NHS
Devon
Clinical Commissioning Group

Meeting of the Devon Formulary Interface Group

Minutes

20th October 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
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
Nick Keysell	GP	NHS Devon CCG
Carole Knight	Formulary Pharmacist	NDHT
James Leavy	Medicines Information Pharmacist	RD&E NHS FT
Sarah Marner	Senior MO Pharmacist	NHS Devon CCG
Bill Nolan	GP	NHS Devon CCG
Jess Parker	GP	NHS Devon CCG
Graham Parsons	Pharmacist	UHP NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Christopher Sullivan	Deputy Chief Pharmacist - Clinical Services	DP NHS Trust
Larissa Sullivan	Pharmacist	T&SD NHS FT
Darren Wright	Joint Formularies Technician	NHS Devon CCG

Guests:

Dr Tony Avades	Consultant Chemical Pathologist	UHP NHS Trust
Jill Ashcroft	Medicines Optimisation Pharmacist	NHS Devon CCG
Rosie Fok	Consultant Microbiologist and Antimicrobial Stewardship Lead	UHP NHS Trust
Natasha Moore	Senior MO Pharmacist	NHS Devon CCG
Karen Northcott	Senior MO Technician	NHS Devon CCG
Dr Aabha Sharma	Consultant Chemical Pathologist	T&SD NHS FT

Observers:

Kenna Frances	Pre-reg Pharmacist	RD&E NHS FT
Liana Reynolds	Pre-reg Pharmacist	RD&E NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Meeting etiquette

Tawfique Daneshmend explained the meeting etiquette.

Chairman's welcome

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

Apologies

Nicola Diffey	Pharmacist	Livewell Southwest
Jamie Smith	Consultant in Diabetes and Endocrinology	T&SD NHS FT
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
Fidaxomicin for the treatment of *Clostridioides difficile* infection *(including formulary guidance on the treatment of C. difficile infection)*	
Fidaxomicin (Dificlir)	Tillotts Pharma UK Limited
Alternative treatments:	
Vancomycin	Various manufacturers
Metronidazole	Various manufacturers
Saccharomyces boulardii	Various manufacturers
NICE TA733: Inclisiran for primary hypercholesterolaemia or mixed dyslipidaemia	
Inclisiran (Leqvio)	Novartis Pharmaceuticals UK Ltd
Alternative treatments:	
Various statins	Various manufacturers
Ezetimibe	Various manufacturers

Bempedoic acid (Nilemdo, Nustendi) Alirocumab Evolocumab	Daiichi Sankyo UK Limited 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
Reducing the carbon footprint for inhaler prescribing in Devon: proposal to add further dry powder inhalers to the Devon Formulary Easyhaler budesonide, Formoterol Easyhaler, Fobumix Easyhaler, Fusacomb Easyhaler Trimbow NEXThaler **Alternative treatments:** Pulmicort Turbohaler, Oxis Turbohaler, Symbicort Turbohaler Kelhale Qvar Clenil Modulite, Atimos Modulite, Fostair / Fostair NEXThaler, Trimbow Flixotide Accuhaler / Evohaler, Seretide Accuhaler / Evohaler, Trelegy Ellipta Luforbec Duoresp Spiromax AirFluSal / AirFluSal Forspiro	 Orion Pharma (UK) Limited Chiesi Limited AstraZeneca UK Limited Cipla EU Ltd Teva UK Limited Chiesi Limited GlaxoSmithKline UK Lupin Healthcare (UK) Ltd Teva Pharma B.V. Sandoz Limited
Diagnostic and monitoring devices for diabetes mellitus **Blood Glucose Meters and Test Strips:** GlucoMen Areo Meter, GlucoMen Glucofix Tech Meter, GlucoMen Areo 2K Meter, GlucoMen Areo Sensor Test Strips, GlucoMen Glucofix Tech Sensor Test Strips, GlucoMen Areo Ketone Sensors Test Strips Accu-Chek Performa Nano Meter, Accu-Chek Instant Meter, Accu-Chek Aviva Expert Bolus Advisor Meter, Accu-Chek Performa Test Strips, Accu-Chek Instant Test Strips, Accu-Chek Aviva Test Strips Contour Next Meter, Contour Next Test Strips	 Menarini Roche Ascensia

Freestyle InsuLinx Meter, FreestyleOptium Neo Meter, Freestyle Lite Test Strips, Freestyle Optium β-ketone Test Strips	Abbott
GlucoRx HCT Meter, GlucoRx HCT Ketone Test Strips	GlucoRx Ltd
AgaMatrix WaveSense JAZZ, AgaMatrix WaveSense JAZZ 'wireless', AgaMatrix WaveSense JAZZ DUO Test Strips	AgaMatrix
Alternative Meters and Test Strips: Various Meters and Test Strips	Various manufacturers
Lancets / Lancing Devices: Glucoject Lancets PLUS Accu-Chek FastClix Lancets AgaMatrix Ultra-Thin Lancets GlucoRx Lancets	 Menarini Roche AgaMatrix GlucoRx Ltd
Alternative Lancets / Lancing Devices: Various Lancets / Lancing Devices	Various manufacturers
Urinalysis Test Strips: Diastix Reagent Strips Ketostix Reagent Strips Combur-Test Strips	 Bayer Ascensia Roche
8.3.4.1 Breast cancer (incl. Raloxifene): update and harmonisation Anastrozole, exemestane, letrozole, tamoxifen, raloxifene	 Various manufacturers
Anal Irrigation Systems Aquaflush Compact, Aquaflush Compact+, Aqualfush Lite, Aquaflush Quick, Aquaflush Self Retaining Cone (SRC)	 Renew Medical
Qufora IrriSedo Mini, Qufora IrriSedo Cone Toilet System, Qufora IrriSedo Klick	MacGregor Healthcare Ltd
Navina Classic, Navina Smart	Wellspect Limited
Peristeen, Peristeen Plus TAI System	Coloplast
IryPump S	B Braun Medical
Alternative Systems: Various systems	 Various manufacturers
Levetiracetam continuous subcutaneous infusion for palliative care Desitrend Keppra	 Desitin Pharma Ltd UCB Pharma Ltd

Alternative treatments: Midazolam solution for infusion	Various manufacturers
Osteoporosis Various treatments	Various manufacturers

e-FIG Item	Company
Concerta XL Concerta XL (Methylphenidate modified release tablets)	Janssen-Cilag Ltd
Alternative brands:	
Xenidate XL	Mylan
Delmosart XL	Accord-UK Ltd
Matoride XL	Sandoz Ltd
Xaggitin XL	Martindale Pharma, an Ethypharm Group Company

Name of attendee	Role	Declaration
Jill Ashcroft	MO Pharmacist	• I work occasional weekend locum community pharmacy shifts (with manager permission). • Husband is asthmatic
Tony Avades	Consultant	• I have received lecture fees in the last 12 months from these companies: – Daiichi Sankyo UK Limited – Sanofi – Amgen Ltd
Graham Parsons	Pharmacist	• I have attended 2 international conferences funded through Martindale Pharma.

2. Minutes of the meeting held on 25th August 2021 and Matters Arising

Minutes of the meeting held on 25th August 2021

The minutes of the meeting held on 25th August 2021 were approved.

Summary of actions			
	Action	**Lead**	**Status**
21/23	Thyroid disorders: Update – redraft final guidance in line with the discussion and discuss with specialists.	Formulary Team	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. 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

Matters Arising

- Report of e-FIG decisions:
  - Concerta XL

    The Devon FIG considered proposed updates to section 4.4 CNS stimulants and drugs for ADHD in August 2021.

    It was agreed that in order to support consistent advice across Devon the Concerta XL brand would be reintroduced in N&E Devon.

    FIG members requested that Xenidate XL be the preferred option for new initiations and those who have not tolerated other formulations, with Concerta XL being limited to existing patients who are already established on the brand. It was recognised that a small number of additional patients require a product with a similar release profile but are unable to tolerate Xenidate XL.

    The formulary team agreed to draft a note for the methylphenidate entry to capture this and circulate via e-FIG for any amendments and final agreement.

    Responses received indicated acceptance of the proposed formulary entry.

    The formulary will be updated.

ACTION: Formulary team to update the formulary entry

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

  Since the last Devon FIG meeting (25th August) the Formulary Team has continued to support the development and dissemination of temporary COVID-19 related guidance from various local and national groups.

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

  As a reminder, this page can be accessed via the Devon Formulary homepages by clicking on the interactive image "Coronavirus – What you need to know".

  Since the last meeting formulary updates specific to the COVID-19 are with regard to:
  - Rare blood clotting syndrome associated with COVID-19 vaccination.

3. Fidaxomicin for the treatment of *Clostridioides difficile* infection *(including formulary guidance on the treatment of C. difficile infection)*

At its meeting on 15th September 2021 the Clinical Policy Committee made a recommendation for the routine commissioning of Fidaxomicin for the treatment of *Clostridioides difficile* infection (CDI).

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

Fidaxomicin is a novel antibiotic for the treatment of CDI in adults and children.

Fidaxomicin was considered by the CPC in 2014 but was not routinely commissioned at that time. The existing policy was reconsidered following an application from specialists in response to new NICE guidelines, which recommend using fidaxomicin as a 2nd line treatment in initial episodes of CDI, and a 1st line option in patients with repeat episodes.

The publication of the NICE guideline and the subsequent CPC recommendation for fidaxomicin prompted a review of Devon Formulary guidance on the treatment of *C. difficile*. Draft guidance based on NICE and refined by local specialist input was presented to the FIG.

The FIG considered and accepted the proposed formulary entry for Fidaxomicin for the treatment of *C. difficile* infection.

The FIG considered and accepted the updated Devon Formulary *C. difficile* guidance subject to minor amendments:

- Add note that Vancomycin 125mg capsules are included on the NHS England Enhanced Service for the Availability of Specialist Medicines and should be available from some pharmacies. It was noted that this is not included in Cornwall and may not be included in Plymouth. The Formulary Team will check the position in Plymouth.

ACTION: Formulary Team to ascertain whether Vancomycin 125mg capsules are included on the Enhanced Service for the Availability of Specialist Medicines in Plymouth.

- Formulary status of Vancomycin to change from 'amber' (specialist) to 'green' (first line) for a first episode of *C. difficile*. A note will be added to state that treatment should begin as soon as *C. difficile* infection is suspected, and prompt advice sought. GPs do not need to wait for stool test results or speak to a microbiologist prior to initiation of treatment.
- Formulary status of Metronidazole to change from 'amber' (specialist) to 'blue' (second line) for a first episode of *C. difficile*. Vancomycin is the preferred option as it has superior efficacy, a note to this effect will be included at the beginning of the guidance for the management of first episodes of *C. difficile*. Local specialists have requested that metronidazole is retained as an option for first episodes of mild cases of *C. difficile* unless the patient is considered to be at high risk of relapse
- It was agreed that Fidaxomicin should be an 'amber' specialist treatment in the formulary.

The discussion included:

- Extensive consideration of not delaying treatment when *C. difficile* infection is suspected.
- Alternative oral treatments for those who cannot swallow capsules.
- Who might be at high risk of relapse on ongoing antibiotic treatment and historic episodes of *C. difficile*.

Formulary team to revise the proposed formulary guidance in line with the discussion and circulate to specialists for comment, prior to consideration via e-FIG

ACTION: Formulary Team to revise the proposed formulary guidance in line with the discussion and circulate to specialists for comment.

ACTION: Formulary Team circulate final draft guidance for consideration via e-FIG.

4. 8.3.4.1 Breast cancer (incl. Raloxifene): update and harmonisation

A request was received from the CCG's Medicines Optimisation Control Centre (MOCC) to update and harmonise the breast cancer drug recommendations included in section 8.3.4.1 of the Devon Formulary, and raloxifene (found in section 6.4.1 Female sex hormones and their modulators). This is to ensure the Devon Formulary supports the NHS Accelerated Access Collaborative (AAC) Rapid Uptake Products (RUP) programme.

One of the 2021/22 RUPs is tamoxifen as a preventative treatment for breast cancer. The objectives of the RUP are to:

- Increase prescribing of tamoxifen for prophylaxis
- Reduce the number of women developing breast cancer
- Reduce the number of women ceasing treatment early

Healthcare professionals within secondary care or specialist genetic clinics should discuss the absolute benefits and risks of options for chemoprevention with women at high or moderate risk of breast cancer (NICE, 2013).

The RUP highlights that prescriptions for chemoprevention can be issued in primary care following recommendation (in some instances following initiation) by a specialist. Repeat prescriptions can also be issued by a GP practice.

It is proposed that the addition of further detail to the formulary entries for aromatase inhibitors (anastrozole, exemestane & letrozole) and tamoxifen may support the implementation of the RUP.

The FIG considered and accepted the amendments to 8.3.4.1 breast cancer and the amendments to the raloxifene drug entry subject to the following amendments to the draft entry:

- the inclusion of the first bullet point from recommendation 1.7.23 from NICE guidance CG164
- the Formulary team noted that an indication not related to the preventative treatment of breast cancer had been included during the drafting of the entry and would be removed before publication of the entry on the website

ACTION: Formulary team to update the formulary with the accepted entries for 8.3.4.1 Breast cancer and 6.4.1 Female sex hormones and their modulators in line with the discussion.

5. Diagnostic and monitoring devices for diabetes mellitus

Following the discontinuation of three current formulary choice blood glucose meters and availability of new products on the market with significant technological advantages over current formulary options, the diagnostic and monitoring devices for the diabetes mellitus section has been reviewed.

A comprehensive evaluation was conducted by the local diabetes specialist nurses from the acute trusts in Devon, whereby consideration was given to all blood glucose devices listed in the Drug Tariff at the beginning part of 2021. Over 70 meters were considered in this evaluation. Ketone meters were considered separately.

A Senior Medicines Optimisation Technician, NHS Devon CCG has been liaising with the diabetes nurse specialists, and with support from the formulary team NHS Devon CCG, work has been undertaken to update and harmonise the formulary diagnostic and monitoring device guidance and recommendations, based on the evaluation and recommendations suggested by the diabetes nurse specialists.

The FIG considered the outcomes of the review. The FIG accepted the proposed formulary guidance without amendment.

- There was discussion about the environmental impact and waste where a new lancing device is supplied with each box of lancets. It was agreed that the Medicines Optimisation technician will contact the company representative with regard to this.

ACTION: Medicines Optimisation technician to contact lancet company reps regarding the environmental impact and waste where a new lancet device is supplied with each box of lancets.

- No formal switching programme is planned, however there is potential for savings to be made via passive switching. Following the formulary update process, communications will be sent to all Diabetes Specialist Nurses across the county to ensure changes to this section are highlighted.

ACTION: Formulary team to update the formulary entry for diagnostic and monitoring devices for diabetes mellitus with the approved formulary entry.

It was noted that the diagnostic and monitoring devices for diabetes mellitus formulary section will not be reviewed again in the immediate future. It is expected that the new guidance and recommendations will take time to be implemented due to capacity issues within the local health system and any benefits may not be realised in the short term. However, the recommendations from the specialists are expected to endure any medium term changes within the UK market with regards to these devices and associated products.

6. Anal irrigation systems

With changes in products available on the UK market and considering a Devon system approach, a review of the current formulary products has been undertaken with support from the specialist teams.

Formulary guidance on the use of anal irrigation systems was considered and accepted by the predecessor FIGs in November 2018, prior to this date anal irrigation products were not included in the Devon Formulary.

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

The FIG considered the proposed formulary entry, the following amendments were agreed:

- 18.5 Anal irrigation systems, second paragraph under 'Assessment' to state "Independent or non-NHS nurses may be involved in individual patient assessment, communication with the GP **will** be in conjunction with the NHS specialist team."
- The Qufora IrriSedo MiniGo was not accepted for addition to the Devon Formulary. The FIG did not feel that the higher price was justified by a clear clinical rationale.
- It was recognised that in the future there may be a move away from disposable products in favour of reusable ones due to the environmental impact of disposable anal irrigations systems.

Subject to these amendments the FIG accepted the proposed formulary entry for anal irrigation systems.

ACTION: Formulary team to update the Formulary entry for anal irrigation systems in line with the discussion.

In addition, the proposed Formulary entry contained a statement that 'Patients should be informed that they have a free choice of route of supply e.g., via community pharmacy or dispensing appliance contractor etc.'. It was agreed that the Formulary team will contact Heidi Campbell at Kernow CCG regarding the supply situation in Cornwall.

ACTION: Formulary team to contact Heidi Campbell at Kernow CCG regarding supplies in Cornwall.

The Clinical Evidence Manager reported that an e-mail had been received from the specialist nurses thanking the Formulary team member for all the work put into producing the paper for this item.

7. Luforbec (BDP extra/formoterol) metered dose inhaler for asthma and COPD

An application has been received from a Senior Medicines Optimisation Pharmacist, NHS Devon CCG for the inclusion of the Luforbec inhaler in the Devon formulary for use in the management of asthma and COPD in line with its licensed indications.

The Luforbec inhaler is a pressurised metered dose inhaler (pMDI) containing 100 micrograms of extrafine BDP and 6 micrograms of formoterol. Luforbec pMDI was licensed by the MHRA, Fostair pMDI was the reference product for comparison.

It is proposed that Fostair 100/6 pMDI is removed from the Devon Formulary, and that Luforbec 100/6 pMDI is included as a replacement, but that it is classified as a blue (second line) option to reflect that due to their environmental impact, pMDI (except salbutamol) are generally not considered first line options in the Devon Formulary. No change was proposed for the Fostair NEXThaler.

Prescribing Luforbec 100/6 pMDI rather than Fostair 100/6 pMDI represents a significant cost saving in Devon if all Fostair 100/6 pMDIs were prescribed as Luforbec 100/6 pMDI.

The Fostair pMDI is available in two strengths (100/6 and 200/6). Luforbec pMDI is available in the lower strength only. Only a small proportion of patients in Devon are receiving the Fostair 200/6 pMDI, which is licensed for asthma only. It is proposed that Fostair 200/6 pMDI is moved to an amber formulary option, as high dose corticosteroid inhalers should be initiated after referral to secondary care. There is an existing note in the Fostair pMDI entry to this effect.

At the time of the meeting a limited number of responses had been received from specialists. A specialist has raised concerns regarding switching to Luforbec 100/6 pMDI in the community for patients who have been started on Fostair 100/6 pMDI by secondary care. This has been passed to the Medicines Optimisation team for consideration. The same specialist wanted to ensure that prescribing is continued in primary care for patients

who were started on Fostair 200/6 pMDI by secondary care. The Formulary team suggested a small addition to the proposed wording for Fostair 200/6 pMDI to support this.

The FIG were asked to consider several questions and make a decision in principle. Specialists will be informed of the FIG decisions following the meeting and asked whether there are any objections to the decisions. If there are no objections the formulary will be updated in line with the proposed formulary entry. If specialists raise any objections, the formulary team will manage this through the e-FIG process if appropriate.

The FIG considered the proposed formulary entry subject to the outcome of a further consultation with specialists. There was discussion about:

- The switching programme, including primary care capacity constraints to undertake a bulk switching initiative from Fostair 100/6 pMDI to Luforbec 100/6 pMDI and that some patients may want to switch back to Fostair 100/6 pMDI.
- The potential costs to secondary care
- It was noted that one specialist had disagreed with the removal of Fostair 100/6 pMDI from the Devon Formulary but had not given a reason for this
- The proposed formulary entry was accepted, including that Luforbec 100/6 pMDI was accepted for inclusion in the formulary entry as 'blue' (second line), Fostair 100/6 pMDI to be removed from the formulary and Fostair 200/6 pMDI will be classified as an 'amber' (specialist) medication.
- Recognising that existing patients receiving Fostair 200/6 pMDI on the advice of a specialist should not be re-referred to secondary care, the Formulary team will propose a time limited note (for six months) to this effect

ACTION: Formulary team to update the proposed formulary entry in line with the discussion and carry out a further consultation with specialists.

ACTION: Subject to the responses from specialists the formulary team will undertake an e-FIG process prior to updating the formulary.

8. Reducing the carbon footprint for inhaler prescribing in Devon: proposal to add further dry powder inhalers to the Devon Formulary

NHS England has recently announced a new initiative for primary care to increase the prescribing of dry powder inhalers (DPIs) and soft mist inhalers (SMIs) where clinically appropriate.

To increase the range of DPIs available for patients, a Senior Medicines Optimisation pharmacist, NHS Devon CCG has submitted an application proposing the addition of four Easyhaler DPIs to the Formulary. In addition, the recently launched Trimbow NEXThaler DPI was included for consideration.

The Formulary team consulted with respiratory consultants and respiratory nurses regarding the proposals to add further dry power inhalers to the Devon Formulary. Two specialists responded, the first specialist agreed with all proposals put to the FIG and the second specialist accepted the inclusion of the four Easyhalers and Trimbow NEXThaler

The FIG was asked to take a decision in principle on these proposals.

Section 3.2 Corticosteroids – Budesonide Easyhaler

- The FIG supported the addition of Budesonide 100mcg, 200mcg and 400mcg Easyhaler alongside Pulmicort Turbohaler as a green (first-line) option.
- The FIG accepted that Kelhale pMDI become a blue (second line) option in line with most pMDIs. A note will be added to the Qvar entry indicating that Kelhale is the preferred option for new initiations in adults requiring BDP extrafine in a pMDI.

Section 3.1.1 Adrenoreceptor agonists

- The FIG supported the addition of Formoterol 12mcg Easyhaler as a green (first-line) option alongside Oxis 12mcg Turbohaler
- The FIG accepted the removal of Oxis 6mcg Turbohaler from the formulary

Budesonide/formoterol combination inhalers

- The FIG accepted the addition of Fobumix (budesonide/formoterol) Easyhaler as a green (first-line) option alongside Symbicort Turbohaler
- The FIG accepted the reclassification Duoresp Spiromax from a green first-line option to a blue second-line option

Fluticasone propionate/salmeterol combination inhalers

- The FIG accepted the addition of Fusacomb 250mcg/50mcg (FP/salmeterol) Easyhaler as a blue (second-line) option.
- The FIG accepted the addition of a note to the Seretide Accuhaler entry indicating that for new initiations in patients aged from 12 years, Fusacomb Easyhaler is the preferred option for cost reasons.

Trimbow NEXThaler

- The FIG supported Trimbow NEXThaler DPI being added to the formulary as a green (first line) option and Trimbow pMDI moved to a blue (second-line) option.

The FIG considered the proposals and took a decision in principle to accept them pending further consultation with specialists.

ACTION: Formulary team to undertake further consultation with respiratory specialists.

The Formulary team will inform specialists of the FIG decision and ask whether they have any objections to the decisions. If there are no objections the decisions will be published on the Formulary website. If there are objections the Formulary Team will manage these through the e-FIG process if appropriate.

ACTION: Subject to the responses from specialists the formulary team will undertake an e-FIG process prior to updating the formulary.

9. Levetiracetam continuous subcutaneous infusion in palliative care

Draft guidance for levetiracetam continuous subcutaneous infusion in palliative care was discussed by the FIG at its meeting in August 2021. At the meeting the FIG requested some additional wording. Palliative care consultants have proposed further amendments and reordered the guidance. The additional wording requested by the FIG and the changes proposed by palliative care consultants have been incorporated into the draft guidance.

A specialist in palliative care is working with the nurses on the Standard Operating Procedure for community services.

The FIG considered the draft formulary guidance for levetiracetam continuous subcutaneous infusion in palliative care.

There was discussion about:

- Whether the compatibility of levetiracetam with other drugs and their management in syringe drivers should be included in the formulary guidance.
- It was noted that data on compatibility may change over time and therefore the preference was to link out to other guidance for this information, so the formulary guidance did not become out of date. GPs can also seek advice from the specialist team.
- The order of some points in the guidance requires consideration

The positioning of the guidance for levetiracetam subcutaneous infusion in the palliative care chapter will be considered in line with the new draft chapter proposed by the specialists.

10. NICE Technology Appraisal (TA) 733: Inclisiran for primary hypercholesterolaemia or mixed dyslipidaemia

NICE issued TA733 inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia on October 6th. NICE has reduced the timeline for implementation of this Technology Appraisal from 90 to 30 days. The FIG was asked to consider the proposed formulary entry to enable this timeline to be met.

Inclisiran is given by subcutaneous administration and it is a SPC requirement that it is given by a health-care professional. Following an initial dose, a further dose is given three months later, and thereafter, a dose is given every six months.

The licensing for inclisiran was supported by three clinical trials. The primary outcomes in these trials measured the effect of inclisiran on LDL-C which is an established surrogate for reduction in cardiovascular outcomes. There are no cardiovascular outcome data for inclisiran, these trials are ongoing.

The NICE TA recommendation for inclisiran is for patients with a history of a cardiovascular event(s) and a LDL-C threshold persistently 2.6 mmol/L or more despite maximum tolerated lipid-lowering therapy as defined in the TA. NICE is supporting the initiation of inclisiran in primary care.

The draft formulary entry was sent to the lipid specialists, cardiologists and stroke physicians for comment. Extensive comments were received. The Formulary team is looking into one on the definition of coronary heart disease, which is a NICE TA criterion for treatment with inclisiran.

The Formulary Team proposed removal of the nominal Drug Tariff cost of inclisiran from the proposed formulary entry as a comment received during the consultation revealed the nominal cost to be potentially misleading. NHS England are paying the majority of costs for primary care via a centralised process. If it is administered in secondary care, the trust will pay the higher commercially agreed cost.

The FIG considered and accepted the proposed formulary entry for inclisiran for primary hypercholesterolaemia or mixed dyslipidaemia without amendment. There was discussion about:

- Cardiovascular outcomes – Specialists contacted during the consultation and FIG members expressed concern regarding the lack of cardiovascular outcome data for inclisiran. These data are available for statins, ezetimibe and alirocumab and evolocumab.
- Inclisiran is the first drug in a new class of treatment.
- The lipid specialists will be developing local guidance to incorporate inclisiran into a simplified lipid pathway. In the meantime, GPs may contact the specialists for advice on inclisiran
- It was agreed that the nominal Drug Tariff price for inclisiran would not be included in the formulary entry so that it was not a factor in decision-making.
- It was agreed that inclisiran will be added to the formulary as a 'blue' (second-line) drug in line with the NICE TA and supporting initiation in primary care.
- It was considered important that patients do not move away from statin interventions simply because inclisiran is considered to be more convenient
- GPs should continue to refer patients who meet the NICE TA criteria for alirocumab or evolocumab
- NHS Digital will be producing software for general practice systems to identify patients.

ACTION: Formulary Team to publish the accepted formulary entry.

11. Osteoporosis

Rheumatologist specialists at the Royal Devon and Exeter Hospital are keen to work with the Formulary Team on updated guidance for osteoporosis. They have sent a draft update for the Formulary team to work on. The Formulary team will be seeking clarification of some proposals from the specialists. The FIG was asked whether there were specific areas where further information would be useful.

The FIG considered the draft guidance, further clarification of the following points was requested:

- Bisphosphonate holidays, how long they should be, when they should be and how to restart treatment.
- Recommendations for DEXA scans need to take into account the waiting time to access the service

- Issues with patients who are receiving bisphosphonates being denied dental treatment due to risk of osteonecrosis of the jaw. It was noted that this may fall outside the scope of formulary guidance

The Formulary team will liaise with the specialists and bring the final draft guidance to a future FIG meeting for agreement.

ACTION: Formulary team to liaise with specialists and bring the final draft guidance to a future FIG meeting.

12. MHRA Drug Safety Updates (Aug to Sept 2021)

Update on previous Drug Safety Update – February 2021

Ulipristal acetate (Esmya)

The Clinical Policy Committee has recommended an update to the CCG's commissioning policy. A link to the policy will be included in the formulary entry for ulipristal acetate (Esmya) when the policy is published. The policy indication is in line with the SPC.

August 2021

Tofacitinib

There was a 'Dear Healthcare Professional' letter for tofacitinib which is a red (hospital) drug. The October safety update includes an article on this subject. The formulary entry for tofacitinib will be updated accordingly.

Desogestrel

The reclassification of desogestrel 75mcg contraceptive pill from prescription-only (POM) to pharmacy (P) products is noted in the safety update. The MHRA's decision to reclassify these desogestrel products follows a safety review by the Commission on Human Medicines (CHM) and public consultation. Currently, desogestrel is a green (first-line) option in North and East Devon and an amber (specialist) option in the South and West Devon – the formulary pages have been amended to indicate they are under review.

13. Recent drug decisions (including NICE)

The recent drug decisions were noted.

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. 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.	Formulary Team	Outstanding
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	Outstanding

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.	Formulary Team	On agenda
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.	Formulary Team	On agenda

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	Formulary Team	On agenda
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	Outstanding