East Region Formulary

East Region Formulary Committee
Minutes

Date: 05 February 2025
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 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
Ryan Headspeath	Lead Pharmacist, Dermatology and Shared Care, 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
Sarah Tait	Lead Advanced Practitioner, NHS Borders

In attendance:
Reshma Chhana-Brown, Clinical Lead Pharmacist, NHS Lothian
Sandra Nash, Lead Pharmacist - Medicine of the Elderly and Stroke, NHS Lothian
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
Dr Konstantinos Dabos – Consultant, GI, NHS Lothian
Dr Paul Neary, Consultant – Cardiology, NHS Borders
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: Dr Andrew Watson. The Chair acknowledged the longstanding membership of Dr Watson, and on behalf of the East Region Formulary Committee, the Chair thanked Dr Watson for his invaluable work and contribution to the committee over the years.
- Joining – The Chair welcomed new members Dr Monica Szabo - Consultant Oncologist, NHS Lothian; Dr Grace Ding - Consultant Oncologist, NHS Lothian; Dr Konstantinos Dabos, Consultant, GI, NHS Lothian and Sarah Tait, Lead Advanced Practitioner, NHS Borders - Dr Monica Szabo and Dr Konstantinos Dabos sent apologies for this meeting.

1.2 Matters arising

1.2.1 ERFC December 2024 Item 3.1.6 FAF1 Follitropin delta: Rekovelle (SMC2670) was reviewed at the ERFC December meeting. The ERFC requested further clarity regarding the replaced therapy costings and whether Meriofert is to remain in the formulary choices.

The applicants have confirmed that they will continue to use all medicines included in the Adult 'Treatment of infertility' pathway, and that the inclusion of Follitropin delta: Rekovelle is as an addition rather than a replacement. The costings have been confirmed as accurate. Action completed.

1.2.2 ERFC December 2024 Item 3.1.8 FAF2 Dienogest 2mg tablets was reviewed at the ERFC December meeting. 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 ERFC acknowledged the revised Adult 'Treatment of endometriosis' pathway included with the submission, noting the updated prescribing guidance for Triptorelin to reflect current practice, as well as the inclusion of additional prescribing notes to support both licensed and off-label prescribing.

Additionally, the clinical team have confirmed that there are robust monitoring processes in place with reviews carried out in secondary care.

The committee noted that the REGAL "Recurrence of Endometriosis: A randomised controlled trial of clinical and cost-effectiveness of Gonadotrophin Releasing Hormone Analogues with add-back hormone replacement therapy versus repeat Laparoscopic surgery" study is currently underway, with a future review of the ERF recommendations welcomed upon the release of the study's results.

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

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 04 December 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 15 January 2025

The ERFC noted that NHS Lothian dietetics team have produced a streamlined list of oral nutritional supplements (ONS); whilst the list has not been produced on behalf of the East Region, the content has been approved through a local group of interested parties within Lothian and is intended to be hosted, when approved, on the ERF as well as on NHS Lothian staff intranet pages for dietetics, with signposting for relevant guidance in NHS Fife and NHS Borders, respectively.

It was also noted that work has been completed to create a list of Enteral Tube Feeding (ETF) products for NHS Lothian which will be hosted on the ERF.

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

None noted.

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Tirzepatide: Mounjaro (SMC2653) - *pre-ERFC panel review*

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

The ERFC discussed the submission in conjunction with 3.1.2 Semaglutide: Wegovy (SMC249).

Indication: For the treatment of obesity prioritised for use in those with a BMI of ≥38kg/m2 (≥35kg/m2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population) in the presence of at least one weight-related comorbidity.

For more information, refer to: Consensus statement: national criteria for the prioritisation of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and GLP-1 RA/glucose-dependent insulinotropic polypeptide receptor agonists (GIP RAs) for the treatment of obesity in NHS Scotland, NHS Scotland Publications.

The finance budget template was included with the FAF.

The proposed Adult and Child ERF 'Obesity' pathways were discussed, noting the feedback from NHS Lothian's clinical team - input from NHS Fife and NHS Borders is yet to be received. The inclusion of obesity treatments as joint position options is based on lack of comparative evidence as well as the limited experience of the GLP-1 RA/GIP RAs class of medicines for this indication. Further input is required from NHS Fife and NHS Borders clinical teams to reach a consensus on the medicine choices and the order of choices for the East Region.

The committee discussed the proposed 'Specialist Initiation' formulary flagging, with GP members of the committee noting that this may have a significant impact on primary care and raised concerns about the impact on existing service delivery. It was agreed that the initiation of the medicine must be carried out by a specialist clinician who may be working in any setting as outlined in the local board care pathways, and, therefore, the medicine is appropriate to be initiated in weight-management clinics and continued in a primary care setting. Currently, individual Board care pathways are being developed to facilitate prescribing.

The ERFC acknowledged the proposed development of shared care agreements by the NHS Lothian clinical team for GLP-1 RA/GIP RAs medicines. Each NHS Board plans to develop prescribing guidance which will be appraised and approved through local Board medicines governance processes. The ERFC recommends communication to advise that GLP-1RAs/GIPRAs for the treatment of obesity are included on the formulary, and that care routes to access these medicines could differ in each board and may not yet be agreed.

The ERFC agreed to classify FAF1 Tirzepatide: Mounjaro (SMC2653) 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

3.1.2 FAF1 Semaglutide: Wegovy (SMC2497) - *pre-ERFC panel review*

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

Indication: For the treatment of obesity prioritised for use in those with a BMI of ≥38kg/m2 (≥35kg/m2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population) in the presence of at least one weight-related comorbidity. For more information refer to Consensus statement: national criteria for the prioritisation of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and GLP-1 RA/glucose-dependent insulinotropic polypeptide receptor agonists (GIP RAs) for the treatment of obesity in NHS Scotland NHS Scotland - Publications

The finance budget template was included with the FAF.

The ERFC discussed the submission in conjunction with 3.1.1 FAF1 Tirzepatide: Mounjaro (SMC2653).

The ERFC agreed to classify FAF1 Semaglutide: Wegovy (SMC2497) 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

3.1.3 FAF1 Foslevodopa/foscarbidopa: Produodopa (SMC2574) - *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: treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.

SMC restriction: For use in patients not eligible for deep brain stimulation (DBS).

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

The ERFC reviewed the submission, noting the 2023 NICE review, which detailed trial data which highlighted the benefit of continuous subcutaneous infusion of foslevodopa/foscarbidopa compared with oral foslevodopa/foscarbidopa, facilitating prolonged symptom-free periods and shortening symptomatic periods. The committee, however, noted that there is limited evidence in support of foslevodopa/foscarbidopa as a direct comparison with the other medicines included in the Adult 'Treatment with advanced Parkinson's disease therapies' pathway. The committee, therefore, requested further clarity as to how patient treatment would be determined should foslevodopa/foscarbidopa be included in the pathway.

Post-meeting note: The applicants clarified that each advanced treatment has nuances that must be tailored to individual patient needs. As a result, treatment decisions will be made collaboratively between clinicians with the most comprehensive understanding of the patient and shared with the advanced MDT.

The committee acknowledged the relatively low patient numbers and queried whether the number of patients stated on the formulary application are already receiving treatment with the other medicines within the pathway, or if all proposed patients will all receive foslevodopa/foscarbidopa by subcutaneous infusion. The committee queried whether patients could potentially receive treatment with foslevodopa/foscarbidopa in the interim until DBS becomes an available treatment option.

Post-meeting note: The applicants confirmed that patient numbers were derived from an analysis of clinical coding, identifying individuals in advanced stages of Parkinson's disease who may be eligible. They also provided additional information stating that DBS is the gold-standard treatment, and, therefore, would be the first-line treatment option for eligible patients. Consequently, it is unlikely that foslevodopa/foscarbidopa would be used as a bridging treatment.

The committee acknowledged the NHS Lothian protocol provided with the submission, which details patient eligibility, and adverse effects as well as instructions for use and handing, and discontinuation of treatment. The committee, however, requested clarification on the availability of protocols for NHS Fife and NHS Borders, or if these boards intend to adopt the NHS Lothian guidance, where relevant.

The ERFC request clarification on guidelines for use in the other Boards or confirmation that the guideline with the submission is being adopted by the other Boards. The applicants are requested to respond with information on the recommended action by 18 March 2025.

ACTION: NHS Lothian Admin Team

In addition to the information detailed in the NHS Lothian protocol regarding discontinuation of treatment, the committee requested further information regarding the estimated length of treatment.

Post-meeting note: The applicants have confirmed that length of treatment is evaluated in collaboration with expert consensus through the NHS Lothian advanced treatments MDT, and will be determined on a case-by-case basis following biannual reviews in specialist clinics.

The ERFC agreed to classify FAF1 Foslevodopa/foscarbidopa: Produodopa (SMC2574) 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 Relugolix: Orgovyx (SMC2678)

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: Prostate cancer:

- for the treatment of adult patients with advanced hormone-sensitive prostate cancer
- for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy
- as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.

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

The ERFC reviewed the submission, with evidence to support the efficacy and safety of Relugolix: Orgovyx for the treatment of prostate cancer provided by the HERO study - an international, open-label, randomised, phase III study.

It was noted that due to the significant cost difference between Leuprorelin and the LHRH antagonists, Leuprorelin will remain the recommended standard of care for men commencing androgen deprivation therapy; however, Relugolix (an oral LHRH antagonist) is considered to be a safer treatment option for patients with previous Major Adverse Cardiac Event (MACE – defined as myocardial infarction and stroke).

The committee discussed the draft 'Treatment of prostate cancer – Endocrine therapies – specialist management' pathway included with the submission, with clinical teams in support of Relugolix as joint third-line treatment option alongside Degarelix, after initial treatment with Leuprorelin and Bicalutamide. It was noted that Leuprorelin is a Gonadotrophin-releasing hormone (GnRH) analogue, and, therefore, a link to the Scottish Drug Tariff 'Part 12: Schedule 2 – drugs not to be prescribed under certain circumstances' document is required within the prescribing notes.

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

The ERFC requested clarification on the financial information presented in the FAF1 application and the accompanying appendix, with differing estimates for replacement costs in the FAF1 compared to the total cost per patient per annum of Degarelix in the appendix.

Post-meeting note: The applicants have confirmed that the replaced costs include a proportion of patients being treated with leuprorelin and a proportion of patients with Degarelix. Action completed.

The ERFC agreed to classify FAF1 Relugolix: Orgovyx (SMC2678) 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

3.1.5 FAF1 Pembrolizumab: Keytruda (SMC2660)

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: First-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS) 1-4. Nivolumab already in place for CPS > 5.

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

The ERFC reviewed the submission, with supporting evidence from the KEYNOTE-590 "Pembrolizumab plus chemotherapy versus chemotherapy alone for first-line treatment of advanced oesophageal cancer" trial.

The committee reviewed the appendix included with the submission, which outlines the estimated annual patient numbers, associated costings, and the impact on pharmacy and nursing resources. In addition, the protocol provides further details regarding pre-treatment evaluations, monitoring requirements, and potential adverse effects.

The ERFC agreed to classify FAF1 Pembrolizumab: Keytruda (SMC2660) 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

3.1.6 FAF3 Apixaban

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: Superficial thrombophlebitis (STP).

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

The ERFC reviewed the submission, acknowledging the proposed off-label use of Apixaban (in adults only) for the treatment of superficial thrombophlebitis, primarily in outpatient settings. It was noted that the proposed inclusion of Apixaban on the ERF provides an alternative, less invasive option to

Dalteparin which is currently used off-label for the same indication. The committee acknowledged that NHS Fife DVT service are currently using Apixaban off-label for this indication.

The ERFC, noted that the evidence summary provided compares Fondaparinux with Rivaroxaban. The committee expressed concerns regarding the significant lack of clinical evidence directly supporting the use of Apixaban for the proposed indication, highlighting the absence of published studies supporting its use in STP and the omission of Apixaban in the BMJ Best Practise. The committee accepted that Apixaban would be an appropriate choice when the STP is designated for therapeutic anticoagulation treatment, mirroring the treatment of DVT. However, evidence of efficacy and safety of the suggested dosing regimen of Apixaban for STP > 5cm in length and >3cm from the saphenofemoral or saphenopopliteal junction has not been provided. The ERFC noted that other UK centres use Fondaparinux and/or Rivaroxaban. The ERFC request applicants to reconsider Fondaparinux and/or Rivaroxaban (off-label) as alternatives for proposed formulary inclusion given available evidence for safety and efficacy as well as peer support for use. The ERFC further noted that Rivaroxaban is off-patent. The committee recommend applicants involve clinicians from the region involved in the care of STP for opinion on proposed formulary choices, including all clinical specialities using the relevant medicines in NHS Fife and NHS Borders. If an alternative option is preferred after further review, the ERFC requests the applicants resubmit for formulary inclusion of the preferred alternative(s).

It was also noted that the Clinical Director sign-off for NHS Fife and NHS Borders is incorrect as the individuals listed do not have budgetary oversight.

If Apixaban remains the preferred choice amongst local specialists, the ERFC requests a revised application with corrected CD support. In addition, further clinical evidence supporting the use of Apixaban for STP (published data and/or local clinical data) as well as information on potential future data collection is required. The applicants are requested to respond with information on the recommended action by 18 March 2025.

ACTION: NHS Lothian Admin Team

The committee further noted that the provided guideline requires review by wider Drug and Therapeutic Committees in the respective Boards (or a specialist group on behalf of the ADTC e.g. NHS Borders Anticoagulant Group and NHS Lothian Thrombosis Committee), as the proposed use of the medicine may impact other clinical specialties, and thus requires additional critical appraisal. Further clarification is also required as to whether NHS Fife and NHS Borders support the NHS Lothian guidance or whether they plan to do develop or update their own local guidelines to reflect.

The ERFC requested clarification on guidelines for use in the other Boards or confirmation that the guideline included with the submission is being adopted by the other Boards. The applicants are requested to respond with information on the recommended action by 18 March 2025.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Apixaban 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

3.1.7 FAF3 Tranexamic Acid

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: Reduction of blood loss in patients at the time of surgery. TXA should be offered (unless the patient has contraindications) as follow: primary unilateral total hip replacement; primary bilateral total hip replacement; primary unilateral total knee replacement; primary bilateral total knee

replacement; unilateral revision hip replacement; unilateral revision knee replacement; colorectal resection for any indication (open or laparoscopic); open arterial surgery such as scheduled (non-ruptured) aortic aneurysm repair, infrainguinal femoropopliteal or distal bypass; primary coronary artery bypass graft valve replacement with or without coronary artery bypass graft; simple or complex hysterectomy; cystectomy; nephrectomy; fracture neck of femur (arthroplasty).

The ERFC noted that the submission is as a result of the Scottish Government Infected Blood Inquiry, published in November 2024, and the recommended use of Tranexamic Acid in elective surgeries to reduce the need for blood transfusions.

The committee acknowledged that patient numbers per annum and the associated costings are difficult to quantify, however, NICE Clinical Guidance referenced throughout the application provides a robust evidence base for the use of Tranexamic Acid in elective surgeries.

It was noted that the formulary application has previously received sign-off from the ADTC in each Board, with agreement across the East Region that a formulary pathway is not required, and the inclusion of Tranexamic Acid on the ERF is most suitable in the Formulary Decisions section only.

The ERFC agreed to classify Tranexamic Acid 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

3.1.8 FAF3 Tenecteplase

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: In adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage (licensed and SMC-approved indication). Additionally, as an alternative to alteplase for use in wake-up stoke or onset over 4.5 hours in the context of advanced imaging (in line with British and Irish Association of Stroke Physicians (BIASP) consensus document October 2024).

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

The ERFC reviewed the submission, noting that proposed dosing for the licensed indication is documented in the summary of product characteristics (SPC) and will also be used for the off-label indications. Prescribers will be stroke consultants and stroke registrars, as well as those deemed appropriate within emergency departments following assessment by the stroke team who provide an on-call service for the region, with adequate stock available in the UK for both licensed and off-label use of medicine.

It was noted that patient selection criteria will be by the acute service only and will be for use in adults (18 years and older) only. The local treatment protocol provided with the submission from NHS Fife has been approved by the managed service Drug and Therapeutic Committee, with additional advice provided by the clinical team in NHS Lothian as to how they will assess patients and adhere to the guidance.

The ERFC acknowledged the queries previously raised at the East Region Working Group meeting regarding the lack of evidence presented by the British and Irish Association of Stroke Physicians consensus document to detail the clinical effectiveness of Tenecteplase for the proposed indication, with the ERWG requesting additional information on the potential for future clinical trials and the recruitment of appropriate patients to generate evidence for Tenecteplase's off-label use. In response,

the applicants confirmed that NHS Lothian and the wider East region have comprehensive Morbidity and Mortality measures in place to monitor all adverse events for patients receiving intravenous thrombolysis; measures which are currently applied to Alteplase and will continue for Tenecteplase. Additionally, the applicants clarified that there are no current plans to further investigate the efficacy of Tenecteplase or conduct additional data collection

The ERFC agreed to classify Tenecteplase 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 Aflibercept 8mg

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

Indication: Neovascular age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DMO)

Application for amendment due to the availability of a new, longer-acting presentation of Aflibercept 8mg or 114.3mg/ml solution for injection.

The ERFC reviewed the supporting evidence.

The committee acknowledged that biosimilar medicines are expected to be available within the year, and noted that the treatment choice will be determined by clinical teams in each individual Board based on operational arrangements and capacity constraints.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Ceyesto – Melatonin 1mg/ml oral solution SF

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 insomnia

Application for amendment to include the Ceyesto brand of Melatonin 1mg/ml oral solution sugar free, which is currently included on the ERF for the treatment of insomnia in children under Specialist Initiation formulary flagging.

The ERFC discussed the supporting evidence, noting that there are now multiple licensed preparations of Melatonin on the market with varying therapeutic indications which has led to some concern over the levels of certain excipients that have been included e.g. sorbitol, propylene glycol and glycol ethanol.

The committee notes that Ceyesto has the widest variability in licensing among the licensed melatonin oral solution products, and ,therefore, would be the most appropriate choice. Additionally, the applicants confirmed that community paediatricians are in support of the inclusion of the Ceyesto brand of Melatonin, with Ceyesto manufacturers confirming that there is stock availability in excess of a year's market demand.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Naloxone

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: Opioid overdose

Application for amendment to include new 1.26mg/0.1ml nasal spray unit dose strength which has been formulated to balance the dose required to reverse an opioid overdose without triggering acute withdrawal symptoms. The nasal spray offers a needle-free solution that requires no prior product assembly, thus reducing risk of delay in administering dose due to difficulty with dexterity during assembly, of needle-stick injury, and of missing needles at time of emergency. The amendment seeks to remove the specialist initiation designation.

The committee noted that the inclusion of an additional Naloxone formulation and removal of the specialist initiation designation supports NHS Scotland's National Naloxone Programme as well as the Scottish Government's key initiative to reduce drug-related deaths.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.4 Formulary Amendment Sertraline 50mg/5ml oral suspension

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: Generalised anxiety disorder, obsessive compulsive disorder, panic disorder, social anxiety disorder and depression.

Application for amendment due to the availably of new licensed Sertraline 50mg/5ml oral suspension.

The ERFC discussed the supporting evidence, noting that the new licensed Sertraline 50mg/5ml oral suspension will replace the unlicensed product in a number of pathways throughout the ERF. This change will ensure that the information presented on the ERF is in alignment with the Neonatal and Paediatric Pharmacy Group who no longer recommend use of the unlicensed formulation, as well as the MHRA who advise against the use of unlicensed medicines when a licensed alternative is available.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.5 Sodium Chloride

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were noted. Clinical team support received from NHS Lothian only as proposed use is within specialist service within NHS Lothian.

Indication: Bronchiectasis

Application for amendment to change formulary flagging from SUO to SI.

The ERFC noted the supporting evidence.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.6 APO-go POD

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 motor fluctuations in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication.

Application for the amendment due to discontinuation of APO-go Pre-Filled Syringe, with supplies exhausted from early April 2025.

The ERFC discussed the supporting evidence, noting that the replacement of APO-go Pre-Filled Syringe with the APO-go POD is in alignment with the Scottish MSAN, with no subsequent cost impact.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra Orphan Medicines Initial Assessment

Fosdenopterin powder for solution for injection: Nulibry (SMC2624) – *for noting.*

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Bictegravir / emtricitabine / tenofovir alafenamide: Biktarvy (SMC2760)
3.4.2 Rozanolixizumab: Rystiggo (SMC2761)
3.4.3 Levodopa / carbidopa monohydrate / entacapone: Lecigon (SMC2507)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

3.5.1 Ciclosporin: Cequa (SMC2739)

The ERFC noted the SMC abbreviated submission for Ciclosporin: Cequa (SMC2739).

Indication: Treatment of moderate-to-severe Dry Eye Disease (keratoconjunctivitis sicca) in adult patients who have not responded adequately to artificial tears.

SMC restriction: Severe keratitis in adult patients with Dry Eye Disease.

The ERFC discussed the supporting evidence, noting that request to include the Cequa 0.9 mg/ml eye drops as joint fourth-line treatment option alongside Ikervis 1mg/ml eye drops in the Adult 'Treatment of severe dry eye' pathway. The applicants confirmed that both medicines offer similar efficacy, and the inclusion of Cequa provides an additional treatment option for patients with low tolerance to Ikervis. The ERFC recommend that Ophthalmology teams consider the removal of Ikervis 1mg/ml eye drops at a future review.

The ERFC agreed to classify Ciclosporin: Cequa (SMC2739) 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

3.5.2 Risankizumab: Skyrizi (SMC2686)

The ERFC noted the SMC abbreviated submission for Risankizumab: Skyrizi (SMC2686).

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

The ERFC agreed to classify Risankizumab: Skyrizi (SMC2686) 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 Ublituximab: Briumvi (SMC2731)

The ERFC noted the SMC abbreviated submission for Ubilituximab: Briumvi (SMC2731).

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 ERFC agreed to classify Ubilituximab: Briumvi (SMC2731) 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 Crovalimab: PiaSky (SMC2728)

The ERFC noted the SMC abbreviated submission for Crovalimab: PiaSky (SMC2728).

Indication: As monotherapy for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH):

- In patients with haemolysis with clinical symptom(s) indicative of high disease activity.
- In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months.

SMC restriction: Under the advice of the national PNH service.

The ERFC agreed to classify Crovalimab: PiaSky (SMC2728) 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 Zanubrutinib: Brukinsa (SMC2684)
3.7.2 Vamorolone: Agamree (SMC2721)
3.7.3 Sirolimus: Hyftor (SMC2710)
3.7.4 Relugolix / estradiol / norethisterone acetate: Ryeqo (SMC2666)
3.7.5 Danicopan: Voydeya (SMC2675)
3.7.6 Iptacopan: Fabhalta (SMC2676)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, and 3.7.6 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

Upon the resignation of NHS Lothian co-Chair, Dr Andrew Watson, the ERFC noted that communication has been sent out to wider governance committees within the NHS Lothian for a Chair nomination. The new co-Chair is expected to be appointed prior to the next meeting.

5 Any other competent business

None noted.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 02 April 2025 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 26 February 2025 (for discussion at the pre-ERFC panel meeting on 05 March 2025).

FAF1s for consideration by the pre-ERFC panel should be submitted by 26 February 2025 (for discussion at the pre-ERFC panel meeting on 05 March 2025).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 18 March 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.