East Region Formulary

East Region Formulary Committee
Minutes

Date: 04 December 2024
Time: 2.00pm – 4:30pm
Location: MS Teams

Present:

Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Malcolm Clubb	Director of Pharmacy (Co-chair), NHS Borders – in the Chair
Dr Joan Egerton	GP, NHS Fife
Dr Tariq Farrah	Consultant - Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist, NHS Fife
Carol Holmes	Pharmacist - Primary Care, NHS Lothian
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist - Medicines Governance and Guidance, NHS Lothian
Alice Mathew	Senior Clinical Pharmacist - Medicines Utilisation and Therapeutics, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Jo Rose	GP, NHS Lothian

In attendance:
Dr Konstantinos Dabos – Consultant, GI, NHS Lothian – left at 16:05
Dr Grace Ding - Consultant Oncologist, NHS Lothian – left at 16:10
Mariam Mustapha – Formulary Pharmacist, NHS Forth Valley – left at 16:15
Dr Monica Szabo - Consultant Oncologist, NHS Lothian – left at 15:50
Sarah Tait, Lead Advanced Practitioner, NHS Borders
Caitlin Satti, Information Officer, NHS Lothian (minutes)

Apologies:
Jane Browning, Associate Director of Pharmacy, NHS Lothian
Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife
Ryan Headspeath, Lead Pharmacist, Dermatology and Shared Care, NHS Fife
Dr Paul Neary, Consultant – Cardiology, NHS Borders
Fraser Notman, Senior Pharmacist – Medicines Management, NHS Fife
Cathryn Park, Deputy Director of Pharmacy, NHS Borders
Dr Andrew Watson, Consultant – Psychiatry (Co-chair), NHS Lothian

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1 Welcome and Apologies

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

- ERFC noted that the meeting is being recorded
- Joining – The Chair welcomed new members Dr Tariq Farrah, Consultant - Renal, NHS Lothian; Ryan Headspeath, Lead Pharmacist - Dermatology and Shared Care, NHS Fife; and Dr Joan Egerton - GP, NHS Fife – Ryan Headspeath sent apologies for this meeting.

1.2 Matters arising

1.2.1 ERFC August 2024 Item 3.1.1 FAF1 Etrasimod: Velsipity (SMC2655) was reviewed at the ERFC August

meeting. The ERFC requested a revised submission with a review of the finance section to account for the new Ozanimod PAS price, as well as evidence comparing Ozanimod and Etrasimod.

It was noted that the clinical team previously wished to move Ozanimod to third-line within the UC pathway alongside Tofacitinib and Ustekinumab, however, the team now wish to remove Ozanimod from the ERF as IBD teams have reviewed recent network meta-analysis which is suggestive that Etrasimod is more efficacious than Ozanimod. It is proposed Etrasimod should sit second-line, as per SMC indication, for moderate-severe UC. Choice of second-line option will be influenced by patient and past medical history including co-morbidities and severity of colitis.

The revised submission noted updated costings and further information as to how the costs were calculated. An updated, streamlined UC biologics algorithm was also provided with the resubmission, with mentions of Tofacitinib, Golimumab and Ozanimod removed.

The ERFC agreed to classify Etrasimod: Velsipity (SMC2655) as Routinely available in line with national guidance. Included in the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 02 October 2024

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

2.2 East Region Working Group (ERWG) meeting minutes 13 November 2024

The minutes of the ERWG meeting on 13 November 2024 were noted for information.

An update was provided regarding the Infected Blood Inquiry CMO letter and the recommendations for Health Boards relating to clinical blood transfusion practice and patient blood management.

The ERFC noted that a formulary application has been drafted and sent to each Board's respective ADTC committee to obtain a Chair's opinion/decision, with a response sought by the Scottish Government by 31st January 2025. The application will then be further reviewed at the next ERFC meeting in February 2025.

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

2.3.1 ERF Pharmacy First, Adult & Child - Gastrointestinal - Acute diarrhoea

The ERFC discussed the updated ERF pathways – Pharmacy First, Adult, and Child 'Acute diarrhoea'.

The ERFC approved the pathway content. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2.3.2 ERF Adult – CNS – Migraine prophylaxis

The ERFC discussed the updated ERF adult pathway – 'Maintenance treatment of bipolar disorder'.

The ERFC approved the pathway content. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2.3.3 ERF Pharmacy First Various Updates

The ERFC discussed the Various Pharmacy First Updates

The ERFC approved the pathway content. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Azacitidine: Onureg (SMC2533) – *pre-ERFC panel review*

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

Indication: Maintenance therapy in adult patients with acute myeloid leukaemia who achieved complete remission or complete remission with incomplete blood count recovery following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation.

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

The ERFC discussed the submission and supporting evidence.

It was noted that the inclusion of Oral azacitidine will incur minimal service impact as Oral azacitidine can be delivered via established out-patient clinics. Patients will also benefit from a longer remission period, therefore, in principle, reducing the burden on day wards and in-patient settings for transfusions, antibiotics etc.

It was further noted that Oral azacitidine has a manageable safety profile with some haematological side-effects and GI toxicities. Additional information provided in the guideline advises of the use of antiemetics before doses for two treatment cycles, however, these additional associated costings have not been included in the financial information provided in the application.

The ERFC agreed that Azacitidine: Onureg (SMC2533) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Azacitidine: Onureg (SMC2533) 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 Olaparib: Lynparza (SMC2617)

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

Indication: In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

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

The ERFC discussed the submission, with supporting evidence provided by the PROpel phase III trial.

In regard to costings, it was noted that the trial reported a median progression-free survival of 24.8 months, and, therefore, year two patient numbers and cost will be doubled and then stabilise at this level in consequent years.

The associated protocol provides extensive additional information regarding adverse effects and contraindications, as well as a comprehensive pre-treatment evaluation, and checklist for monitoring of response. It was noted that minimal service implications are expected as treatment will be delivered in established consultant and pharmacist NMP clinics for metastatic prostate cancer patients and to an existing patient cohort.

The ERFC agreed that Olaparib: Lynparza (SMC2617) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Olaparib: Lynparza (SMC2617) 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

3.1.3 FAF1 Talazoparib: Talzenna (SMC2607)

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

Indication: As monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy.

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

The ERFC discussed the submission and supporting evidence.

The committee noted the manageable safety profile of Talazoparib: Talzenna with common side effects such as thrombocytopenia, anaemia, GI side effects, and fatigue. The committee further noted the minimal service impact with small patient numbers across the East region; all patients will already be on systemic anti-cancer therapy and treated in established clinics.

The ERFC requested named CD support from NHS Fife. The applicants are requested to respond with information on the recommended action by 21 January 2025.

ACTION: Alice Mathew, Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife, and NHS Lothian Admin Team

The ERFC agreed that Talazoparib: Talzenna (SMC2607) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Talazoparib: Talzenna (SMC2607) 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 Dabrafenib: Finlee + Trametinib: Spexotras (SMC2667)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Named CD support was received from NHS Lothian and NHS Fife.

Indication: In combination with trametinib (Spexotras®) for:

• the treatment of paediatric patients aged 1 year and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.
• the treatment of paediatric patients aged 1 year and older with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and / or chemotherapy treatment.

The finance budget template was included with the FAF.

The ERFC discussed the submission and supporting evidence.

The committee noted that the treatment can be taken at home, reducing the burden of treatment and hospital visits. The committee further noted that the safety profile in paediatric populations was considered manageable and generally similar to the adult population, with the exception of increased weight gain which was considered a new adverse event report. The accompanying protocol provides additional guidance regarding dose delays, modifications, and toxicity management including guidelines to support the treatment of drug-related toxicities.

In regard to guidelines, it was noted that there will be an updated UK guideline incorporating the proposed treatment, and an interim communication has been shared among paediatric oncology networks to address any concerns in the meantime.

A discrepancy between the patient numbers estimated throughout the formulary application was noted with 3-5 new patients a year noted for 'Incidence', but costings based on <1 patient a year.

The ERFC requested the submission of a revised form with corrected patient numbers. The applicants are requested to respond with information on the recommended action by 21 January 2025.

ACTION: NHS Lothian Admin Team

The ERFC requested named CD support from NHS Borders for cross-charging purposes. The applicants are requested to respond with information on the recommended action by 21 January 2025.

ACTION: Malcolm Clubb, Director of Pharmacy (Co-chair), NHS Borders

The ERFC agreed that Dabrafenib: Finlee + Trametinib: Spexotras (SMC2667) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Dabrafenib: Finlee + Trametinib: Spexotras (SMC2667) 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 Icatibant

The ERFC noted and discussed the previously circulated FAF submission. As the request is for the generic medicine, the correct form is a FAF2. The ERFC agreed sufficient information for proposed use in adults is included in the FAF1 paperwork and accompanying information in the original (SMC467/08) submission. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency).

The local clinical management guideline and finance budget template were included with the FAF.

The ERFC discussed the submission, noting that the proposed medicine is administered via Homecare and is only used when a patient suffers a HAE; the standard 30mg dose can be repeated after six hours, if required, up to a maximum dose of three doses per day, however, it is recommended that if symptoms have not subsided after the second dose, then the patient should seek medical attention and receive a second-line treatment option of either C1-esterase inhibitor, Berinert or Cinryze.

The committee acknowledged that a revision of both the Adult and Child 'Acute attacks of hereditary angioedema' pathways is required with detailed prescribing notes included to provide reasoning between each medicine's place in therapy. New pathways for both Adult and Child 'Prophylaxis of acute attacks of hereditary angioedema' are also required. The medicine choices and order of preference within the pathways will mirror the local treatment guideline provided with the application.

It was noted that Berinert is currently on the ERF for Child 'Prophylaxis of acute attacks of hereditary angioedema'. The ERFC discussed and agreed that sufficient information has been provided to include Berinert in the Adult 'Acute attacks of hereditary angioedema' pathway, as well as in both the Adult and Child 'Prophylaxis of acute attacks of hereditary angioedema' pathways.

The committee noted that the NHS Lothian clinical team predominantly treat adult patients, and, therefore, further collaboration with the applicants and the chapter experts in each Board is required to ensure the relevant paediatric content is accurate. Icatibant is licensed for use in children and the ERFC request clarification from the applicants on whether routine use for eligible patients would be proposed in the paediatric cohort.

Further information will be sought regarding the appropriate contacts in each Board to provide input on the proposed pathway content. Relevant updates will be made, if required, and further appraised at the East Region Working Group meeting.

ACTION: Alice Mathew, Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife, and Diane Murray, Formulary Pharmacist, NHS Lothian, and NHS Lothian Admin Team

The ERFC agreed to classify Icatibant 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

3.1.6 FAF1 Follitropin delta: Rekovelle (SMC2670)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific declaration of interest was received. Named CD support was received from NHS Lothian and NHS Borders; CD support from NHS Fife is not required as the relevant patients will be treated in NHS Tayside.

Indication: Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle.

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

The ERFC acknowledged the submission, noting that the clinical team wish to use the medicine in a more restricted patient group than the SMC-approved indication.

The committee discussed the proposed inclusion of Follitropin delta: Rekovelle as a replacement for Meriofert and queried the validity of the replaced therapy costings provided in the application as the comparator costings have been provided by the manufacturer directly.

The ERFC requested further clarity regarding the replaced therapy costings and whether Meriofert is to remain in the formulary choices. The applicants are requested to respond with information on the recommended action by 21 January 2025.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify FAF1 Follitropin delta: Rekovelle (SMC2670) 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

3.1.7 FAF1 Empagliflozin: Jardiance (SMC2642)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest was received. Named CD support was received from all three Boards.

Indication: In adults for the treatment of chronic kidney disease (CKD).

SMC restriction: in patients having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment:

- an estimated glomerular filtration rate (eGFR) of 20 mL/min/1.73m2 up to 45 mL/min/1.73m2, or
- an eGFR of 45 mL/min/1.73m2 up to 90 mL/min/1.73m2 and either:
    - A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or
    - Type 2 Diabetes Mellitus (T2DM).

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

The ERFC discussed the submission, noting the substantial evidentiary information provided in support of Empagliflozin's clinical efficacy.

The ERFC noted the proposed inclusion of Empagliflozin on the ERF is alongside Dapagliflozin in the Adult 'Treatment to slow progression of chronic kidney disease' pathway as it will negate unnecessary switching of SGLT2 inhibitors in patients with CKD who are already stabilised on Empagliflozin, or as an alternative to Dapagliflozin for those who cannot tolerate Dapagliflozin, or in the case of any supply issues. It was noted that Empagliflozin is already on the ERF as a joint treatment option with Dapagliflozin for both diabetes and heart failure. The inclusion of Empagliflozin would, therefore, bring CKD in line with these other conditions and in line with SMC.

The committee noted the somewhat low patient numbers, rationalising that the number of patients stated on the application is likely to be a reflection of the number of patients that are referred for treatment in renal clinics and is not reflective of the total number of patients treated in primary care. It was further noted that additional scrutiny regarding the estimated patient numbers is required to ensure robust financial forecasting as the proposed inclusion of Empagliflozin on the ERF as a replacement of other SGLT2 inhibitors or as an alternative for patients who cannot tolerate Dapagliflozin may result in an exponential increase in patient numbers per annum.

The ERFC agreed to classify FAF1 Empagliflozin: Jardiance (SMC2642) as Routinely available in line with local or regional guidance. Included on the ERF with criteria added in addition to SMC advice. Refer to

EDREN website for local criteria - upper eGFR limit removed as not reported by labs, PCR measurement used locally rather than ACR. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.8 FAF2 Dienogest 2mg Tablets

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: Treatment of endometriosis and prevention of post-operative recurrence of endometriosis.

The finance budget template was included with the FAF.

The ERFC discussed the submission, noting the proposed inclusion of Dienogest 2mg tablets as an alternative second-line treatment option alongside Triptorelin, after initial treatment with Norethisterone or Medroxyprogesterone in the 'Treatment of endometriosis' pathway, or as an alternative post-operative treatment in women who have undergone surgical excision of endometriosis to prevent disease recurrence.

It was noted that the proposed formulation of oral tablet requires less supervision, therefore, reducing associated costings and alleviating pressure on gynaecology services.

The committee noted that Triptorelin is included in the 'Treatment of endometriosis' pathway, with dosing information to advise that treatment should occur for a maximum of 6 months, however, it was noted that Triptorelin is more frequently used out with current licensing, with common use of the medicine for 6-18 months, on average. The committee discussed and agreed that a revision of the 'Treatment of endometriosis' pathway is required to provide further prescribing guidance for the use of both Triptorelin and Dienogest in primary care and to align with current practise.

The ERFC requested the submission of a revised application with further prescribing guidance to support prescribing of Triptorelin in primary care. The ERFC further requested that the applicants liaise with a GP and include the required advice within their guidance. The applicants are requested to respond with information on the recommended action by 21 January 2025.

ACTION: Malcolm Clubb, Director of Pharmacy (Co-chair), NHS Borders, Alice Mathew, Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife, and Diane Murray, Formulary Pharmacist, NHS Lothian

The ERFC agreed to classify Dienogest 2mg Tablets 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

3.1.9 FAF2 Carbetocin

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: To prevent post-partum haemorrhage following caesarean delivery.

The finance budget template and local clinical management guideline were included with the FAF.

The ERFC discussed the submission, noting that Carbetocin will be a locally agreed alternative treatment to IM Syntometrine or IV oxytocin following caesarean birth. The committee further noted the

supporting evidence provided in the most recent network meta-analysis of the clinical effectiveness of Carbetocin which was commissioned as part of the updated NICE NG235 Intrapartum care: Evidence review guideline.

The ERFC agreed to classify Carbetocin as Routinely available in line with local or regional guidance. Included in the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.10 FAF3 Bladder carbogen and nicotinamide (BCON) radiotherapy - *pre-ERFC panel review*

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: To radiosensitise bladder cancer undergoing radical radiotherapy treatment.

The local clinical management guideline and finance budget template were included with the FAF.

The ERFC discussed the submission, noting the proposed use of BCON radiotherapy as an alternative to Mitomycin C/5FU for a small group of patients who cannot tolerate Mitomycin C/5FU or choose not to have it, with patients treated in the Edinburgh Cancer Centre only.

It was noted that BCON radiotherapy is used in a number of cancer centres in England, with some consultation across Scotland. The ERFC acknowledged that upon review at East Region Working Group (ERWG), a query was sent to the National Cancer Medicines Advisory Group to enquire about the scope for appraisal of BCON radiotherapy for use in other regional cancer centres within NHS Scotland.

The ERFC further noted that there is no evidence base for the licensed medical gas alternative, however, agreed with the recommendation from the ERWG that the associated guideline requires additional appraisal and final approval by the relevant oncology Drug and Therapeutic committee. Any amendments to the guideline will be communicated back to the ERF team for necessary updates to be carried out. The guideline will also undergo appraisal by the NHS Lothian Medical Gases Committee to provide additional scrutiny regarding the use in practise.

The ERFC agreed that Bladder carbogen and nicotinamide (BCON) radiotherapy is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify Bladder carbogen and nicotinamide (BCON) radiotherapy 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

3.2 Formulary Amendment Form

3.2.1 Levonorgestrel

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

Indication: Contraception

Application for amendment due to the Faculty of Sexual and Reproductive Healthcare statement extending use of all 52mg Levonorgestrel IUD for use to 8 years.

The ERFC discussed the supporting evidence, noting that there is no local clinical guidance available for contraception, with clinicians advised to refer to the FSRH guidance and the BNF for additional prescribing guidance.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Ustekinumab Biosimilars – Pyzchiva (Sandoz), Wezenla (Amgen)

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

Indication: Addition of Ulcerative Colitis to existing approved formulary uses.

Application for amendment due to new licensing approval. To be included on the ERF for Specialist Use only.

The ERFC discussed the supporting evidence, noting that the Pyzchiva (Sandoz) SPC does not currently list Ulcerative Colitis as an approved indication; the ERF will be updated once the SPC has been revised.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Siponimod

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

Indication: Treatment of secondary progressive MS (SMC2265)

Application for amendment to include new 1mg tablet strength. To be included on the ERF for Specialist Use only.

The ERFC discussed the supporting evidence, noting that the new 1mg tablet will replace the current practice of prescribing four 0.25mg tablets.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.4 Amgevita (Adalimumab)

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

Indication: Treatment of Crohn's disease and Ulcerative Colitis

Application for amendment due to availability of new 80mg HCF pre-filled pen and 80mg HCF pre-filled syringe Amgevita formulations and the change of the existing formulations to a new 100mg/ml strength. To be included on the ERF for Specialist Use Only.

The ERFC discussed the supporting evidence, noting that the availability of new formulations will reduce the number of injections patients are required to administer for those who require 80mg weekly/2-weekly dosing. The ERFC noted that the new formulations will be added to all relevant Adult and

Paediatric pathways. The existing strength formulations will remain on the formulary until the transition to the new strength formulation is complete.

Post-meeting note: The update to formulations also applies to the following indications in line with product licensing: Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Uveitis, Hidradenitis Suppurativa and Psoriasis, pending clarification with local specialists.

The formulary website will be updated.

ACTION: Alice Mathew, Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife, and Diane Murray, Formulary Pharmacist, NHS Lothian

3.2.5 Dexcom One+

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

Indication: Treatment of Type 1 diabetes.

Application for amendment due to impending discontinuation of Dexcom One. Dexcom One+ to be included on the ERF for Specialist Initiation.

The ERFC noted the supporting evidence.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.6 Fobumix Easyhaler

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

Indication: Asthma for MART.

Application for the amendment to include Fobumix Easyhaler as a treatment option for children aged 12 years and above.

The ERFC discussed the supporting evidence. The committee noted that Fobumix Easyhaler is currently on the ERF for use in Adults, but new licensing allows for use in children aged 12-17 years and can be used for Maintenance And Reliever Therapy (MART) therapy - MART is now the recommended treatment for patients with mild to moderate asthma, as noted in the new SIGN245 guideline.

The ERFC agreed to classify Fobumix Easyhaler as Routinely available in line with local or regional guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra Orphan Medicines Initial Assessment – *none noted.*

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Cemiplimab concentrate for solution for infusion: Libtayo (SMC2724)
3.4.2 Drospirenone film-coated tablets: Slynd (SMC2725)
3.4.3 Nivolumab concentrate for solution for infusion: Opdivo (SMC2726)

3.4.4 Pembrolizumab: Keytruda (SMC2688)
3.4.5 Enzalutamide: Xtandi (SMC2742)
3.4.6 Durvalumab: Imfinzi (SMC2677)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

3.5.1 Faricimab: Vabysmo (SMC2685)

The ERFC noted the SMC abbreviated submission for Faricimab: Vabysmo (SMC2685).

Indication: Treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO). Faricimab offers an additional treatment choice in the therapeutic class of antineovascularisation agents.

The ERFC agreed to classify Faricimab: Vabysmo (SMC2685) 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

3.5.2 Somapacitan: Sogroya (SMC2629)

The ERFC noted the SMC abbreviated submission for Somapacitan: Sogroya (SMC2629).

Indication: For the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).

The ERFC agreed to classify Somapacitan: Sogroya (SMC2629) 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

3.5.3 Tenecteplase: Metalyse (SMC2697)

The ERFC noted the SMC abbreviated submission for Teneteplase: Metalyse (SMC2697).

Indication: In adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.

The ERFC agreed to classify Teneteplase: Metalyse (SMC2697) 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

3.5.4 Bismuth subcitrate potassium/ metronidazole/ tetracycline hydrochloride: Pylera (SMC2701)

The ERFC noted the SMC abbreviated submission for Bismuth subcitrate potassium/ metronidazole/ tetracycline hydrochloride: Pylera (SMC2701).

Indication: In combination with omeprazole, for the eradication of Helicobacter pylori and prevention of relapse of peptic ulcers in patients with active or a history of H. pylori associated ulcers.

SMC restriction: restricted to use in accordance with clinical guidelines for the eradication of H. pylori.

The ERFC agreed to classify Bismuth subcitrate potassium/ metronidazole/ tetracycline hydrochloride: Pylera (SMC2701) 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

3.5.5 Vibegron: Obgemsa (SMC2696)

The ERFC noted the SMC abbreviated submission for Vibegron: Obgemsa (SMC2696).

Indication: Symptomatic treatment of adult patients with overactive bladder (OAB) syndrome.

The ERFC agreed to classify Vibegron: Obgemsa (SMC2696) 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 None noted.

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 Rezafungin acetate: Rezzayo (SMC2659)
3.7.2 Selinexor: Nexpovio (SMC2673)
3.7.3 Selinexor: Nexpovio (SMC2674)
3.7.4 Pembrolizumab concentrate for solution for infusion: Keytruda (SMC2689)
3.7.5 Relugolix film-coated tablets: Orgovyx (SMC2678)
3.7.6 Lebrikizumab: Ebglyss (SMC2707)
3.7.7 Quizartinib: Vanflyta (SMC2699)
3.7.8 Axicabtagene ciloleucel dispersion: Yescarta (SMC2695)
3.7.9 Linzagolix: Yselty (SMC2631)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, 3.7.6, 3.7.7, 3.7.8, and 3.7.9 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 National Cancer Medicines Advisory Group

Quarterly Update - *for noting.*

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

The ERFC noted that an outstanding action from the East Region Working Group meeting in May 2024 has been resolved - in all relevant Adult ERF pathways, Prednisolone 5mg tablets remain available and an additional prescribing note included to advise: "For patients with swallowing difficulties prednisolone oral solution or soluble tablets may be considered. Prednisolone tablets may be dispersed in water as an alternative to soluble tablets or oral solution preparations. This is an off-label use but more cost-effective option. Refer to local board policies on the use of unlicensed (and off-label) medicines for further guidance". In child pathways, Prednisolone 5mg soluble tablets removed and updated to Prednisolone 5mg soluble tablets sugar free to align with dm+d update.

The ERFC further discussed the potential removal of Prednisolone 5mg soluble tablets from paediatric pathways, with off-label use of Prednisolone 5mg tablet or Prednisolone Oral Solution as remaining treatment options. The committee noted that there are practical considerations for administering the proposed Prednisolone alternatives to young children. It was, therefore, agreed to leave all formulations of Prednisolone in the relevant paediatric pathways, and allow for further decision making at local Board level.

4.3 NHS Lothian

A local enquiry was made regarding Doxylamine succinate and pyridoxine hydrochloride: Xonvea (SMC2140), for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. The SMC Not Recommended medicine is the only licensed treatment available and has been included on the NHS Grampian formulary as first-line treatment option for both primary and secondary care via local submission, as well as noted as an available treatment option in both the NICE CKS guideline and the Royal College of Obstetrics and Gynaecology guideline The ERFC acknowledged that there has been use of Xonvea in primary care across the East region as well as PACS2 requests in Lothian and other Scottish boards in the previous year.

The ERFC noted that a resubmission by the company to the SMC is expected, however, a timeline for the resubmission is unavailable at present. The committee discussed whether to accept a submission for the proposed inclusion of Xonvea on the ERF, and noted that an oversight of the discussion at the relevant NHS Grampian formulary committee meeting would be beneficial to understand the rationale for their approval, however, ultimately agreed to await the appraisal of the impending SMC resubmission and subsequent advice for NHS Scotland rather than consider regional approval in advance.

ACTION: Diane Murray, Formulary Pharmacist, NHS Lothian

5 Any other competent business

5.1 Pabrinex shortage - new Thiamine 50mg/ml licensed update; all teams to consider adding new product onto formulary

The committee discussed the ongoing use of unlicensed IV/IM thiamine alternatives with the long-term shortage of Pabrinex IV until September 2025, and agreed that an assessment is required by clinical teams across the East region to determine if a formulary application is required for the inclusion of Thiamine 250mg/5ml solution for injection ampoules on the ERF and submit an application with collaborative input from all three Boards in due course.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 05 February 2025 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 08 January 2025 (for discussion at the pre-ERFC panel meeting on 15 January 2025).

FAF1s for consideration by the pre-ERFC panel should be submitted by 08 January 2025 (for discussion at the pre-ERFC panel meeting on 15 January 2025).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 21 January 2025.

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 eos.prescribing@nhs.scot.