East Region Formulary

East Region Formulary Committee
Minutes

Date: 28 May 2025
Time: 2.00pm – 4:15pm
Location: MS Teams

Present:

Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Dr Grace Ding	Consultant Oncologist, NHS Lothian
Dr Joan Egerton	GP, NHS Fife
Dr Tariq Farrah	Consultant - Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist, NHS Fife
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist - Medicines Governance and Guidance, NHS Lothian
Iain Macintyre	Consultant – Renal (Co-Chair), NHS Lothian – in the Chair
Alice Mathew	Senior Clinical Pharmacist - Medicines Utilisation and Therapeutics, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant – Cardiology, NHS Borders
Dr Jo Rose	GP, NHS Lothian
Sarah Tait	Lead Advanced Practitioner, NHS Borders

In attendance:
Jewel (Hui Syuen) Tan, Pharmacist, NHS Fife
Richard Longville Taylor, Clinical Pharmacist – Surgery, NHS Lothian
Caitlin Satti, Information Officer, NHS Lothian (minutes)
Zarah Swain, Principal Pharmacist, Medicines Information, NHS Lothian

Apologies:
Jane Browning, Associate Director of Pharmacy, NHS Lothian
Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife
Malcolm Clubb, Director of Pharmacy (Co-Chair), NHS Borders
Dr Konstantinos Dabos, Consultant, GI, NHS Lothian
Ryan Headspeath, Senior Clinical Pharmacist, Dermatology and Shared Care, NHS Fife
Carol Holmes, Pharmacist - Primary Care, NHS Lothian
Fraser Notman, Senior Pharmacist – Medicines Management, NHS Fife
Cathryn Park, Deputy Director of Pharmacy, NHS Borders
Dr Monica Szabo, Consultant Oncologist, 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
- Leaving – Alice Mathew; The Chair noted acknowledged the departure of Alice Mathew, Senior Clinical Pharmacist - Medicines Utilisation and Therapeutics, NHS Fife, as she embarks on a career break for 18 months. On behalf of the East Region Formulary Committee, the Chair thanked Alice for her work and contribution to the committee. Alice will rejoin the ERFC upon her return.

1.2 Matters arising

None noted.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 02 April 2025

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 07 May 2025

The ERFC received a verbal update highlighting key discussions at the previous ERWG meeting.

A FAF3 application for use of Zoledronic Acid was reviewed for fracture prevention in osteopenia for women aged over 65, with feedback returned to the applicants to provide additional information clinical evidence and information regarding peer review, a revision of the financial modelling, as well as Clinical Director sign-off from all three Boards. FAF3 applications for Human Chorionic Gonadotropin (HCG) and Zivafert were also subject to review with discussions ongoing with Fertility and Endocrine specialists across the East Region as concerns were raised regarding the disconnect between highly specialised and general services sharing patient care. All applications are expected to come to the next East Region Formulary Committee meeting for review.

The committee further noted the ongoing work to revise ERF content in response to the 'Prolonged-release opioids: Removal of indication for relief of post-operative pain' MHRA Drug Safety Update. Relevant updates will be appraised by the East Region Working Group prior to receiving final endorsement at the next ERFC meeting.

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

2.3.1 Asthma Adult & Paediatric Chapters

The ERFC received an update on the draft ERF Asthma (Adult & Paediatric) chapters. It was noted that the initial Chapter Expert Working Group (CEWG) meeting was quorate with representation from all three Boards, with several follow-up meetings carried out with specific specialists.

Adult

There was discussion and suggestions were made to the following areas:

- The ERFC agreed that supporting guidance developed by local experts to accompany the formulary recommendations would be helpful.
- Pathway opening text has been revised, removing obsolete information and updating relevant links
- 'General information on inhalers' moved to top of the pathway, with revised prescribing notes
- All patients will receive Anti-inflammatory reliver (AIR) therapy as first-line treatment with Symbicort 200/6 Turbohaler as only treatment option.
- 'Maintenance and Reliever Therapy (MART) plus add on therapy' included as pathway 3, with Fobumix Easyhaler (160micrograms/4.5micrograms) or Fostair NEXThaler 100/6 micrograms/Bibecfo 100/6 micrograms inhaler included as first-line treatment options. It was noted that Chapter Experts wished to remove Luforbec from the ERF, initially agreeing to replace with Bibecfo; however, a further change to Proxor 100/6 micrograms inhaler has been proposed. Chapter experts supported the change. A formulary amendment form has been completed and included on the agenda – item 3.2.8, for discussion. The ERFC discussed points raised on comparative pricing, and local experts experience with beclomethasone/formeterol branded inhalers. Patients who are well managed on Luforbec are recommended to continue their prescribed inhaler, new patients are recommended to be prescribed Proxor.
- Third-line treatment option is the addition of either Montelukast or Tiotropium LAMA soft-mist inhaler – Spiriva Respimat to MART.

- Pathway 4 will be for 'Patients not suitable for AIR / MART', with updated prescribing notes to include relevant MHRA advice. Further discussion with Chapter Experts is required regarding the proposed inclusion of Proxor as a second-line treatment option. As there was no evidence of agreement from all three boards, the proposers are advised to submit a formulary amendment form showing support of all three Boards if they agree to add Proxor for patients not suitable for AIR/MART.
- The prescribing notes will be updated to advise "patients prescribed more than 3 SABAs in a 12-month period should be offered a review to assess asthma symptoms and control".
- Pathway 5 will be 'Additional high-strength add on therapies' and will include all high-strength formulations of prior mentioned medicines with dosing recommendations from the BNF.
- Pathway 6 is for the treatment of 'Acute asthma'. Formulary flagging for Salbutamol 500micrograms/1ml solution for injection ampoules has been change from SI to SUO.
- Revisions to the prescribing notes for pathway 7 'Immunotherapy in asthma' following SMC resubmission to reflect updated restriction from four to three asthma exacerbations. Relevant Formulary Amendment submission noted under item 3.2.3.
- Volumatic removed from Pathway 10 'Spacer devices'
- No changes to pathways 8,9, and 11.
- Chapter experts suggested the potential removal of IV Magnesium formulations from the formulary. However, these medicines are still used in ICU settings, and, therefore, will remain on the ERF with a SUO formulary flagging.

***Post-meeting note**:* The ERFC note that cough is a listed side-effect of beclomethasone/formeterol branded inhalers, local health professionals are reminded to submit Yellow Card submissions to the MHRA to report any suspected adverse drug reactions (ADRs).

Post-meeting note: In regard to pathway 2 'Anti-inflammatory reliever (AIR) therapy', it was noted at ERWG that whilst Symbicort has already undergone formulary appraisal (including estimated financial modelling), new SIGN guidelines recommend it's use in a broader patient population. The clinical team will be asked to account for the additional cost impact through local budget holders or finance teams to ensure robust financial planning.

ACTION: NHS Lothian Admin Team

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

ACTION: Lothian Admin Team

Paediatric

There was discussion and suggestions were made to the following areas:
- Pathway opening text has been revised and relevant links updated
- 'General information on inhalers' moved to top of the pathway, with revised prescribing notes
- The pathways for children over 12 years old closely mirror the Adult pathways, but unlicensed products have been removed. For AIR therapy treatment, Symbicort remains the preferred choice, with the same dosage as in the Adult pathway.
- Pathway 3 'Children over 12 years old: Maintenance and Reliever Therapy (MART) plus add on therapy' includes low dose MART then moderate dose MART. The inclusion of Tiotropium LAMA soft-mist inhaler – Spiriva Respimat was recommended to mirror recommendations in the Adult MART pathway. Proxor has not been included as it is not licensed for children over 12 years.
- It was noted that Fobumix Easyhaler 160/4.5 micrograms has been approved for use in patients over 12 years old, however two Boards are hesitant to include it in the ERF. Their concerns include Fobumix's short four-month expiry, requiring three inhalers per year, which leads to excess waste. Additionally, GPs would need to issue prescriptions every four months, regardless of usage, while Symbicort, with a three-year expiry, is more cost-effective, environmentally friendly, and requires fewer prescriptions.
- SI formulary flagging will be added to relevant medicines in pathway 6 'Children between 5 -11-year old: Specialist therapies' to ensure consistency throughout the ERF.
- Revisions to the prescribing notes for pathway 9 'Biological medicines in asthma' following SMC resubmission to reflect updated restriction from four to three asthma exacerbations. Relevant Formulary Amendment submission noted under item 3.2.3.

- Volumatic removed from Pathway 11 'Spacer devices'
- No changes to pathway 10, 12 and 13

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

ACTION: NHS Lothian Admin Team

2.3.2 MSK Joint Disease & Bone – Rheumatology (Paediatric) Chapter

The ERFC received an update on the draft ERF Rheumatology (Paediatric) chapter.

There was representation from three consultants – two from NHS Lothian and one from NHS Borders. No pharmacists were in attendance at the meeting; however, extensive post-meeting email feedback has been received from experts across the three boards with representation from primary care, nursing and pharmacy. The expert group includes members of the Scottish Paediatric and Adolescent Rheumatology Network (SPARN). SPARN maintain their own guidelines which are written by a group of consultants with additional pharmacist input. Links to these guidelines have been included, where relevant.

The review considered Adult formulary recommendations, Paediatric Licence Extensions, and background information provided by local specialists on prescribing practice. The group agreed to include items of routine use in the paediatric population with supporting information of safety and efficacy. Items that are rarely used with limited information on safety and efficacy in children will continue to be considered when required via local non-formulary processes.

There was discussion and suggestions were made to the following areas:

- Throughout the Paediatric chapter review process, some revisions to Adult treatment pathways were identified. The NHS Lothian Adult Rheumatology team confirmed that Colchicine is used in the treatment of Adult 'Prophylaxis of Familial Mediterranean Fever', and it will, therefore, be included within the treatment pathway. The NHS Lothian Adult Rheumatology team also agreed with the proposed recommendations for the Adult 'Prophylaxis of Raynaud's phenomenon' pathway. Signposting to relevant British Rheumatology Guidelines will be included.
- The group agreed recommendations for Juvenile Idiopathic Arthritis, Still's disease, and Systemic Lupus Erythematosus.
- More generalised pathways have been included to capture a wide range of paediatric rheumatology conditions e.g. Juvenile Localised Scleroderma, Systemic Sclerosis, Juvenile Dermatomyositis, Chronic Non-Infective Osteitis Vasculitis, Periodic Fever Syndromes, and other auto inflammatory conditions. The initial management of generalised paediatric rheumatology conditions will be with Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and DMARDs to support seamless prescribing across the interface. DMARDs medicine selection will be based on clinician experience and recommendations noted in both UK and SPARN guidance.
- Use of biologics and synthetic DMARDs in rare conditions will be managed by paediatric rheumatology teams, and will adopt a case-by-case approach following non-formulary process
- There is a separate pathway for Uveitis, managed in partnership with paediatric Ophthalmology specialists. Local ophthalmologists have reviewed and approved new pathways for children which were developed from the existing adult recommendations, with reference to Paediatric Licence Extension and recommendations in the BNF for children. It was noted that Infliximab is not included in the Adult Uveitis formulary recommendations, but is used in children as monthly IV-infusions are preferred over more frequent subcutaneous injections. Despite preference for Infliximab as first-line treatment option, guidelines recommend Adalimumab as first-line due to its stronger evidence base, with Infliximab as second-line. The ERFC agreed to include Infliximab, second-line, in the paediatric Uveitis formulary recommendations.
- The Formulary Decision for Rituximab: MabThera (SMC894/13) will be updated from brand to generic and remain 'Routinely available' with SUO formulary flagging to cover use in adults and the Paediatric Licence Extension.
- The committee noted that licensed Triamcinolone products are being discontinued, with stock expected to run out by June 2025. Triamcinolone was the preferred choice for paediatrics, but the available unlicensed product has intermittent supply and is not a reliable alternative. The paediatric

team are seeking advice from the wider UK network on their preferred alternative to Triamcinolone injections before making local recommendations.
- The discontinued products will be removed from the Adult ERF, and a link to the MSAN will be included with guidance on alternatives.

The ERFC approved the pathway content. The formulary website will be updated on final approval from the chapter experts.

ACTION: Diane Murray, NHS Lothian Formulary Pharmacist and NHS Lothian Admin Team

2.3.3 ERF Adult - Dry mouth - BioXtra discontinued, Oralieve moisturising mouth gel added

The ERFC noted that BioXtra products included on formulary are due to be deleted from the Scottish Drug Tariff (SDT) on 1 June 2025 having been discontinued.

Whilst included in the ENT chapter, BioXtra products are not often used by ENT specialists, but rather in Palliative Care and Care of the Elderly settings. Oralieve moisturising mouth gel proposed as alternative option, with support received from NHS Lothian ENT, Maxillofacial, and Palliative Care consultants, with additional support noted from NHS Fife ENT consultants.

The ERFC approved the amendment. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

2.3.4 ERF Adult – Obesity

The ERFC noted the new 'Adjunctive treatment for weight management' treatment recommendations.

The committee acknowledged that the update is to reflect the formulary classification and should not be confused with the pathway for patient access which are yet to be agreed in each Board, with information to follow locally. For NHS Lothian, information will be held on RefHelp; however, the clinical team are not currently accepting referrals whilst patient access pathways are being developed. Signposting will be included for relevant information and guidance in NHS Fife and NHS Borders.

All GLP-1 RA/GLP-1 RA Glucose dependent insulinotropic polypeptide receptor antagonists are included as joint second-line treatment options. The committee agreed with the proposed inclusion of Orlistat as third-line treatment option, noting its previous inclusion in NHS Lothian and NHS Borders respective formularies, as well as in recently published SIGN172 guidance recommending its use in patients who cannot tolerate other agents.

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

ACTION: NHS Lothian Admin Team

2.3.5 ERF Child - Obesity

The ERFC noted the new 'Adjunctive treatment for weight management' treatment recommendations.

The committee acknowledged the inclusion of Liraglutide: Saxenda and Semaglutide: Wegovy as joint second-line treatment option, with all medicines included for Specialist Initiation. Experts across the East Region have concluded that they expect Wegovy to be the preferred medicine choice due to its weekly dosing schedule, in comparison to daily administration of Liraglutide.

A review of the order of medicine choices within the pathway may occur at a future date taking into consideration latest evidence, cost, and experience in use.

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

ACTION: NHS Lothian Admin Team

2.3.6 ERF Child – MHRA DSU Prolonged-Release Opioids

The ERFC noted the changes to ERF content in response to the 'Prolonged-release opioids: Removal of indication for relief of post-operative pain' MHRA Drug Safety Update, published in March 2025.

A number of revisions have been made to ERF content in response to the DSU including prolonged-release opioids will be removed from acute pain management broadly, not just post-operative pain; MR oxycodone will be removed from the peri-operative analgesia pathway; and the 'Peri-operative analgesia' pathway will be renamed 'Peri and post-operative analgesia'.

Upon discussion, the ERFC requested the inclusion of Specialist Initiation formulary flagging for Tramadol in the new 'Peri and Post-operative analgesia' pathway. Additionally, the committee agreed to remove Codeine and Co-codamol from relevant paediatric pain pathways. It was noted that Dihydrocodeine is used as an alternative to Codeine and Co-codamol in NHS Borders; further comments and approval will be sought from paediatric pain specialists in NHS Lothian and NHS Fife prior to inclusion in the relevant pathways.

ACTION: Diane Murray, NHS Lothian Formulary Pharmacist

The NHS Lothian paediatric team have provided robust clinical justifications for the continued use of Fentanyl patches as third-line treatment option in the 'Analgesic treatment for peri-operative use only' pathway. It was noted that use of Fentanyl patches in paediatric pain management is most commonly used after major spinal surgery, with additional information included in the pathway to advise that Fentanyl patches are 'Restricted to use in the acute post operative setting in RHCYP under the management of the paediatric pain team'. The ERFC agreed with the consensus of the East Region Working Group that an update an update to each Board's ADTC regarding this patient cohort is required. Assurance will be provided that there is extensive historical use and clinical justification for the use of Fentanyl patches in paediatric patients, with treatment decisions continuing to be based on individual patient needs. In addition, similar information will be shared with the MHRA to highlight the specific patient subset that was not addressed in the guidance.

The ERFC approved the pathway content subject to CEWG agreement on actions in relation to Codeine, Co-codamol and Dihydrocodeine. The formulary website will be updated.

ACTION: Diane Murray, NHS Lothian Formulary Pharmacist and NHS Lothian Admin Team

2.3.7 ERF Adult & Child - Hereditary Angioedema

The ERWG noted and approved the amendment. The pathway can be updated.

ACTION: ERF Administration Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Ublituximab: Briumvi (SMC2731)

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: Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

SMC restriction: treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

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

The ERFC reviewed the submission, noting the proposed inclusion of IV Ublituximab as first-line treatment option in the 'Treatment of highly active relapsing remitting multiple sclerosis' pathway, with Ocrelizumab moved to second-line. The clinical team have confirmed that any new patients who will be starting, or existing patients escalating to high efficacy treatment will be offered Ublituximab as first-line IV infusion option over IV Ocrelizumab. Patients with highly active RRMS who are already established on IV Ocrelizumab will remain on Ocrelizumab.

The committee acknowledged that Ublituximab has similar clinical efficacy to other medicines on the ERF and recognised the cost-saving advantage of including it as a first-line treatment option.

The ERFC agreed to classify FAF1 Ublituximab: Briumvi (SMC2731) 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 Pembrolizumab: Keytruda (SMC2689) - *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: As monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy.

SMC restriction: adults whose tumours express programmed death-ligand 1 (PD-L1) with less than 50% (0 to 49%) tumour proportion score (TPS).

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

The ERFC reviewed the submission, with supporting evidence provided by the KEYNOTE-091 study which demonstrated that in the overall study population, Pembrolizumab significantly improved DFS versus placebo. Pembrolizumab (used for one year as adjuvant therapy) was associated with statistically significant benefits in disease-free survival over placebo in patients with completely resected stage IB-IIIA NSCLC.

It was noted that the inclusion of Pembrolizumab: Keytruda on the ERF fills an unmet need in this therapeutic area, since patients with early-stage NSCLC and PD-L1 TPS <50%, who are not EGFR mutation-positive, do not receive active treatment at present following complete resection and platinum-based chemotherapy. As a result, Pembrolizumab: Keytruda is considered to be a therapeutic advancement for these patients.

The committee acknowledged the concerns previously raised by the pre-ERFC panel regarding the proposed patient numbers per annum. It was noted that whilst the SMC data predicts 6 patients across SCAN would be eligible for treatment per annum, the NHS Lothian Edinburgh Cancer Centre lung cancer team predict approximately 39 eligible patients annually across SCAN would be eligible. As a consequence, the patient numbers detailed in the submission is based on the higher figure of 39 patients, supported by SCAN data on patients meeting the eligibility criteria. The ERFC noted that treatment duration for adjuvant therapies may be shorter due to disease progression, particularly in lung cancer, which could lead to an initial high uptake followed by a decline—potentially overestimating patient numbers.

Post-meeting note: The applicants have submitted additional information addressing concerns raised regarding annual patient numbers, providing clarification that the figures provided represent the maximum potential number of patients. It should be noted that not all patients will be eligible for treatment, as candidates must successfully complete four cycles of chemotherapy prior to consideration for immunotherapy. Consequently, the clinical team has confirmed that the actual patient numbers are expected to be lower than those indicated in the application, though still exceeding the estimates previously provided by the SMC.

The ERFC requested the application form to be re-submitted with the updated patient numbers and revised costings. The applicant is requested to respond with information on the recommended action by 8 July 2025.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify FAF1 Pembrolizumab: Keytruda (SMC2689) 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

3.2 Formulary Amendment Form

3.2.1 Domperidone

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: Augmentation of lactation

Application for amendment to allow for further supply of Domperidone beyond one week, if necessary; mainly, with the aim of facilitating slow wean-off of Domperidone if abrupt stop has caused drop in supply, and to support prescribing in line with UK Drugs in Lactation Advisory Service (UKDILAS) advice.

The ERFC reviewed the supporting evidence. A link in prescribing notes to the SPS/UKDILAS information will be added for NHS Fife and NHS Borders staff who do not have access to the NHS Lothian guideline.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Metronidazole

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: Dental Abscess

Application for amendment to update relevant ERF recommendations to reflect the Scottish Dental Clinical Effectiveness Programme (SDCEP); specifically, to amend the dose of Metronidazole in the 'Treatment of dental abscess' pathway to 400mg three times daily for 5 days (instead of 200mg dose) to be in line with BNF dosing and SDCEP guideline.

The ERFC acknowledged the supporting evidence, noting the decision to include a weblink directly to the current national guidance for dental prescribing for ease of use in practice. The committee noted

that the new guidance is more comprehensive, and provides dosing recommendations for both adults and children.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Mepolizumab: Nucala (SMC2765)

The ERFC noted and discussed the previously circulated Formulary Amendment form. One personal non-specific declaration of interest was noted. Clinical team support received from all three Boards.

Indication: As an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents, and children aged 6 years and older who have eosinophils of at least 150 cells per microlitre (0.15 x 109/L) at initiation of treatment, and have has at least three asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.

Application for amendment to update prescribing notes following SMC resubmission to reflect updated restriction from four to three asthma exacerbations.

The ERFC noted the Formulary Amendment submission as part of the Adult and Paediatric Asthma chapter review (item 2.3.1).

Post-meeting note: The ERFC agreed to classify Mepolizumab: Nucala (SMC2765) 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

3.2.4 Ocrelizumab: Ocrevus

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: Multiple Sclerosis. Treatment of adult patients with:

- Relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features
- Early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity

Application for amendment to include a sub-cutaneous injection formulation as a cost-neutral alternative within the relevant multiple sclerosis ERF pathways.

The ERFC noted the supporting evidence.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.5 Jaydess Intra-Uterine Device

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

Indication: Contraception

Application for amendment to provide a lower-dose Levonorgestrel formulation option in the 'LARC – hormone releasing intrauterine devices' pathway.

The ERFC reviewed the supporting evidence, noting that the inclusion of Jaydess is cost-neutral and intended for patients who may benefit from a lower dose.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.6 Tobramycin

The ERFC noted and discussed the previously circulated formulary amendment form. Two personal specific and one personal non-specific declarations of interest were noted. Clinical team support received from all three Boards.

Indication: Chronic pulmonary Pseudomonas aeruginosa infection in patients with cystic fibrosis (adults).

Application for amendment to update the ERF to reflect the current range and choice of various Tobramycin products for inhalation: Tobi Podhaler powder for inhalation, Tobramycin 300mg/5ml generic solution for nebulisation, Bramitob 300mg/4ml solution for nebulisation, and Vantobra 170mg/1.7ml with Tolero handset.

The ERFC acknowledged the supporting evidence. It was noted that the clinical team wish to update the ERF entries for Tobramycin nebules to generic so that the respective Boards have freedom in the choice of nebuliser with the designation 'Specialist Initiation', and Tobramycin TOBI Podhaler 'Specialist Intiaition' to reflect current practice.

The applicants advised that the adult CF service in Lothian prefer the Vantobra 170mg nebuliser solution to be delivered via homecare. The NHS Fife service intend to use generic Tobramycin nebulisers.

The Tobramycin: TOBI Podhaler Formulary Decisions entry will also be updated.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.7 Chloramphenicol 0.5% eye drops PF

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: Bacterial conjunctivitis, blepharitis, corneal abrasions

Application for amendment to include preservative-free (PF) formulation option – multi-dose bottle and single-dose units depending on patient compliance

The ERFC reviewed the supporting evidence, noting there is currently no preservative-free option on the formulary. Whilst preservative-free is a more expensive formulation, a preservative-free option is required for patients who do not tolerate the preservative containing drops.

The committee noted that Chloramphenicol eye drop formulations are available on the formulary for 'Bacterial Conjunctivitis' only, not for 'Blepharitis' or 'Corneal Abrasions', which recommend eye ointment only. As a result, further information has been requested from the applicants regarding the potential inclusion of Chloramphenicol 0.5% eye drops PF in 'Formulary Decisions' only to avoid

inadvertent use or to include in the 'Bacterial Conjunctivitis' pathway with an information note to advise use of the preservative-free formulation when clinically indicated, and to select the product of lowest acquisition cost.

ACTION: Diane Murray, NHS Lothian Formulary Pharmacist

The clinical team will be contact to review, and the amendment will receive final approval at the next East Region Working Group meeting.

ACTION: NHS Lothian Admin Team

3.2.8 Proxor

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
Proxor is indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2- agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta2- agonists.

COPD
Symptomatic treatment of patients with severe COPD (FEV1< 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

Application for amendment to include Proxor as a cost-saving alternative to Bibecfo.

The ERFC noted the Formulary Amendment submission as part of the Adult and Paediatric Asthma chapter review (item 2.3.1).

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.9 Thiamine Hydrochloride

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: Prophylaxis and treatment of Wernicke's encephalopathy

Application for amendment due to long-term manufacturing issue of Pabrinex IV and the discontinuation of Pabrinex IM. Boards have been using unlicensed parenteral Thiamine in the interim period; however, licensed Thiamine Hydrochloride is now available. As per SPS guidance, parenteral Thiamine (vitamin B1) is the recommended alternative to Pabrinex in the prevention and treatment of Wernicke's encephalopathy.

The ERFC noted the supporting evidence.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra Orphan Medicines Initial Assessment

3.3.1 Exagamglogene autotemcel: Casgevy (SMC2709) – *noted for information.*

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Tebentafusp: Kimmtrak (SMC2746)
3.4.2 Donanemab: Kisunla (SMC2687)
3.4.3 Fruquintinib: Fruzaqla (SMC2748)
3.4.4 Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film-coated tablet 90 mg / 90 mg / 120 mg / 6 mg: Genvoya (SMC2809)
3.4.5 Sarilumab: Kevzara (SMC2810)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

3.5.1 Eplontersen: Wainzua (SMC2755)

The ERFC noted the SMC abbreviated submission for Eplontersen: Wainzua (SMC2755).

Indication: For the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 or 2 polyneuropathies.

The ERFC agreed to classify Eplontersen: Wainzua (SMC2755) 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 Futibatinib: Lytgobi (SMC2661)

The ERFC noted the SMC abbreviated submission for Futibatinib: Lytgobi (SMC2661).

Indication: As monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

The committee acknowledged the supporting evidence, noting the proposed inclusion of Futibatinib: Lytgobi as an alternative to Pemigatinib as a second-line treatment option for patients with cholangiocarcinoma and an FGFR2 fusion. The inclusion of Futibatinib: Lytgobi is cost neutral as it will be a direct replacement for Pemigatinib, and will be used to treat 1-2 patients across SCAN per annum.

The ERFC agreed to classify Futibatinib: Lytgobi (SMC2661) 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

3.5.3 Dapagliflozin: Forxiga (SMC2763)

The ERFC noted the SMC abbreviated submission for Dapagliflozin: Forxiga (SMC2763).

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) or 20 mL/min/1.73 m^2 up to 45mL/min/1.73m^2, or
- an eGFR of 45 mL/min/1.73m^2 up to 90 mL/min/1.73m^2 and either:
    - a urine albumin-creatinine ratio (uACR) or 22.6 mg/mmol or more, or
    - Type 2 Diabetes Mellitus (T2DM).

Post-meeting note: The ERF includes advice for Dapagliflozin in the treatment of CKD (SMC2428).

The formulary decision entry for SMC2428 will be updated to reflect the new recommendations.

ACTION: NHS Lothian Admin Team

3.5.4 Bevacizumab gamma: Lytenava (SMC2744)

The ERFC noted the SMC abbreviated submission for Bevacizumab gamma: Lytenava (SMC2744).

Indication: in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD).

The ERFC agreed to classify Bevacizumab gamma: Lytenava (SMC2744) 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 Bimekizumab: Bimzelx (SMC2698)
3.7.2 Elafibranor: Iqirvo (SMC2714)
3.7.3 Alectinib: Alecensa (SMC2749)
3.7.4 Sodium thiosulfate: Pedmarqsi (SMC2730)

The ERFC noted that a FAF1 submission has been received for Sodium thiosulfate: Pedmarqsi (SMC2730) post-paper deadline. The FAF1 submission qualifies for pre-ERFC panel review and will be appraised at the meeting on June 18th, 2025. Feedback will be provided to the applicants, if required, and the FAF1 application will be reviewed at the next East Region Formulary Committee meeting.

3.7.5 Erdafitinib: Balversa (SMC2738)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, and 3.7.5 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

None noted.

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

None raised.

4.3 NHS Lothian

The ERFC discussed the previously circulated FAF1 Daridorexant: Quviviq (SMC2611) for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning; SMC restriction: in patients who have failed cognitive behavioural therapy for insomnia (CBT-I) or for whom CBT-I is unsuitable or unavailable.

The committee noted that the application was approved by NHS Lothian REAS Drug and Therapeutics Committee in April 2025. The discussion at REAS Drug and Therapeutics centred around the proposed 'Specialist Initiation' formulary flagging, with some members cautioning against SI and favouring primary care availability. The applicants have advised that the reluctance to switch the application to primary care comes mainly from concerns around cost and the need for wider stakeholder engagement from both primary and secondary care.

NHS Borders have communicated that they cannot support this application and have no support from their consultant psychiatry team either. Concerns were raised about polypharmacy and cost implications, with the Mental Health Clinical Pharmacy team stating there are too many unknowns regarding place in treatment, criteria, and indication, as well as a lack of experience in concurrent mental illness. In regard to NHS Fife, the application has been discussed with the deputy Medical Director and the Lead Clinical Psychiatrist, with wider consultation sought from experts, including from specialists in the adult sleep clinics. Further discussion with the Fife LMC will occur and feedback will be provided to the applicants.

The ERFC noted the small patient study with minimal clinical evidence presented in the application. The committee agreed that further evidence highlighting Daridorexant: Quviviq's clinical effectiveness is required, as well as wider stakeholder engagement from both primary and secondary care in support of the application. The ERFC did not support progression of the proposal for specialist initiation in a restricted group of patients. The ERFC agreed to share feedback to the applicants.

ACTION: NHS Lothian Admin Team

The ERFC acknowledged the recent collaborative NICE/SMC advice for Nirmatrelvir and Ritonavir (Paxlovid) and Molnupiravir: Lagrevio (SMC2556). Local Boards have been asked to review their current guidance based on new recommendations, confirm whether they will adopt the changes, advise on anticipated patient numbers and provide an update to the ERFC. It was noted that stock, which was previously free-of-charge, now has a cost, and, therefore, Boards have been advised to gather updated financial information and plan anticipated annual spend through local budget holders or finance teams. Boards have been advised to raise this through their usual financial planning processes.

Post-meeting note: The ERFC agreed to classify Molnupiravir: Lagrevio (SMC2556) as Routinely available in line with local or regional guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

5 Any other competent business

None noted.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 23 July 2025 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 11 June 2025 (for discussion at the pre-ERFC panel meeting on 18 June 2025).

FAF1s for consideration by the pre-ERFC panel should be submitted by 11 June 2025 (for discussion at the pre-ERFC panel meeting on 18 June 2025).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 08 July 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.