# East Region Formulary

**East Region Formulary Committee**
**Minutes**

---

Date: 17 September 2025
Time: 2.00pm – 3:45pm
Location: MS Teams

---

**Present:**

| | |
|---|---|
| Farrah Al-Ghita | Senior Pharmacist - Renal, NHS Fife |
| Malcolm Clubb | Director of Pharmacy (Co-Chair), NHS Borders |
| Dr Konstantinos Dabos | Consultant, GI, NHS Lothian |
| Dr Grace Ding | Consultant Oncologist, NHS Lothian |
| Dr Joan Egerton | GP, NHS Fife |
| Dr Tariq Farrah | Consultant - Renal, NHS Lothian |
| Ryan Headspeath | Senior Clinical 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 |
| Dr Iain Macintyre | Consultant – Renal (Co-Chair), NHS Lothian – in the Chair |
| Noreen Mohammed | Senior Practice Pharmacist, NHS Fife |
| Diane Murray | Formulary Pharmacist, NHS Lothian |
| Fraser Notman | Senior Pharmacist – Medicines Management, NHS Fife |
| Dr Jo Rose | GP, NHS Lothian |

**In attendance:**
Ommar Ahmed, Clinical Pharmacy Lead, NHS Lothian – *left at 14:50*
Julia Anderson, Consultant Haematologist, NHS Lothian – *left at 14:50*
Maggie Davidson, Pharmacist - Renal, NHS Lothian – *left at 14:50*
Andrew Page, Consultant Haematologist, NHS Lothian – *left at 14:50*
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 David Griffith, Consultant – Microbiologist, NHS Fife
Dr Paul Neary, Consultant – Cardiology, NHS Borders
Cathryn Park, Deputy Director of Pharmacy, NHS Borders
Dr Monica Szabo, Consultant Oncologist, NHS Lothian
Sarah Tait, Lead Advanced Practitioner, NHS Borders

---

## 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 Farrah Al-Ghita - Senior Pharmacist - Renal, NHS Fife and Noreen Mohammed, Senior Practice Pharmacist, NHS Fife.

**1.2 Matters arising**

**1.2.1** ERFC 23.07.25 Item 3.1.10 FAF1 Elranatamab: Elrexfio (SMC2669) was reviewed at the July ERFC meeting. The ERFC requested named CD sign off from NHS Fife as whilst Oncology applications are approved through SCAN for the East Region, separate Clinical Director sign-off is required for Malignant Haematology applications in each respective Board.

Following discussions within NHS Fife, it has been confirmed that all Oncology and Malignant Haematology applications are considered approved once they have been reviewed by the NHS Lothian governance process and approved via SCAN. No further action is required. Action complete.

**1.2.2** ERFC 23.07.25 Item 3.1.10 FAF1 Loncastuximab tesirine: Zynlota (SMC2609) was reviewed at the July ERFC meeting. The ERFC requested named CD sign off from NHS Fife as whilst Oncology applications are approved through SCAN for the East Region, separate Clinical Director sign-off is required for Malignant Haematology applications in each respective Board.

Following discussions within NHS Fife, it has been confirmed that all Oncology and Malignant Haematology applications are considered approved once they have been reviewed by the NHS Lothian governance process and approved via SCAN. No further action is required. Action complete.

**1.2.3** ERFC 23.07.25 Item 3.1.9 FAF1 Selpercatinib: Retsevmo (SMC2370) was reviewed at the July ERFC meeting. The ERFC requested further information from the applicants to provide clarification on patient access to Cabozantinib and Vandetanib for earlier lines of therapy, given that these treatments are not approved by the SMC.

The applicants provided clarification that eligible patients are being considered for access through the current non-formulary governance processes for access to Cabozantinib and Vandetanib.

The ERFC agreed that Selpercatinib: Retsevmo (SMC2370) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Selpercatinib: Retsevmo (SMC2370) 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**

**2 Governance**

**2.1 East Region Formulary Committee (ERFC) meeting minutes 23 July 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 27 August 2025**

The minutes of the ERWG meeting on 27 August 2025 were noted for information.

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

**2.3.1 ERF Adult & Child - Low molecular weight heparins (LMWH)**

The ERFC discussed the amendment in conjunction with 3.1.7 FAF3 Enoxaparin.

The committee acknowledged the amendment, which proposes to switch the preferred low molecular weight heparin (LMWH) from Dalteparin to Enoxaparin in a number of treatment pathways throughout the formulary. This change is primarily driven by a significant increase in the cost of Dalteparin, which would result in substantial financial pressure if retained as the first-line treatment option. The change

has been supported by multidisciplinary teams across the East Region, with a target implementation date of October 2025 in NHS Lothian.

Enoxaparin has been added to several formulary pathways, including for the Adult treatment and prophylaxis of venous thromboembolism (VTE), treatment of acute Deep Vein Thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism, acute treatment of pulmonary embolism (PE), ST-elevation myocardial infarction (STEMI), and unstable angina. In paediatrics, Enoxaparin has been added for acute treatment of PE and DVT, while Dalteparin remains preferred for prophylaxis due to its once-daily dosing advantage. The preferred brand is Inhixa, except for the 300mg/3ml solution for injection vials, which are available only as Clexane. Syringe graduation details have also been clarified to ensure safe dosing, particularly in paediatric settings. Dalteparin will remain on formulary as an alternative.

Updates to relevant Formulary Decision entries will be made, including Enoxaparin: Clexane SMC (380/07) for Myocardial infarction with ST-segment elevation (STEMI) which will now be considered 'Routinely available in line with local or regional guidance'. Required updates to other formulary decision entries will also be made.

New pathways have also been created for Adult 'Anticoagulation - prevention and treatment of thrombotic events' and 'Anticoagulation in patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy', as well as 'Prevention of clotting in extracorporeal circuits'. A draft pathway for the treatment of superficial thrombophlebitis (STP) is on hold pending further input from regional experts on Apixaban use.

Specialist Initiation (SI) formulary flagging has been applied to Enoxaparin for all indications except for the prevention of clotting in extracorporeal circuits in adult patients, which is designated as Specialist Use Only. SI flagging covers prescribing under the care of a hospital consultant, including generalists, junior team members, and GPs acting on specialist advice.

The ERFC acknowledged that implementation planning has been robust across the East Region, with confirmation from national procurement on Enoxaparin supply chains, alongside plans for additional staff training and the future adaptation of NHS Lothian's guidelines by NHS Fife and NHS Borders.

***Post-meeting note**:* Local experts have recommended that enoxaparin be omitted from the Adult pathway for thromboprophylaxis post-MI at present whilst supporting guidelines are under review. In the meantime, the ERF will signpost to local specialist advice.

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

**ACTION: NHS Lothian Admin Team**

### 2.3.2 ERF Adult & Child – Skin, GI, Musculoskeletal and Joint disease (Wezenla PFP)

The amendment is in conjunction with 3.2.4 Formulary Amendment Ustekinumab (Wezenla).

The ERFC noted the inclusion of new Ustekinumab biosimilar pre-filled pens in relevant Adult and Child Skin, Gastrointestinal, and Musculoskeletal treatment pathways.

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

**ACTION: NHS Lothian Admin Team**

### 2.4 Tirofiban and Prasugrel SBAR

The committee acknowledged the NHS Lothian Neurology team's request to add Tirofiban and Prasugrel to the East Region Formulary. These medicines were previously approved in 2016 for use at the Edinburgh tertiary centre in aneurysm treatment, but were missed during the East Region

Formulary project due to being listed as 'additional list' items rather than incorporated within a formal treatment pathway.

The Neurology team confirmed that they do not intend to include these medications in a treatment pathway but stated that the use of Tirofiban and Prasugrel remains standard practice. Both medicines are routinely used by NHS Lothian's Department for Clinical Neurosciences (DCN), which provides neurosurgical services on behalf of the East Region. As a result, no new service or financial impact is anticipated.

The ERFC were in support of the proposed inclusion of Tirofiban (Specialist Use Only) and Prasugrel (Specialist Initiation) in the Formulary Decisions section of the ERF.

Prasugrel Indication: Patients undergoing intracranial flow diverter stenting who are resistant to clopidogrel on VerifyNow assay.

The ERFC agreed to classify Prasugrel as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicines.

Tirofiban Indication: Second-line rescue treatment of thromboembolic complications during endovascular treatment of cerebral aneurysms (where aspirin is contra-indicated or has been ineffective). Patients are routinely pre-medicated with IV heparin.

The ERFC agreed to classify Tirofiban 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 New Medicines

## 3.1 Formulary Application Forms (FAF)

### 3.1.1 FAF1 Avacopan: Tavneos (SMC2578)

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 all three Boards.

Indication: In combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

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

The ERFC reviewed the submission, noting evidence presented in the ADVOCATE study which showed that Avacopan demonstrated superiority to Prednisone over a one-year treatment period and provides clinically meaningful benefits for patients with severe GPA or MPA.

It was noted that only a small number of patients across the UK have required Avacopan treatment beyond one year, with extended use generally reserved for those intolerant to alternative therapies. The committee also acknowledged that within the East Region, Avacopan is currently used in a limited number of patients, with clinical teams appropriately restricting its use to those most likely to benefit from minimising or avoiding glucocorticoid use.

Avacopan is currently available via Homecare in NHS Lothian and NHS Borders, but not yet implemented in NHS Fife. Each Board's respective Renal service retains ownership of the treatment, with strict monitoring protocols in place including safety checks, liver function tests, and infection surveillance.

The ERFC agreed to classify FAF1 Avacopan: Tavneos (SMC2578) 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 Erdafitinib: Balversa (SMC2738)

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 treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting.

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

The ERFC reviewed the submission, noting that use of Erdafitinib represents a targeted therapy approach applicable to a very small patient population. Evidence to support the use of Erdafitinib for the proposed indication comes from the THOR study, which demonstrated that Erdafitinib treatment resulted in a median survival of 15.9 months compared to chemotherapy. Erdafitinib is considered to fill an unmet treatment need for patients with metastatic urothelial carcinoma who have FGFR2 or FGFR3 mutations as there are limited effective treatment options.

It was noted that Erdafitinib requires FGFR mutation testing, but no approved or funded testing pathway currently exists. The committee recognised that this is a wider issue within Oncology; however, acknowledged that discussions are ongoing between the manufacturer and relevant pathology committees to resolve the testing issue. Despite the testing gap, the medicine is considered clinically and cost-effective, and safe.

The ERFC agreed that Erdafitinib: Balversa (SMC2738) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Erdafitinib: Balversa (SMC2738) 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 Ivosidenib: Tibsovo (SMC2664)

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 Borders.

Indication: As monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy.

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

The ERFC reviewed the submission, with Ivosidenib monotherapy proposed for inclusion in line with SMC recommendations for second-line use following Gemcitabine and Durvalumab. As a result, it is expected that Ivosidenib will replace CAPOX.

Evidence to support the use of Ivosidenib for this indication from the ClarIDHy study, which noted that Ivosidenib significantly improved progression-free survival by around 1.3 months compared to placebo with Ivosidenib regarded as a therapeutic advancement for the proposed indication due to its targeted mechanism of action, efficacy, and convenient oral administration.

The committee discussed concerns regarding long-term funding for IDH1 mutation testing. The manufacturer has agreed to cover testing for the first 12 months, but responsibility will shift to the NHS thereafter. It was noted that the IDH1 R132 mutation is found in approximately 15% of intrahepatic cholangiocarcinomas, meaning many patients will be screened to identify a small number of eligible candidates. However, based on current data, the East Region is likely to have fewer than three eligible patients at any given time.

A minor discrepancy was identified between the patient numbers reported for NHS Borders and NHS Dumfries & Galloway in the formulary application and the accompanying appendix.

***Post-meeting note:*** A revised application has been received with patient numbers corrected to match the appendix.

The ERFC agreed that Ivosidenib: Tibsovo (SMC2664) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Ivosidenib: Tibsovo (SMC2664) 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 Nivolumab + Relatlimab: Opdualag (SMC2645)

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 advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older.

The clinical management guideline, 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 Nivolumab + Relatlimab for this indication from the ongoing RELATIVITY-047 study. It was noted that Nivolumab + Relatlimab exhibited higher toxicity compared to Nivolumab alone, including a higher incidence of severe adverse events. However, most adverse events were mild to moderate, and the safety of the combination treatment was considered manageable with no new safety concerns identified compared to Nivolumab alone.

The committee noted an estimated 5 eligible patients in year 1, increasing to around 10 patients in year 2 in the SCAN region. The clinical team advised that they plan to restrict use beyond the SMC approval and only use Nivolumab + Relatlimab in patients who are not fit enough for first-line treatment with line Ipilimumab/Nivolumab, and prefer Nivolumab + Relatlimab over Pembrolizumab.

The ERFC agreed that Nivolumab + Relatlimab: Opdualag (SMC2645) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Nivolumab + Relatlimab: Opdualag (SMC2645) 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 Polatuzumab vedotin: Polivy (SMC2525)

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.

Indication: In combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL).

**SMC restriction**: patients with an International Prognostic Index (IPI) score of 2 to 5 Polatuzumab vedotin, in combination with R-CHP, resulted in a statistically significant improvement in investigator-assessed progression-free survival compared with rituximab, cyclophosphamide, vincristine, doxorubicin and prednisone (R-CHOP).

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

The ERFC reviewed the submission, noting the evidence presented in the POLARIX which found that pola-R-CHP significantly improved progression-free survival compared to the standard R-CHOP treatment after a median follow-up of 28 months. There is a very specific cohort of patients with for which Polatuzumab vedotin is to be used, including patients under 80 years old, have non-GC subtype, IPI score of 2-5 with no significant GI comorbidities; thereby influencing the estimated patient numbers per annum across the East Region.

It was noted that the treatment regimen will initially be given over two days before switching to a one-day treatment schedule. Whilst this places some additional pressure on local Oncology units, it is considered manageable. The ERFC acknowledged that initial treatment cost is considerable; however, this is balanced by lower costs from fewer subsequent treatments and reduced use of additional resources as a consequence of disease progression. The SMC financial assessment found the treatment to be cost-effective in the long term.

The ERFC agreed that Polatuzumab vedotin: Polivy (SMC2525) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Polatuzumab vedotin: Polivy (SMC2525) 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 FAF2 Methylprednisolone acetate suspension for injection vials (Depo-Medrone)

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: Keloid Scar Management.

The finance budget template was included with the FAF.

The ERFC reviewed the submission, noting that the proposed use is in alignment with the licensed indication for keloid scars, and the dose (20-40mg, up to 4 injections) is consistent with the SPC.

Methylprednisolone acetate suspension for injection vials is intended to replace licensed Triamcinolone, which is now discontinued. An unlicensed alternative has been identified and can be prescribed by doctors, however, nurses administering the medication under a PGD require a licensed preparation.

The ERFC noted that prevalence and incidence figures are based on NHS Lothian clinic data, with limited extrapolation to NHS Borders and NHS Fife. Whilst not perfectly aligned with financial estimates, there is minimal cost impact with no additional service implications. The committee also acknowledged that despite the limited clinical evidence presented in the application, the indication is well-established and the safety profile is comparable to that of Triamcinolone.

The ERFC agreed to classify FAF2 Methylprednisolone 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**

### 3.1.7 FAF3 Enoxaparin

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.

The ERFC discussed the submission in conjunction with 2.3.1 ERF Adult & Child - Low molecular weight heparins (LMWH).

Indication:
1. Prevention of thrombus formation in extra corporeal circulation during haemodialysis (licenced indication but off label dosing).
2. Prophylaxis of venous thromboembolic disease in CrCl15ml/min) or renal replacement therapy
3. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in CrCl 15ml/min) or patients on renal replacement therapy
4. Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI) in CrCl <20ml/min or patients on renal replacement therapy (licensed >15ml/min but used if <20ml/min as used in place of fondaparinux.

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

The ERFC reviewed the submission, noting that whilst there are no large randomised controlled trials supporting use of Enoxaparin for the proposed indications, available evidence from small pharmacokinetic studies and extensive UK renal unit experience suggests that Enoxaparin is at least as effective as Dalteparin when used at lower doses, with no increased risk of bleeding.

The committee noted that whilst the BNF recommends a 1mg/kg dose for indication 1, clinical experience from other UK renal units supports using lower doses that are both clinically safe and effective. Upon review of the application at the East Region Working Group (ERWG), further evidence from these units was requested to justify deviating from the licensed dosing. In response, the clinical team provided data from several UK renal units (including NHS Ayrshire & Arran, NHS Leeds, and NHS Portsmouth) confirming widespread use of the lower-dose Enoxaparin regimen in haemodialysis. The clinical team explained that their protocol pragmatically substitutes Dalteparin doses (2500 and 5000 units) with equivalent Enoxaparin doses (20mg and 40mg, respectively) in line with current NHS Lothian dialysis practice. The team highlighted that this simplified dosing reduces the risk of dosing errors.

Regarding the use of subcutaneous Enoxaparin for thromboprophylaxis in renal failure, the committee acknowledged the question raised at the previous ERWG meeting as to why use of unfractionated heparin is not preferred for thromboprophylaxis in patients with severe renal impairment (<15 mL/min). Although unfractionated heparin was historically used within NHS Lothian, Enoxaparin provides simplified administration and standardisation, especially in dialysis settings. Upon request, the clinical team presented additional evidence from a large observational study of 7,000 dialysis patients (one-third receiving subcutaneous enoxaparin, two-thirds unfractionated heparin) which showed no difference in rates of bleeding or clotting events between the two groups. This supports the safety and efficacy of Enoxaparin as an alternative to unfractionated heparin for this indication. The clinical team additionally confirmed that unfractionated heparin is not preferred as it is approximately four times more expensive than Dalteparin, and its twice-daily injection schedule increases both the treatment burden on patients and the workload for nursing staff, compared to the once-daily dosing of Enoxaparin.

In regard to the accompanying thromboprophylaxis guidelines, the applicants confirmed that routine anti-Xa monitoring is not recommended. This decision was made following multidisciplinary discussions and is based on the rationale that anti-Xa testing is rarely performed correctly and seldom leads to changes in treatment. It was noted that Enoxaparin's pharmacokinetics suggest limited risk of accumulation in most patients, and clinical monitoring is considered more important than laboratory testing. Whilst some other Boards recommend monitoring at 10 days in patients with poor kidney function (CrCl <30 mL/min), the clinical team felt this approach would offer limited value and add unnecessary complexity. Anti-Xa monitoring may be considered for higher-risk patients, such as those with very low or high body weight, but it will not be standard practice.

The ERFC agreed to classify FAF3 Enoxaparin as Routinely available in line with local or regional guidance. Included on the ERF for indication 1 - Specialist Use Only; indication 2,3, and 4 - Specialist Initiation. 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 FAF4 Isoniazid/Rifampicin/Pyrazinamide/Ethambutol: Rimstar/Voractiv

The ERFC noted and discussed the previously circulated FAF4 submission. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: Initial treatment of tuberculosis.

The finance budget template was included with the FAF.

The ERFC reviewed the submission, noting that the holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication, with SMC not recommended advice SMC876/13. The ERFC accepted a FAF4 application as the advice is > 10 years old.

Rimstar/Voractiv is a fixed-dose combination tablet containing four first-line anti-tuberculosis (TB) drugs: isoniazid, rifampicin, pyrazinamide, and ethambutol, in World Health Organisation (WHO) approved doses. Current TB treatment in the UK often involves prescribing the four drugs individually, whilst Rimstar/Voractiv offers a simplified regimen in a single tablet form, which aligns with WHO and NICE recommendations.

Proposed use in patients with Pulmonary and Non-Pulmonary sensitive TB who are unable to manage a large tablet burden, and otherwise at risk of treatment failure. Two non-inferiority multinational randomised trials, a systematic review, and a Cochrane review have demonstrated that fixed dose, four drug combination tablets are equivalent in efficacy to single tablets in smear-positive pulmonary

tuberculosis in terms of smear conversion, culture conversion, failure, death and relapse. Additionally, patient satisfaction was higher among those treated with fixed-drug regimens.

In response to concerns raised at a previous East Region Working Group meeting regarding how prescribing will be monitored and managed, the clinical team have confirmed that TB services in each Board are small and managed by specialists, with all treatment decisions made on an individual basis by the TB team. Although excessive use is not anticipated, usage and costs will be monitored through financial reports and MDT meetings. The clinical team additionally clarified that all prescriptions for Rimstar/Voractiv will be issued in secondary care, either by a TB specialist or in consultation with one. Prescribing in general practice is not anticipated.

The ERFC agreed to classify FAF4 Isoniazid/Rifampicin/Pyrazinamide/Ethambutol: Rimstar/Voractiv 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**

### 3.2 Formulary Amendment Form

#### 3.2.1 Raltegravir

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: HIV treatment and PEP.

Application for amendment to include Raltegravir 600mg generic tablets as a cost-saving alternative to Isentress branded tablets. It was noted that the medicine is currently included as a Formulary Decision only, and the updated decision entry will retain the link to the original SMC advice 1280/17.

The formulary website will be updated.

**ACTION: NHS Lothian Admin Team**

#### 3.2.2 Enoxaparin (Adult)

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

Indication:
1.Treatment and prophylaxis for VTE
2. Treatment of acute ST-segment elevation myocardial infarction
3. Unstable angina
4. Non-ST-segment- elevation myocardial infarction
5. Prevention of clotting in extracorporeal circuits

Application for amendment to include Enoxaparin as an alternative to Dalteparin in relevant Adult treatment pathways throughout the ERF.

The amendment is discussed under item 2.3.1 ERF Adult & Child - Low molecular weight heparins (LMWH).

The formulary website will be updated.

**ACTION: NHS Lothian Admin Team**

### 3.2.3 Enoxaparin (Child)

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: Acute treatment of pulmonary embolism / Acute treatment deep vein thrombosis.

Application for amendment to include Enoxaparin as an alternative to Dalteparin in relevant Child treatment pathways throughout the ERF.

The amendment is discussed under item 2.3.1 ERF Adult & Child - Low molecular weight heparins (LMWH).

The formulary website will be updated.

**ACTION: NHS Lothian Admin Team**

### 3.2.4 Ustekinumab (Wezenla)

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: PsA, Crohn's, Ulcerative Colitis, Psoriasis

Application for amendment to include new licensed injection device. It was noted that the initial launch of Ustekinumab biosimilars included only pre-filled syringes, which are more difficult to administer than pre-filled pens and unsuitable for patients with needle phobia. The introduction of biosimilar pre-filled pens will allow Boards to transition more patients away from the originator, enabling substantial cost savings.

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** Dupilumab: Dupixent (SMC2801)
**3.4.2** Letermovir: Prevymis (SMC2853)
**3.4.3** Trastuzumab deruxtecan: Enhertu (SMC2854)
**3.4.4** Belzutifan: Welireg (SMC2864)
**3.4.5** Encorafenib: Braftovi (SMC2865)

The formulary website will be updated.

**ACTION: NHS Lothian Admin Team**

## 3.5 Abbreviated submissions

### 3.5.1 Zanubrutinib: Brukinsa (MCL) (SMC2819)

The ERFC noted the SMC abbreviated submission for Zanubrutinib: Brukinsa (MCL) (SMC2819).

Indication: As monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

The ERFC noted that a SACT protocol is in place and will be adapted for this indication. It is anticipated that the inclusion of Zanubrutinib on the formulary will be as a cost-saving replacement for Ibrutinib.

The ERFC agreed to classify Zanubrutinib: Brukinsa (MCL) (SMC2819) 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**

**3.5.2 Olaparib: Lynparza (SMC2737)**

The ERFC noted the SMC abbreviated submission for Olaparib: Lynparza (SMC2737).

Indication: 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 previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

The ERFC noted that Olaparib: Lynparza will be used to treat 6 patients per annum for the proposed indication, with treatment split between Olaparib and Talazoparib. Choice of drug will be based on patient preference and side effect profiles.

The ERFC agreed to classify Olaparib: Lynparza (SMC2737) 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 Mirikizumab: Omvoh (SMC2822)**

The ERFC noted the SMC abbreviated submission for Mirikizumab: Omvoh (SMC2822).

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

The ERFC agreed to classify Mirikizumab: Omvoh (SMC2822) 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** Brentuximab vedotin: Adcetris (SMC2762)
**3.7.2** Ripretinib: Qinlock (SMC2821)
**3.7.3** Blinatumomab: Blincyto (SMC2808)
**3.7.4** Rucaparib: Rubraca (SMC2799)

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

None raised.

**5 Any other competent business**

None raised.

**6 Date of next meeting**

The next ERFC meeting is scheduled for Wednesday 12 November 2025 at 1400 - 1630 hours via MS Teams. NHS Fife will be hosting the meeting.

FAF3s should be submitted by 07 October 2025 (for discussion at the ERWG meeting on 22 October 2025).

FAF1s and FAF2s should be submitted by 28 October 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.