East Region Formulary

East Region Formulary Committee
Minutes

Date: 7 June 2023
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	(Acting) Associate Director of Pharmacy (Specialist Services, Development and Innovation), NHS Lothian
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Steven Fenton	Project Manager, ERF Project Team
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Peter Hall	Consultant - Oncology, NHS Lothian
Carol Holmes	Pharmacist - Primary care, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Diane Murray	Formulary Pharmacist, NHS Lothian
Fraser Notman	Formulary Pharmacist, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian – in the Chair
Alison Wilson	Director of Pharmacy, NHS Borders
Sandra MacDonald	Meeting Administration, NHS Fife

Guests/Observing: None

Apologies: Gillian Donaldson, Nurse - Cardiology, NHS Borders
Dr Paul Neary, Consultant - Cardiology, NHS Borders

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1 Project update

1.1 Welcome and Apologies

The Chair welcomed those present to the East Region Formulary Committee (ERFC).

- ERFC noted that the meeting is being recorded.
- Observing - none
- Welcome - as above
- Leaving - none
- Declaration of Interest (DOI) – there were no additional declarations of interest declared for this meeting. ERFC members were reminded to return their DOI forms if appropriate. DOI forms will be requested yearly with completed DOIs

retained by the project team and shared with the individual's board. ERFC members were advised that annual DOI forms had recently been circulated for completion and return.

ACTION: ALL

1.2 Update on progress with Chapter Expert Working Groups (CEWG)

The ERFC received an update on progress with the Chapter Expert Working Groups and the transition to the business-as-usual phase.

Three Paediatric ERF chapters are progressing – Cardiovascular (chapter to be discussed under agenda item 2.3), Gastroenterology and Respiratory. The Paediatric Gastroenterology and Respiratory Chapters are nearing completion, with the aim of submission to the August ERFC meeting. The next Paediatric ERF chapter scheduled for review thereafter is CNS. Three CEWGs are being established and meeting dates are being sought to take forward the review of the Paediatric CNS chapter.

The Lothian Joint Formulary website has now been rebranded as the ERF website and the website and mobile app are available for all three Boards to use.

The ERFC thanked the members of the project team for the work involved in implementation of the ERF and rebranding of the website.

1.3 Matters arising

1.3.1 ERFC 29.03.23 Item 3.1.2 FAF1 Imlifidase: Idefirix (**SMC2445**) was reviewed at the ERFC March meeting. The ERFC requested that comments raised around potential central retention of stock be fed into national discussions.

The ERFC noted the additional information received regarding plans for retention of stock. The proposal is that sufficient vials for one dose for one patient will be kept in the Pharmacy fridge which has a robust, automated monitoring process. Action completed.

1.3.2 ERFC 28.09.22 Item 3.1.3 FAF1 Atezolizumab: Tecentriq (SMC2267) was reviewed at the ERFC September meeting. Clarification on the SMC decision is still awaited.

The ERFC requested clarification on SMC approval.

ACTION: NHS Fife Formulary Pharmacist

1.3.3 ERFC 01.02.23 Item 3.1.8 FAF2 Rituximab: Ruxience was reviewed at the ERFC February meeting and a decision on Formulary classification was deferred pending clarification on potential changes to SMC out of remit guidance. The ERFC noted that SMC guidance is still awaited and agreed to defer this item to the August ERFC.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

1.3.4 ERFC 29.3.23 Item 3.1.3 FAF1 Faricimab: Vabysmo **(SMC2499).** Updated FAF1 received - discussed under agenda item 3.1.8.

1.3.5 ERFC 29.3.23 Item 3.1.3 FAF1 Faricimab: Vabysmo **(SMC2512).** Updated FAF1 received - discussed under agenda item 3.1.9.

1.3.6 ERFC 29.3.23 Item 3.1.6 FAF2 Ceftazidime-avibactam: Zavicefta (SMC1307/18) was withdrawn from the ERFC March meeting. Post meeting the ERFC contacted the SMC for clarification on plans for further advice to be issued. The ERFC noted the response from the SMC and agreed that pending the availability of further national advice, the ERF decision would be updated in line with the statement on the SMC website (that this product can be accessed for individual patients where required through local Health Board processes based on appropriate specialist advice). The ERFC noted that it was up to individual Boards to agree their own local processes. Action completed for ERFC.

1.3.7 ERFC 29.3.23 Item 3.1.7 FAF2 DEKAs plus was reviewed at the ERFC March meeting. The ERFC requested separate applicant/supporting pharmacist details and confirmation of NHS Borders CD support.

The ERFC discussed the updated FAF1 which included separate applicant/supporting pharmacist details, confirmation of NHS Borders CD support and a revision to the financial template.

The ERFC agreed to classify DEKAs plus as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

1.3.8 ERFC 29.3.23 Item 3.2.2 Dapagliflozin – SGLT2 inhibitors for type 2 diabetes mellitus formulary amendment was reviewed at the ERFC March meeting. The ERFC requested confirmation of NHS Fife support for the proposed Formulary amendment and confirmation that ERF pathway revisions were in line with SMC/HTA approvals.

The ERFC discussed the additional information received and agreed that the outstanding actions were complete. The updated pathways ERF diabetes mellitus type 2 were discussed under agenda item 2.3.1.

The ERFC agreed to classify Dapagliflozin for type 2 diabetes as Routinely available in line with local or regional guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 29 March 2023

The minutes of the previous meeting were approved as an accurate record with no changes noted.

2.2 East Region Working Group (ERWG) meeting minutes 17 May 2023

The minutes of the ERWG meeting on 17 May 2023 were noted for information. The ERFC noted assurance that progress is being made with gender re-assignment work.

2.3 East Region Formulary (ERF) sections/amendments for approval

- **Cardiovascular Chapter (Paediatric)**

The ERFC discussed the key updates to the ERF chapter Cardiovascular (Paediatric).

The chapter details the pathways included in the adult chapter that are not currently in the Paediatric chapter as well as the additional pathways included in the Paediatric chapter.

Specific neonatal medicine formulations have not been included and there will be further discussions around this in due course. The unlicensed indication formulary flag is only used where the medicine is unlicensed for use in all ages of children.

The review was undertaken by a small group with Consultant and Specialist Paediatric Pharmacist representation. There was no GP representation on the group but it was agreed that this was acceptable as the majority of the medicines in the chapter are specialist use only/specialist initiation.

The ERFC discussed the chapter content and the rationale for any variations between the Adult and Paediatric chapter content/pathways.

The ERFC noted that there are a number of medicines within the chapter that are contraindicated in pregnancy and would not be suitable for sexually active young people. The ERFC requested that the ERWG discuss this as a general rule in formulary content, with work to follow at a later stage.

ACTION: ERWG

The ERFC approved the new chapter content. The formulary website will be updated.

ACTION: ERF Admin Team

- **Nutrition and Blood Chapter – Coeliac (Adult and Paediatric)**

The ERFC discussed the key updates to the ERF chapter Nutrition and Blood – Coeliac (Adult and Paediatric).

The ERFC noted that the regional gluten free food list was produced by Dietitians across the three Boards. The products on the regional list are in line with the recently updated national list. A revision of the gluten free foods order form is being progressed and will be uploaded to the Community Pharmacy Scotland website in due course.

The ERFC agreed that going forward minor basic changes to the national list would be taken forward by the ERWG. Significant changes to the national list to be taken to the CEWG for discussion.

The ERFC approved the new chapter content. The formulary website will be updated.

ACTION: ERF Admin Team

2.3.1 ERF diabetes mellitus type 2

The ERFC discussed the key updates to the adult ERF section diabetes mellitus type 2. The pathways have been amended to include dapagliflozin and rationalise SGLT2 inhibitors within the Formulary. Canagliflozin is removed from the formulary.

The ERFC noted that the proposed amendments have been discussed and agreed by the established diabetes working group members with additional input from Cardiology and Renal representatives across the Region.

The ERFC noted feedback around potential further refinement and requested that comments with tracked changes be fed back to the CEWG. The ERFC also noted some inconsistencies

with local Primary Care prescribing guidance at present. It was suggested that a demonstration of the proposed content on the ERF website would be useful.

The ERFC requested that comments on further refinement be fed back to the diabetes CEWG.

ACTION: Dr Jane Goddard/NHS Lothian Formulary Pharmacist/CEWG

The ERFC agreed that following consideration by the CEWG the revised chapter content did not require to be brought back to the ERFC.

The ERFC approved the new chapter content with requested revisions to be agreed by the CEWG. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

2.3.2 ERF adult Malignant Disease Prostate Pathway and Androgen Hot Flushes Prostate and Breast

The ERFC discussed the revisions to the ERF Malignant Disease (Adult) prostate pathways.

The ERFC noted that the prostate pathways have been updated and simplified where required.

The ERF approved the pathway amendments. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2.3.3 ERF warts

The ERFC discussed the updated ERF pathway for the treatment of warts.

The ERFC noted the updates including the removal of several products due to discontinuation and the rationale for the addition of salicylic acid 26% gel.

The EFC approved the pathway amendments. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2.3.4 ERF adult Injectable treatment of schizophrenia

Discussed under agenda item 3.1.10.

The EFC approved the pathway amendments subject to clarification on the formulary flags and with updates to paliperidone products as agreed by ERFC. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

2.4 Pharmacy First

The ERFC noted the proposed amendments to Pharmacy First. The ERWG is reviewing the list to compare with the ERF to ensure that there is equitable access to the medicines available via Pharmacy First. Any anomalies/concerns will be fed back to the Scottish Government. The ERWG response will be shared with the three regional Boards. Individual Boards were also encouraged to respond through their ADTCs.

The ERC noted the process for review and feeding back comments on the proposed amendments to Pharmacy First.

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 daratumumab: Darzalex (SMC2447)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support was received from all three Boards.

Indication: In combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic light chain (AL) amyloidosis.

The local treatment protocol and finance budget template were included with the FAF. A typographical error within the finance budget template was noted. It was also unclear whether the updated PAS for daratumumab was reflected in the financial section.

The ERFC requested that the financial budget template be reviewed and updated as required.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify daratumumab: Darzalex as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.2 FAF1 liraglutide: Saxenda (SMC2455)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from all three Boards.

Indication: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:

- ≥30kg/m² (obese), or
- ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

SMC restriction: BMI ≥35kg/m^2 (obesity class II and above) with:

- Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either:
  - Fasting plasma glucose level of 5.5 to 6.9mmol/L or
  - HbA_{1c} of 6.0 to 6.4% (42 to 47mmol/mol), and
- High risk of cardiovascular disease (CVD):
  - Total cholesterol >5mmol/L, or
  - High-density lipoprotein (HDL) <1.0mmol/L for men and <1.3mmol/L for women, or
  - Systolic blood pressure (SBP) >140mmHg.

Patients should be treated in a specialist weight management service.

The ERFC noted that a local treatment protocol has not been developed. The finance budget template was included with the FAF.

The ERFC noted that the patient selection criteria is in line with the SMC restriction. The proposed place in therapy is second choice after diet and lifestyle support. Liraglutide to be prescribed by brand name (Saxenda). Treatment to be discontinued after 12 weeks of maintenance dose if patients have not lost at least 5% of their initial body weight.

The ERFC noted the slight variations in the weight management service across the three Boards and proposals for ongoing prescribing following initiation of treatment by the weight management service.

The ERFC noted the potential for demand in Primary Care and workload implications for GPs and the weight management service. It was suggested that a patient information leaflet be developed.

The ERFC agreed to classify liraglutide: Saxenda as Routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated**.**

ACTION: NHS Lothian Admin Team/ERF admin

3.1.3 FAF1 pembrolizumab: Keytruda (SMC2474)

The ERFC noted and discussed the previously circulated updated FAF1 submission. No declarations of interest were received. CD support was received from all three Boards.

Indication: In combination with lenvatinib, for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation. **SMC restriction**: treatment with pembrolizumab is subject to a two-year clinical stopping rule..

The local treatment protocol and finance budget template were included with the FAF.

The ERFC discussed the supporting evidence. The proposed place in therapy is second line treatment for patients who have disease progression after platinum-containing therapy.

The ERFC agreed to classify pembrolizumab: Keytruda as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated

ACTION: NHS Lothian Admin Team

3.1.4 FAF1 pembrolizumab: Keytruda (SMC2501)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific interest was declared. CD support was received from all three Boards.

Indication: in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1. **SMC restriction**: treatment with pembrolizumab is subject to a two-year clinical stopping rule

The local treatment protocol and finance budget template were included with the FAF.

The proposed place in therapy is first choice for the treatment of persistent, recurrent or metastatic cervical cancer.

The ERFC noted a typographical error/discrepancy in the patient numbers and finance template.

The ERFC requested that the financial budget template be reviewed and updated as required.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify pembrolizumab: Keytruda as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.5 FAF1 empagliflozin: Jardiance (SMC2523)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from NHS Borders and NHS Lothian. Confirmation of NHS Fife CD support is awaited.

Indication: in adults for the treatment of symptomatic chronic heart failure with preserved ejection fraction (left ventricular ejection fraction [LVEF] >40%).

The ERFC noted that a local treatment protocol has not been developed. The finance budget template was included with the FAF.

The proposed place in therapy is first choice within a treatment pathway for the management of heart failure (pathway 3). The criteria for patient selection is in line with SMC advice.

The ERFC requested confirmation of NHS Fife CD support.

ACTION: NHS Fife Formulary Pharmacist

The ERFC agreed to classify empagliflozin: Jardiance as Routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Borders Formulary Pharmacist

3.1.6 FAF1 upadacitinib: Rinvoq (SMC2575)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support was received from all three Boards.

Indication: treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

The local treatment protocol and finance budget template were included with the FAF.

The proposed place in therapy is second line alongside ustekinumab and vedolizumab. 1st line treatment remains anti-TNF alpha inhibitors, infliximab and adalimumab. Upadacitinib is cost effective compared to other second line treatment options within the pathway.

It was noted that vedolizumab and ustekinumab are not currently in the ERF pathway however both products were on the previous Lothian Joint Formulary additional list and in the NHS Fife Biologics Guidance. Positioning of ustekinumab and vedolizumab in all three Boards to be clarified with the CEWG. The ERFC agreed that going forward applications for amendments should be based on the current ERF content.

The ERFC requested clarification of the positioning of ustekinumab and vedolizumab in all three Boards.

ACTION: NHS Lothian Formulary Pharmacist/NHS Lothian Admin Team

The ERFC agreed to classify upadacitinib: Rinvoq as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.7 FAF1 ozanimod: Zeposia (SMC2478)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support was received from all three Boards.

Indication: for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.

The local treatment protocol and finance budget template were included with the FAF.

The proposed place in therapy is 2nd line in the ulcerative colitis pathway alongside vedolizumab, ustekinumab, tofacitinib and upadacitinib. 1st line therapy remains infliximab (IV or SC) or filgotinib or vedolizumab (in the elderly).

The ERFC requested that comparative treatment costs of second line options be reviewed to confirm that they sit equally within the pathway.

ACTION: NHS Lothian Admin

The ERFC agreed to classify ozanimod: Zeposia as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.8 FAF1 faricimab: Vabysmo (SMC2499)

The ERFC noted and discussed the previously circulated updated FAF1 submission. One personal specific and two personal non-specific interests were declared. CD support was received from all three Boards.

Indication: For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO). **SMC restriction**: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.

The local treatment protocol, implementation plan and finance budget template were included with the FAF.

The FAF1 had been reviewed at the ERFC March meeting and the ERFC requested clarification on patient numbers/costs and information from all three Boards on the proposed order/positioning of faricimab compared to other therapies in the pathway. The ERFC also requested details of CD support.

The ERFC noted the updated information provided in the revised FAF1 which confirmed CD support from all three Boards and provided clarification on the points raised at the March ERFC meeting. The proposed place in therapy for DMO is first line along with aflibercept and ranabizumab.

The ERFC agreed to classify faricimab: Vabysmo as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.9 FAF1 faricimab: Vabysmo (SMC2512)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific interest and two personal specific interests were declared. CD support was received from all three Boards.

Indication: for the treatment of adult patients with neovascular (wet) age related macular degeneration (nAMD).

The local treatment protocol and finance budget template were included with the FAF.

The FAF1 had been reviewed at the ERFC March meeting and the ERFC requested details of service/staffing implications and clarification of the cost of faricimab/replaced therapy. The ERFC also requested details of CD support and confirmation of separate applicant/supporting pharmacist details.

The ERFC noted the updated information provided in the revised FAF1 which confirmed details of CD support and provided clarification on the points raised at the March ERFC meeting. The proposed place in therapy is second choice alongside aflibercept for this indication. Ranibizumab is the current first choice in the treatment pathway. The ERFC noted feedback regarding declared personal specific interests.

The ERFC agreed to classify faricimab: Vabysmo as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.10 FAF2 paliperidone: Byannli and formulary amendment form paliperidone: Trevicta.

The ERFC noted and discussed the previously circulated FAF2 submission for paliperidone: Byannli. No declarations of interest were received. There were no details of Clinical Director support.

Indication: For the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly (PPM1M) or 3-monthly (PP3M) paliperidone palmitate injectable products.

A local treatment protocol has not been developed. The finance budget template was completed with NHS Lothian information only.

Application is for prolonged-release suspension for injection in pre-filled syringe to be administered every six months. It was noted that monthly injections are used predominantly in practice but that a 6 monthly option may be useful in selected patient groups. It was noted that the application refers to both Specialist Use Only and Specialist Initiation formulary flags due to differences in practice between the three Boards. It was noted that most use would be by Specialist use only however there could potentially be local agreements/pathways for prescribing in Primary Care under Specialist supervision.

The ERFC noted and discussed the previously circulated Formulary amendment form for paliperidone: Trevicta. No declarations of interest were received.

Indication: Paliperidone palmitate (Trevicta), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product.

Application is for prolonged-release suspension for injection in pre-filled syringe to be administered every three months by specialist initiation.

It was proposed and agreed that the generic formulation is included for the monthly formulation in the pathway and the brand names are included for the three monthly and six monthly formulations where there is no current generic available.

The ERFC requested confirmation of NHS Borders' established practice on either specialist use only or occasional prescribing in primary care under specialist supervision to inform the decision on formulary flag.

ACTION: NHS Borders Formulary Pharmacist

The ERFC agreed to classify Paliperidone Byannli as Routinely available in line with local or regional guidance. Included on the ERF (with formulary flag to be confirmed) . The formulary website will be updated when the formulary flag is confirmed.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Paliperidone Trevicta as Routinely available in line with national guidance. Included on the ERF (with formulary flag to be confirmed). The formulary website will be updated when the formulary flag is confirmed.

ACTION: NHS Lothian Admin Team/ NHS Lothian Formulary Pharmacist

3.1.11 FAF2 Prucalopride

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. CD support was received from NHS Lothian and NHS Fife; CD support from NHS Borders received post meeting.

Indication: Symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

The finance budget template was included with the FAF. The ERFC noted that a local treatment protocol has not been developed. The criteria for patient selection is patients with resistant constipation symptoms in whom at least two laxatives from different classes (e.g. bulk forming agents such as fybogel, and osmotic laxatives), at the highest tolerated recommended doses

for at least 6 months, has failed to provide adequate relief and invasive treatment for constipation is being considered.

The ERFC noted that prucalopride: Resolor was reviewed by the SMC in 2011 and was not approved at that time as the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.

The ERFC noted that the application is for generic prucalopride 2mg tablet formulation. In the event that the generic product is not cost effective compared to the original product assessed by the SMC in 2011 the SMC advice would still stand.

The ERFC requested clarification on the price of the original product assessed by SMC in 2011 compared to the generic product.

ACTION: NHS Fife Formulary Pharmacist

The ERFC discussed the supporting evidence. The proposed place in therapy is second line when other medicines have failed or were not tolerated. It was noted that prucalopride would likely be third choice within the treatment pathway (first choice is bulk forming laxatives and second choice is osmotics). It was noted that non-Formulary use of Linaclotide has been used for comparator medicine purposes.

The ERFC agreed to classify Prucalopride as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.12 FAF3 Faecal Microbiota Transplant

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. CD support received from NHS Borders and NHS Lothian; CD support from NHS Fife was also confirmed at the meeting.

Indication: Recurrent Clostridioides difficile associated diarrhoea.

The local treatment protocol and finance budget template were included with the FAF. Criteria for patient selection is patients who have had multiple recurrences of CDI and failed to respond to standard treatment. Patients would be reviewed and assessed by an ID or GI consultant. The proposed delivery route is via Tertiary Service outwith the East Region.

The ERFC noted the supporting evidence.

The ERFC agreed to classify Faecal Microbiota Transplant as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use only. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Borders Formulary Pharmacist

3.1.13 FAF3 Melatonin Liquid

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. CD support received from NHS Lothian.

Indication: To induce sleep to facilitate MRI examination in young children.

The local treatment protocol and finance budget template were included with the FAF. The ERFC noted that the application is exclusively for use within the Imaging department at RHCYP, Edinburgh.

The application is for off-label use of a licensed medication. A guideline has been produced and is awaiting approval by the Paediatric Drug and Therapeutics Committee.

The ERFC noted that the clinical evidence presented for this indication was for use of melatonin tablets. The tablet formulation is more cost effective compared to the liquid formulation. There are no liquid melatonin formulations currently on the ERF. The ERFC noted that use of the tablet formulation (crushed) for this indication would be appropriate.

The ERFC agreed to classify melatonin tablets as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use only. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/ERF admin

3.2 Formulary Amendment Forms

3.2.1 Beclometasone + formeterol: Luforbec inhaler

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support received from all three Boards.

Indication: Initial add on therapy for asthma, management of COPD.

Application to replace Fostair 100/6 and 200/6 with Luforbec 100/6 and 200/6 (beclometasone and formoterol). The proposed position is first choice within a treatment pathway.

The ERFC noted that Luforbec is significantly more cost effective compared to Fostair. The environmental implications of Luforbec compared to Fostair were also discussed. The EFRC noted that there are proposals to switch to more environmental propellants in the future but the timeframe for this is unclear.

The ERFC agreed to classify beclometasone + formeterol: Luforbec inhaler as Routinely available in line with local or regional guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

3.2.2 Timolol 1mg/g eye gel drops 0.4g preservative free unit dose

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support confirmed from all three Boards.

Indication: Ocular hypertension, chronic open angle glaucoma.

Application to include generic preservative-free once daily preparation of timolol 1mg/g eye gel drops in the ERF. The proposed position within the ERF is second choice within a treatment

pathway (timolol 0.25% eye drops first line, then timolol 0.25% once daily eye gel and timolol 1mg/g preservative free eye gel drops second line).

The ERFC agreed to classify timolol 1mg/g eye gel drops 0.4g preservative free unit dose as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/ NHS Borders Formulary Pharmacist

3.2.3 Sucralfate 1g tablets

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received.

Indication: NSAID associated ulcers and dyspepsia.

Application to replace a licensed product which is now no longer available.

The ERFC agreed to classify sucralfate 1g tablets as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/ NHS Lothian Formulary Pharmacist

3.2.4 Ranibizumab 2.3mg/0.23ml solution for injection vials

The ERFC noted and discussed the previously circulated formulary amendment form. One personal non-specific interest was declared. Support received from all three Boards.

Indication: The treatment of neovascular (wet) age-related macular degeneration (AMD); the treatment of visual impairment due to diabetic macular oedema (DME); the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO); the treatment of visual impairment due to choroidal neovascularisation (CNV).

The ERFC noted that the proposal is to replace the Lucentis brand vials with generic vials to allow the most cost effective product to be used. Proposed pathway updates to be agreed by the Eye CEWG and submitted to the ERWG for approval.

The ERFC agreed to classify Ranibizumab 2.3mg/0.23ml solution for injection vials as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/ NHS Lothian Formulary Pharmacist

3.3 Ultra-Orphan Pathway

3.3.1 Metreleptin: Myalepta (SMC2559)

The ERFC noted the SMC Ultra-orphan advice for information.
The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Tafasitamab: Minjuvi (SMC2522)
3.4.2 Icosapent ethyl: Vazkepa (SMC2531)
3.4.3 Darolutamide: Nubeqa (SMC2544)
3.4.4 Rimegepant: Vydura (SMC2567)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Patiromer sorbitex calcium: Veltassa (SMC2568)

The ERFC noted the SMC abbreviated submission Patiromer sorbitex calcium: Veltassa (SMC2568).

Indication: Continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.

The ERFC noted that ERF inclusion was not requested at this stage.

The ERFC agreed to classify Patiromer sorbitex calcium: Veltassa as Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.6 Paediatric licence extensions

3.6.1 There were no paediatric licence extensions for consideration. The ERFC noted the current process for sharing of information on paediatric licence extensions and that going forward information would also be shared with the NHS Border and NHS Fife Formulary Pharmacists.

3.7 Non-submissions within 90 days of SMC publishing

The ERFC noted the non-submissions within 90 days of SMC publishing.

3.7.1 Nivolumab: Opdivo (OSCC) (SMC2519)
3.7.2 Rimegepant: Vydura (acute) (SMC2521)
3.7.3 Polatuzumab vedotin: Polivy (SMC2525)
3.7.4 Pembrolizumab: Keytruda (SMC2526)
3.7.5 Treosulfan powder for solution for infusion: Trecondi (SMC2527)
3.7.6 Pembrolizumab: Keytruda (TNBC) (SMC2538)
3.7.7 Trastuzumab deruxtecan: Enhertu (SMC2545)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, 3.7.6 and 3.7.7 as Not routinely available as local clinical experts do not wish to add the medicine to the formulary

at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.8 Central Alerting System COVID-19 Alerts

The ERFC noted the publication of NICE Technology Appraisal (TA) - Treatment Recommendations for COVID-19 (NICE TA 878; CAS-ViewAlert (mhra.gov.uk)). NICE TA878 has also been shared with local specialist teams.

The ERFC agreed to reflect the new NICE guidance, by including a link to NICE TA878 for formulary decision entries for Nirmatrelvir and Ritonavir:Paxlovid, Sotrovimab:Xevudy and Tocilizumab: RoActerma for COVID-19.

The ERFC agreed to classify Casirivimab and Imdevimab: Ronappreve for COVID-19 as not recommended. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.9 National Cancer Medicines Advisory Group

The ERFC noted the NCMAG Quarterly update.

No National Cancer Medicines Advisory Group advice documents were available for noting at the time of the ERFC meeting.

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

Ongoing queries regarding testosterone use in women were highlighted. The NHS Fife Formulary Pharmacist to follow up progress with production of a FAF3 and guidance.

ACTION: NHS Fife Formulary Pharmacist

4.3 NHS Lothian

It was noted that the formulary amendment application for pentasa is being refined and will be submitted for review at the August meeting.

The ERFC also noted discussions at the ERWG relating to Riluzole for use in Motor Neurone Disease(MND). A Draft pathway for MND is being produced for submission to the ERWG/ERFC. Two other specialist neurology medicines that were previously on the LJF will be presented to the CEWG seeking regional support and the ERWG before being present to ERFC for formulary classification.

5 Any other competent business

None raised.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 9 August 2023 at 1400 - 1630 hours via MS Team. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 4 July 2023 (for discussion at the ERWG meeting on 19 July 2023).

FAF1s and FAF2s should be submitted by 25 July 2023.

All FAFs need to include information on proposed use and confirmation of clinical director (or equivalent medical manager) support from all three boards [including names], to be added to the agenda. In the case where the service is only provided by one of the boards, this should be clearly stated in the application. Confirmation of clinical director (or equivalent medical manager) support from all three boards is required where cross board charging applies.

Apologies for the meeting to be sent to prescribing@nhslothian.scot.nhs.uk