the formulary with the accepted entry for 2.12 Lipid-regulating drugs.

6. Luforbec (BDP extrafine/formoterol) pressurised metered dose inhaler for asthma and COPD

During the October meeting, the FIG discussed an application from a CCG Senior Medicines Optimisation Pharmacist for the addition of Luforbec pressurised meter dose inhaler (pMDI) to the Devon Formulary in place of Fostair 100/6 pMDI.

Luforbec pMDI has the same licensed indications as the Fostair 100/6 pMDI. It contains the same medicinal products in the same strengths at a lower cost. Luforbec is licensed for the treatment of COPD and asthma in adults as a maintenance therapy and a maintenance and reliever (MART) therapy.

The Formulary team had consulted with respiratory consultants and respiratory nurses before the October FIG meeting. During that meeting, the FIG took a decision in principle on proposed amendments to the formulary entry pending further consultation with specialists.

Further responses have been received from consultants who raised concerns about the immediate removal of Fostair 100/6 pMDI from the formulary following the FIG's final decision, so an interim solution was proposed. Fostair 100/6 pMDI will no longer be formally recommended in the Formulary, but the proposed wording would recognise and accept non-formulary use for existing patients, whilst supporting a move away from its use in a managed way. At an appropriate time in the future, the FIG will be asked to consider the removal of this wording from the formulary.

The FIG was asked to consider the proposed formulary entry. The applicant was present for the discussion. The FIG considered and accepted:

- the proposed formulary entry for Luforbec inhaler,
- that Fostair 100/6 pMDI will no longer be formally recommended in the Formulary and the proposed interim wording for Fostair 100/6 pMDI
- the proposed wording for Fostair 200/6 pMDI.

ACTION: Formulary team to update the formulary entry for Luforbec inhaler and the entries for Fostair 100/6 and 200/6 pMDI.

7. Proposal to add various Easyhaler Dry Powder Inhalers and Trimbow NEXThaler

During the October FIG meeting, the FIG discussed a proposal for the addition of four Easyhaler dry powder inhalers and Trimbow NEXThaler to the Devon Formulary. This was prompted by an announcement from NHS England of a new initiative for primary care to increase the prescribing of dry powder inhalers (DPIs) and soft mist inhalers (SMIs) where clinically appropriate.

The Formulary team consulted with respiratory consultants and respiratory nurses before the October FIG meeting. During that meeting, the FIG took a decision in principle on the proposals pending a further consultation with the specialists.

Subsequent to the consultation with specialists some amendments were made to the proposed formulary entry. These were presented at the FIG meeting for consideration. The applicant was present for the consideration of the item. The FIG accepted the following proposals:

Corticosteroid inhaler

- The addition of budesonide 100mcg, 200mcg and 400mcg Easyhaler alongside Pulmicort Turbohaler as a green (first-line) option for the treatment of asthma from six years of age.
- Kelhale (BDP extrafine) 50mcg and 100mcg pMDI is moved to a blue (second-line) option in line with most pMDIs, and a note is added to the entry for Qvar (BDP extrafine) 50mcg and 100mcg pMDI indicating that for cost reasons, Kelhale is the preferred option for new initiations of BDP extrafine pMDI in adults.

Adrenoreceptor agonist inhalers

- The addition of formoterol 12mcg Easyhaler as a green (first-line) option alongside Oxis (formoterol) 12mcg Turbohaler for the treatment of COPD.
- The removal of Oxis (formoterol) 6mcg Turbohaler from the Devon Formulary, as the daily dose is 12mcg twice daily and the 6mcg Turbohaler is twice the price per daily dose compared with Oxis 12mcg Turbohaler.

Combination LABA / ICS inhalers

- The addition of Fobumix (budesonide / formoterol) Easyhaler as a green (first-line) option alongside Symbicort Turbohaler for the treatment of asthma in adults and COPD.
- The reclassification of Duoresp Spiromax (budesonide/formoterol) from a green (first-line) option to a blue (second-line) option. Duoresp Spiromax is licensed for COPD only, it is the same cost as Symbicort Turbohaler and is a higher cost than Fobumix Easyhaler.

- The addition of Fusacomb 250mcg/50mcg (FP/salmeterol) Easyhaler as a blue (second-line) option for the treatment of asthma from 12 years of age.
- The addition of a note to the Seretide Accuhaler entry indicating that for new initiations of FP 250mcg/salmeterol 50mcg in patients aged from 12 years, Fusacomb Easyhaler is the preferred DPI option for cost reasons. No change is proposed to Seretide Evohaler pMDI and Seretide 100/50 Accuhaler which remain in the formulary for the treatment of children aged ≥4 years.

Triple combination inhalers

- The addition of Trimbow NEXThaler DPI to the Devon Formulary as a green (first-line) option and Trimbow pMDI moved to a blue (second-line) option, as most formulary pMDIs are blue options (supporting steps to reduce the carbon footprint of inhaler use).

The FIG considered and accepted the draft formulary entry, including the additional changes suggested in the meeting papers.

ACTION: Formulary Team to update the formulary with the entries for the Easyhaler Dry powder Inhalers and Trimbow NEXThaler and in line with the additional changes accepted by the FIG.

8. Sacubitril valsartan for chronic heart failure: partial review

Sacubitril valsartan was included in the Devon Formulary on the publication of NICE technology appraisal TA388: Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (27 April 2016). The formulary entry was agreed by the respective predecessor FIGs taking into account the NICE TA recommendation: "Treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults: diagnosis and management."

Heart failure consultants from University Hospitals Plymouth supported by a consultant from North Devon Healthcare Trust and a consultant from Torbay and South Devon NHS Foundation Trust have asked for the formulary entry for sacubitril valsartan to be reconsidered.

The first request was for sacubitril valsartan to be a first-line option in the heart failure pathway. This is outside the NICE TA and therefore not within the remit of the FIG to consider. The NICE committee for TA388 found sacubitril valsartan was not cost effective as a first-line option. The Formulary team have responded to the heart failure teams on this point.

The second request was for the current formulary statement on the initiation, titration and stabilisation of sacubitril valsartan to be amended to: "Treatment with sacubitril valsartan should be initiated on the advice of a heart failure specialist with follow up performed by the most appropriate member of the MDT." The current formulary statement requires treatment to be initiated by a heart failure consultant and for the heart failure specialist team to be responsible for prescribing, titration and optimisation of sacubitril valsartan, usually for up to three months.

In support of their request, the consultants indicated that: fewer dose titrations are now required to reach a maximum dose of sacubitril valsartan; the specialist teams have gained experience with its use; all other heart failure drugs can be prescribed by a GP on the advice of a specialist, citing NICE TA679 for dapagliflozin as an example. In addition, there was reference to the PARADIGM trial which forms the basis for NICE TA388 for sacubitril valsartan.

The heart failure teams in Devon provided extensive feedback during the consultation.

The FIG meeting paper included the feedback from the heart failure teams in addition to relevant information from NICE TA388 and NICE guidance for chronic heart failure (NG106), the British Society of Heart Failure position statement on non-medical prescribers and the position/guidance for sacubitril valsartan in other formularies in South West England. The heart failure teams were given the opportunity to provide comments on the paper before the meeting.

The FIG was asked to consider whether there were reasonable grounds to support the proposal to change the formulary entry for sacubitril valsartan. To facilitate the discussion, the FIG was asked to consider four proposals which were based on the responses received from specialists to the consultation. The discussion was an initial discussion with no guests present. The proposals considered were:

- **Proposal 1**: no change to note 3:
  - "Treatment with sacubitril valsartan should be initiated by a heart failure Consultant. Following dose titration and once the patient is stabilised on treatment by the specialist heart failure team, ongoing management and monitoring of the patient may be performed in primary care. Initial clinical assessment and monitoring will usually remain the responsibility of the specialist heart failure team for up to the first three months"
- **Proposal 2**: note 3 is amended to remove the reference to a heart failure consultant and enable a heart failure specialist (e.g. nurse, pharmacist, GPwSI) to initiate treatment with sacubitril valsartan.
- **Proposal 3**: similar to proposal 2 but further amended to support GP prescribing of sacubitril valsartan during the initial dose titration and stabilisation.
- **Proposal 4**: Note 3 is replaced with "Treatment with sacubitril valsartan should be initiated on the advice of a heart failure specialist with follow up performed by the most appropriate member of the Multi-Disciplinary Team."

The FIG agreed there were reasonable grounds to support amendment of the formulary entry for sacubitril valsartan in line with proposal 2:

a. The formulary entry should be updated to remove the reference to initiation by a heart failure "consultant" and to change this to initiation by a heart failure "specialist" to enable a specialist nurse, specialist pharmacist or cardiology GPwSI to initiate treatment with sacubitril valsartan.

b. Prescribing of sacubitril valsartan should remain the responsibility of the specialist heart failure teams during initiation, titration and stabilisation of treatment, however,

the current time period of up to three months for prescribing by the specialist teams should be removed from the entry

The FIG was not persuaded that there were reasonable grounds to progress proposal 3 or 4.

There was discussion about:

- The FIG GPs considered that GPs should not be asked to prescribe sacubitril valsartan from the start of treatment. The FIG members considered that optimisation of treatment with sacubitril valsartan is the role of the heart failure team, but changes could be made to the current formulary entry to assist the heart failure teams in this aspect of their role. The importance of specialist input and the role of the non-medical prescriber in optimising certain "specialist" heart failure medicines is recognised by the NICE guidance for chronic heart failure and the sacubitril valsartan TA.

- The meeting paper included extensive feedback from the heart failure teams in Devon and gave an insight into the concerns raised particularly those of the West Devon teams.

- The FIG members agreed that it was not necessary for a heart failure "consultant" to initiate treatment and this wording should be replaced to enable a heart failure "specialist" to initiate treatment without the requirement to discuss a patient with a consultant unless they consider it is appropriate to do so. All heart failure teams had indicated that this change to the formulary entry would assist in the initiation of treatment with sacubitril valsartan. It was apparent that the integrated teams had adopted a pragmatic approach with regard to the level of involvement of a consultant in the decision to initiate treatment and the consultants were only involved in stabilisation of treatment when the heart failure specialist requested advice. A different approach has been adopted in West Devon where the community heart failure team in Plymouth is separate from the in-patient team and is led by a GPwSI. The teams are using the weekly MDT meeting to obtain consultant support. The proposed change in wording would enable a GPwSI, specialist nurse or specialist pharmacist in the Plymouth community heart failure team to initiate sacubitril valsartan without the requirement to discuss the patient with a consultant.

- The consultants indicated that fewer dose titrations are now required to reach the maximum dose of sacubitril valsartan. The FIG members considered that the heart failure teams should determine when a patient is stabilised on treatment and it would be appropriate to ask a GP to continue prescribing rather than the current recommendation for prescribing to remain with the team for up to the first three months of treatment. This could free up time for other patients requiring input from the heart failure team.

- The in-patient and community heart failure teams for West Devon raised some concerns about their processes for initiating and prescribing sacubitril valsartan. It was considered that the changes proposed by the FIG would assist these teams in redesigning their processes if they choose to do so, however, some of the points raised were inherent to the system and need to be addressed at a local level. The Formulary team had identified areas raised by the Plymouth in-patient team which could be addressed outside the FIG. These were:

- *Supply of sacubitril valsartan from secondary care:* It was suggested in an e-mail from Rebecca Horne that there may have been delays in the supply of sacubitril valsartan from UHP. The Formulary team has asked the UHP pharmacy representative to liaise with Rebecca to determine whether this is a current issue

- *Concern that GPs will continue to prescribe an ACE inhibitor or ARB when patients are prescribed sacubitril valsartan by the heart failure team:* This is relevant to all patients prescribed sacubitril valsartan by the heart failure teams. The Formulary team will liaise with the CCG's Medicines Optimisation team on information for GPs to add medicines prescribed by secondary care to the patient's medical record to reduce the possibility of concurrent treatment. More detail on this could be included in the formulary entry for sacubitril valsartan

ACTION: Formulary team to communicate the outcome of the discussion to the heart failure teams

There is an ongoing review of the formulary guidance and medicines for chronic heart failure which includes harmonisation of the entries for sacubitril valsartan.

9. Consideration of Inhixa (enoxaparin) for addition to the formulary

Inhixa is an enoxaparin sodium biosimilar, available as standard strength (100mg/ml) pre-filled syringes containing 20mg, 40mg, 60mg, 80mg or 100mg enoxaparin, or as higher strength (150mg/ml) pre-filled syringes containing 120mg or 150mg enoxaparin. It was the first enoxaparin biosimilar launched in the UK and the indications and recommended doses for Inhixa are identical to that of Clexane.

An application has been received, from a Senior Pharmacist and the Deputy Director of Pharmacy supported by the Deputy Medical Director and Chair of the Drug and Therapeutics Committee at University Hospitals Plymouth NHS Trust, for inclusion of Inhixa in the Devon formulary for use in line with its licensed indications.

Currently the Devon Formulary lists three low molecular weight heparins:

- Dalteparin is amber for use in East and South Devon only.
- Enoxaparin (as the brand Clexane) is amber for use in North and West Devon only.
- Tinzaparin is red for use in North, East, and West Devon, and is included in the formulary for the prevention of clotting in the extracorporeal circuit during haemodialysis in patients with chronic renal insufficiency only.

The applicants also proposed that Clexane be removed from the Devon Formulary.

The applicant has indicated that the manufacturer of Inhixia has committed to providing support with needle device training and were asked if adequate supplies are available.

If Clexane is not removed from the formulary and the multidose vial is to be retained, consideration should be given to whether it should be classified as red or amber.

Pharmacy teams at the acute trusts have been consulted.

The FIG agreed the following:

- Inhixa was accepted as an amber (specialist) drug with the exception of use in acute coronary syndrome and prevention of clotting in the extracorporeal circuit which are red (hospital only) indications. The FIG accepted the proposed formulary entry.
- Clexane to be retained in the Devon Formulary
- Enoxaparin multidose vials to be retained in the Devon Formulary
- Tinzaparin to be retained in the Devon Formulary
- Historic Western locality "shared care" information to be withdrawn from the formulary.

There was discussion about:

- The practicality of only having one brand in the formulary when there are several available.
- In the South West of England, a number of approaches are taken.
- Training resources. The Formulary team will seek to identify training resources and add links in the formulary as appropriate.

ACTION: Formulary to identify training resources for Inhixa and add links in the formulary as appropriate.

- Supply issues were noted. The FIG considered that it was pragmatic to retain Clexane in the formulary and that there was minimal clinical risk in having two drugs. Both the ERIS and PREVENTIS safety devices have been used as a result of Clexane injections switching to the PREVENTIS device due to a temporary shortage of the ERIS safety system.

ACTION: Formulary team to add Inhixa (enoxaparin) to the formulary in line with the discussion.

10. Lyumjev insulin lispro

Lyumjev is an ultra-rapid-acting formulation of insulin lispro, developed by the manufacturer of Humalog. It is indicated for adults with type 1 and type 2 diabetes mellitus. It should be administered by the subcutaneous route zero to two minutes before the start of a meal, with the option to administer up to 20 minutes after starting a meal. It is licensed for use with a continuous subcutaneous insulin infusion.

An application has been received from, the lead diabetes specialist nurse at University Hospitals Plymouth NHS Trust for the addition of the Lyumjev insulin lispro to the Formulary in the same strengths and formulations as Humalog, which will remain in the formulary. The application is supported by a consultant diabetologist from University Hospitals Plymouth NHS Trust and a consultant endocrinologist from Torbay and South Devon NHS Foundation Trust.

Lyumjev insulin lispro was proposed as an amber (specialist) option for patients who, due to work/lifestyle commitments, are unable to give their mealtime insulin 15 to 20 minutes prior to a meal.

Evidence of the efficacy and safety of Lyumjev insulin lispro from clinical trials was presented to the FIG. All Lyumjev insulin lispro products are the same price as the existing Humalog insulin lispro products. From a safety perspective, there are a number of insulin lispro products. Lyumjev insulin lispro is licensed only for adults. Brand prescribing will be important to ensure that Lyumjev insulin lispro is not inadvertently prescribed in place of Humalog insulin lispro and it is not prescribed for children.

The FIG considered and accepted the proposed formulary entry for Lyumjev insulin lispro without amendment.

ACTION: Formulary team to add the accepted entry for Lyumjev insulin lispro to the formulary.

11. Treatment of *Clostridioides difficile* (*C. difficile*)

Revised Formulary guidance on the treatment of *C. difficile* was considered by the FIG in October 2021. At that meeting the FIG accepted the proposed guidance subject to some clarification and amendments.

Redrafted guidance including those changes was circulated to specialists resulting in some additional minor amendments in relation to the management of recurrent episodes. These were presented to the FIG for agreement together with questions on harmonisation of the Formulary presentations for metronidazole and vancomycin

The FIG considered and accepted the proposed changes without amendment. The FIG accepted the inclusion of metronidazole 200mg/5ml oral suspension and metronidazole 500mg and 1g suppositories for North and East Devon. These are currently included in the formulary for South and West Devon only.

The formulary team will seek clarification from Trusts regarding some areas of proposed harmonisation.

There was discussion about when in the pathway patients receive faecal microbiota transplant.

ACTION Formulary team to update the accepted formulary guidance for the treatment of Clostridioides difficile and the entries for fidaxomicin, metronidazole and vancomycin.

12. Giardiasis: Tinidazole (Fasigyn) discontinuation

In September 2018, the South and West Devon FIG considered an application for Fasigyn (tinidazole) to be added to the formulary. At this time the Devon Formulary did not include guidance specifically on the management of giardiasis.

At that meeting it was agreed to add giardiasis management guidance to the formulary, which recommended tinidazole as a green option for the treatment of giardiasis and metronidazole as a green alternative. The tinidazole application was not discussed at the

North and East FIG meeting and it is not currently included in the North and East Devon formulary presentation.

In March 2021, Pfizer discontinued Fasigyn (tinidazole) 500mg tablets from the UK market. There are currently no other medicines available in the UK that contain tinidazole as the active ingredient.

The Department of Health and Social care states "UKMI have advised that the discontinuation of tinidazole should not cause any major problems as the product is rarely used and most patients would be able to use metronidazole." Prescribing figures in the community also support this statement with 19 prescriptions issued in Devon in the last 12 months. Although tinidazole is not available in the UK, it appears that stock can be obtained through the 'unlicensed specials and imports' route. The invoice price of imported tinidazole is not known and may be variable, and it is not known whether individual community pharmacies would be able to source imported tinidazole, or how long it would take for them to obtain it.

The Formulary team consulted with microbiology and pharmacy teams in South and West Devon to gather feedback on giardiasis management with tinidazole being discontinued. Based on the comments from specialists and the information provided in the meeting paper, the FIG was asked to consider next steps for giardiasis and tinidazole within the Devon Formulary.

The FIG considered four proposed options.

It was agreed to classify tinidazole to 'red' (hospital only) to support use within trusts. This requires all prescriptions to be issued in secondary care but could avoid unnecessary delays in accessing treatment via GP/community pharmacy.

It was also agreed to note in the Devon Formulary that tinidazole has been discontinued and that GPs should not be asked to prescribe it.

The formulary will continue to recommend that "treatment failure should be discussed with or referred to a specialist, who should exclude underlying problems."

ACTION: Formulary Team to update the South and West Devon Formulary entry for tinidazole for the management of Giardiasis in line with the FIG's recommendation

13. Management of Epilepsy: partial update

Earlier this year, the Commission on Human Medicines (CHM) reviewed available safety data relating to the use of key antiepileptic drugs in pregnancy for the risk of major congenital malformations, neurodevelopmental disorders and delay, and other effects on the baby. The outcomes of the review were published in the MHRA Drug Safety Update in January 2021 and were included in the summary of Drug Safety Update articles presented at the February 2021 meeting of the FIG. Advice for health care professionals and the key conclusions of the review were included under Management of Epilepsy in the Devon

Formulary, and a link to the Drug Safety Update was included under section 4.8.1 Control of the Epilepsies which includes the monographs for the antiepileptic drugs.

The NICE guidance for epilepsy (CG187) was subsequently updated in line with the MHRA updated safety advice on antiepileptic drugs in pregnancy. The key changes relevant to the formulary guidance for the management of epilepsy and the proposed updates to the current formulary guidance were presented to the FIG. These included updates to the antiepileptic drugs recommended for individual seizure types, the subsection on prescribing for women and girls with epilepsy and information on valproate medicines.

The Formulary team consulted with epilepsy specialists before the FIG meeting. A response was received from one specialist who had no objection to the proposed changes.

The FIG considered and accepted in principle the proposed partial update to the formulary guidance for the Management of Epilepsy pending further consultation with specialists.

ACTION: Formulary team to undertake further consultation with specialists on the Management of Epilepsy.

14. 9.4.1 Foods for special diets: Gluten-free update

Following various national and local consultation and engagement processes, the predecessor North & East and South & West Devon FIGs agreed to include guidance on the prescribing of gluten-free foods in line with the national decision from the Department of Health and Social Care and in line with the CCG's decision on prescribing of Gluten Free foods.

In November 2018, the Gluten-Free Prescribing Regulations became law and in December 2018, the revised Drug Tariff in England was introduced. The Drug Tariff only lists gluten-free bread and flour mixes; other gluten-free foods are no longer available on prescription in England. The formulary preferred brands for gluten-free bread and flour mixes were chosen by the CCG's Medicines Optimisation Team because they represent the best value for money amongst the commonly prescribed brands.

The Formulary Team was informed of a query from a dispensing practice in Devon, who were unclear why a gluten-free lasagne prescription had been disallowed by the NHS Business Services Authority; the practice suggested that the Devon formulary indicated gluten free lasagne was suitable to prescribe.

The Formulary Team reviewed the gluten-free guidance in the formulary and no gluten-free products other than the agreed breads and food mixes were found, however it was noted that there is a hyperlink to Coeliac UK's 2011 guidance on units for prescribing gluten-free products which contains outdated reference to products no longer prescriptible on NHS FP10 (including pasta, pizza bases, biscuits etc.).

Therefore, to avoid confusion and to clarify the NHS Devon CCG position on gluten-free products, it was proposed that the formulary section is amended. The update removes the link to the Coeliac UK website and replaces it with relevant recommended quantities and unit information extracted from the original Coeliac UK guidance. A link to NHS England

Guidance for CCGs: Prescribing Gluten- Free Foods in Primary Care (November 2018) has also been added.

The FIG considered and accepted the proposed amendments to the gluten free guidance page without amendment.

ACTION: Formulary team to publish the accepted amendments to the formulary gluten-free guidance page.

15. Osteoporosis

A draft update to the formulary guidance for osteoporosis, developed by rheumatology services from the Royal Devon and Exeter Hospital, was included in the meeting papers for the October Devon FIG meeting. At that time the FIG was asked to consider whether there were any areas where further information is required in the formulary. FIG members raised dental problems with bisphosphonate treatments.

An MHRA safety update on this subject is included in the Devon Formulary under section 6.6.2 Bisphosphonates and other drugs affecting bone metabolism and the section Management of osteoporosis.

At the FIG meeting on 8th December, the FIG was asked to clarify the additional information which is required on dental problems with bisphosphonate treatments. It was noted that patients are increasingly being given bisphosphonates long term and that there is some concern about osteonecrosis of the jaw. The FIG clinicians considered the safety update was informative and no further information was required from a clinician perspective. The Formulary team will check the MHRA and British Dental Association websites for patient information and add a link to the proposed update to the formulary sections on osteoporosis if appropriate.

ACTION: Formulary team will check the MHRA and Dental Association websites for patient information on bisphosphonates and osteonecrosis of the jaw and add to the formulary if appropriate.

16. MHRA Drug Safety Updates (October to December 2021) including Emerade re-introduction

September 2021

Topical corticosteroids: information on the risk of topical steroid withdrawal reactions

A particularly severe type of topical steroid withdrawal reaction is currently an under-recognised side effect of topical corticosteroid treatment. The National Eczema Society and British Association of Dermatologists has issued a joint position statement on topical steroid withdrawal.

Formulary section 13.4 Topical Corticosteroids will be updated with a summary and link to the Drug Safety Update including a link to the NES/BAD position statement and the MHRA safety information leaflet for patients on topical corticosteroid withdrawal reactions.

Letters and medical recalls sent to healthcare professional in August 2021

No updates to the formulary were required.

ACTION: **MHRA Drug Safety Update September 2021– Formulary team to add to the formulary in line with the discussion**

October 2021

Tofacitinib (Xeljanz): new measures to minimise risk of major adverse cardiovascular events and malignancies

- Tofacitinib is indicated for the treatment of rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. It is a red (hospital only) formulary option.
- Dear Healthcare Professional Letters for tofacitinib were reported at the June 2021 and October 2021 FIG meetings on the findings of a clinical safety study. This article includes new measures taken in light of the final results of the clinical safety trial in patients with rheumatoid arthritis aged 50 years or older with at least one cardiovascular risk factor. The measures have been introduced to reduce the risk of major cardiovascular events and malignancies in patients receiving tofacitinib.
- The drug entry for tofacitinib under section 10.1.3 of the Devon Formulary will be updated with the advice for healthcare professionals and a link to the Drug Safety Update.

Chloral hydrate, cloral betaine (Welldorm): restriction of paediatric indication

- The CHM recommended that the paediatric indication of all chloral hydrate and chloral betaine products should be restricted to use only in children and adolescents with suspected or definite neurodevelopmental disorders, where the benefits of short-term use outweigh any potential risk. Use should only be under the supervision of a specialist.
- The North and East Devon Formulary does not include chloral hydrate. The South and West Devon Formulary includes chloral hydrate 500mg/ml solution with no indication listed and a note indicating that it is for use by specialists in paediatrics. The Formulary team will include a summary of the article and link to the Drug Safety Update in the South and West Devon Formulary, and follow up the entry with the FIG representatives for Torbay Hospital and University Hospital Plymouth. The Medicines Optimisation FIG representatives were made aware that there are a small number of prescriptions for chloral hydrate oral solution in primary care which will need to be followed-up.

Letters and medical recalls sent to healthcare professionals in September 2021

ACTION: **MHRA Drug Safety Updates October 2021– Formulary team to add to the formulary in line with the discussion.**

ACTION: Formulary team to follow up South and West Devon Formulary entry for chloral hydrate with FIG representatives for Torbay Hospital and University Hospitals Plymouth.

ACTION: Medicines Optimisation team to look into prescribing of chloral hydrate oral solution in the community in Devon.

November 2021

Adrenaline auto-injectors: reminder for prescribers to support safe and effective use

- This article reports on the re-supply of Emerade 300 micrograms and 500 micrograms auto-injectors and the report of the Adrenaline Auto-injector Expert Working Group.

- Key points from the expert working group's advice for healthcare professionals and patients were proposed for addition to the formulary entry for adrenaline including a link to the Drug Safety Update. In addition, it was proposed that a note is added with information on the re-supply of Emerade 300 microgram and 500 microgram auto-injectors.

- The FIG considered and accepted the proposed changes to the formulary entry for adrenaline.

Letters sent to healthcare professionals and drug alerts in October 2021

- Champix (varenicline) - batches to be recalled due to presence of impurity N-nitrosovarenicline above the acceptable intake limit.
    - A Supply Disruption Alert was issued for varenicline on 28 October 2021. The formulary entry for varenicline has been updated with a link to the alert and a summary of the key points from the advice to healthcare professionals.
- Forxiga (dapagliflozin) 5mg should no longer be used for the treatment of Type 1 Diabetes Mellitus.
    - The company has decided to remove the indication of type 1 diabetes mellitus. This indication was licensed for the 5mg tablet only. The 5mg tablet is recommended for severe hepatic impairment in the existing indications (type 2 diabetes mellitus and chronic heart failure) and this remains available. The formulary entry for dapagliflozin and relevant notes under section 6.1.2 Antidiabetic drugs have been updated to remove the indication for type 1 diabetes.

ACTION: Formulary team to update the formulary entry for adrenaline with information on the resupply of Emerade 300 microgram and 500 microgram and advice from the expert working group.

Post Meeting Note:

Drug Safety Update November 2021: Yellow fever vaccine (Stamartil): new pre-vaccination checklist

- A standardised pre-vaccination checklist has been introduced to ensure the yellow fever vaccine is indicated for the intended travel destination and to enable vaccinators to identify existing contraindications or precautions in individuals before vaccination.
- Formulary section 14.1 Vaccines and antisera refers to the Green Book for further information on dosing and treatment regimens. It was noted that the Green Book chapter on Yellow fever vaccine has not been updated since the MHRA safety update was issued.

ACTION: Formulary team to update the formulary entry for Yellow Fever vaccine with a link to the Drug Safety Update.

17. FIG meeting duration consultation outcome

Over recent years the volume of formulary content has increased considerably; these pages all require maintenance and review, resulting in increasing demands on FIG time to consider and agree updates. In addition, requests are frequently received for new guidance and additional drugs, adding to the immediate workload and increasing the volume requiring future review.

It was noted that the quality and consistency of input from all FIG members over the past few years has been remarkable and includes a significant amount of "homework" in reading the papers prior to each meeting, as well as considering and responding to multiple e-FIG discussions during the year. The Formulary team are also aware that as a result of the FIG merger, some FIG members have rearranged other commitments and give up time off in order to continue to attend meetings - this is hugely appreciated.

In November, FIG members were consulted on possible changes to the duration of FIG meetings. A number of options were proposed.

Responses were received from almost all the FIG members. No clear consensus emerged; therefore, the Formulary team propose to retain the existing meeting duration and timings. The e-FIG will continue to be utilised as much as possible to free up face to face time in FIG meetings.

Moving forward the Formulary team will continue to consider whether the best is being made of FIG time and consider ways to improve efficiency, and the work that is a priority for consideration.

18. Recent drug decisions (including NICE)

The recent drug decisions were noted. These included:

- Publication of the Esmya commissioning policy.

- Discontinuation and removal of Instillamed bladder instillation, Farco-fill catheter solution, IryPump S anal irrigation system, and Bard Lubri-Sil Female Foley Tray.

Amendments to the formulary included:

- A new pack size of Soolantra (ivermectin) cream, and the changes to varenicline and dapagliflozin as mentioned in the Drug Safety Updates.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	Ongoing
21/24	Thyroid disorders: Update – circulate the final draft via e-FIG for agreement.	Formulary Team	Ongoing
21/46	Palliative care: Levetiracetam 100mg/ml concentrate solution for intravenous infusion - circulate the final draft of the proposed formulary entry via the e-FIG process or bring the item back to a future meeting. This is now with nurses and will be circulated to the FIG for final agreement.	Formulary Team	Ongoing
21/54	Methotrexate/folic acid dose scheduling clarification – Folic acid recommendations in the gastroenterology Shared Care prescribing guideline for west Devon to be reviewed following contact with gastroenterology specialists at UHP to discuss a more specific definitive statement. *Post meeting note: RD&E gastroenterologists have requested updates to the N&E methotrexate guidelines. A Devon-wide review is proposed and the folic acid prescribing notes in the west Devon gastroenterology guideline will be considered as part of this review.*	Formulary Team	Ongoing
21/56	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	Complete
21/65	Anal Irrigation Systems – update the formulary entry for anal irrigation systems in line with the discussion.	Formulary Team	Complete
21/72	Osteoporosis – liaise with specialists and bring final draft to a future FIG meeting.	Formulary Team	Ongoing
21/73	New drug entries for COVID-19 vaccines and Ronapreve to be added to the local formulary.	Formulary team	Complete
21/74	Update the formulary with the accepted entry for Alirocumab 300mg/2ml solution for injection, pre-filled pen.	Formulary Team	Complete
21/75	Inclisiran: Royal College of General Practitioners and BMS statement - update the formulary with the accepted entry for 2.12 Lipid-regulating drugs.	Formulary Team	Complete
21/76	Update the formulary entry for Luforbec inhaler and the entries for Fostair 100/6 and 200/6 pMDI.	Formulary Team	Ongoing
21/77	Update the formulary with the entries for the Easyhaler Dry Powder Inhalers and Trimbow NEXThaler and in line with the additional accepted changes.	Formulary Team	Ongoing

21/78	Sacubitril valsartan for chronic heart failure: partial review – communicate the outcome of the discussion to the heart failure teams.	Formulary Team	Complete
21/79	Consideration of Inhixa (enoxaparin) for addition to the formulary - identify training resources and add links in the formulary as appropriate.	Formulary Team	Complete
21/80	Consideration of Inhixa (enoxaparin) for addition to the formulary – add Inhixa to the formulary in line with the discussion.	Formulary Team	Complete
21/81	Lyumjev insulin lispro - add the accepted entry for Lyumjev to the formulary.	Formulary Team	Complete
21/82	Treatment of *Clostridioides difficile* (*C. difficile*) update formulary guidance for the treatment of *Clostridioides difficile* and the entries for fidaxomicin, metronidazole and vancomycin.	Formulary Team	Complete
21/83	Update the South and West Devon Formulary entry for tinidazole for the management of giardiasis in line with the discussion.	Formulary Team	Complete
21/84	Undertake further consultation with specialists on the Management of Epilepsy.	Formulary Team	Ongoing
21/85	Publish the accepted amendments to the formulary gluten-free guidance page.	Formulary Team	Complete
21/86	Osteoporosis – Check the MHRA and Dental Association websites for patient information on bisphosphonates and osteonecrosis of the jaw and add to the formulary if appropriate.	Formulary Team	Ongoing
21/87	MHRA Drug Safety Update (September 2021) - add to the formulary in line with the discussion.	Formulary team	Complete
21/88	MHRA Drug Safety Updates (October 2021) - add to the formulary in line with the discussion.	Formulary Team	Complete
21/89	Follow up South and West Devon Formulary entry for chloral hydrate with FIG representatives for Torbay Hospital and University Hospitals Plymouth.	Formulary Team	Complete
21/90	Medicines Optimisation team to look into prescribing of chloral hydrate oral solution in the community in Devon.	Sarah Marner	Ongoing
21/91	MHRA Drug Safety Updates (November 2021) - update the formulary entry for adrenaline with Emerade 300 microgram and 500 microgram adrenaline auto-injectors: re-supply to market and advice from expert working group.	Formulary Team	Complete
21/92	MHRA Drug Safety Updates (November 2021) – update the formulary entry for yellow fever vaccine	Formulary Team	Complete