



East Region Formulary Committee Minutes

Date: 02 October 2024 Time: 2.00pm – 3:15pm

Location: MS Teams

Present:

Carla Capaldi Senior Practice Pharmacist, NHS Fife

Malcolm Clubb Director of Pharmacy (Co-chair), NHS Borders – in the Chair

Nicole Cromar Pharmacist – Neurology, NHS Lothian
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 Paul Neary Consultant – Cardiology, NHS Borders

Dr Jo Rose GP, NHS Lothian

Dr Lucy Wall Consultant – Oncology, NHS Lothian

Dr Andrew Watson Consultant – Psychiatry (Co-chair), NHS Lothian

In attendance: Joanna Hornal, Senior Pharmacist – Medical Education, NHS Fife

Natasha Kellet, Professional Secretary for New Drugs and Formulary Group, NHS

Forth Valley

Lawrence Li, Consultant - Anaesthetist, NHS Fife (left meeting at 14:45)

Piera Nadali-Gupta, Specialist Clinical Pharmacist, NHS Lothian

Róisín O'Donoghue, Cancer Care Pharmacist, NHS Greater Glasgow & Clyde

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

Gillian Donaldson, Nurse – Cardiology, NHS Borders Dr David Griffith, Consultant – Microbiologist, NHS Fife

Fraser Notman, Senior Pharmacist – Medicines Management, NHS Fife

Cathryn Park, Deputy Director of Pharmacy, 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
- Leaving Dr Lucy Wall, Nicole Cromar, and Gillian Donaldson; the Chair acknowledged the
 longstanding membership of the departing committee members with Lucy undertaking
 eight years of membership within the medicines governance committees of NHS Lothian,
 and both Nicole and Gillian's membership on the East Region Formulary Committee since
 its inception in 2021. On behalf of the East Region Formulary Committee, the Chair thanked
 Lucy, Nicole, and Gillian for their work and contribution to the committee over the years.
- Membership The Chair noted the current gaps in ERFC membership, and acknowledged

that the ERFC is seeking representation from Oncology/Haematology teams as well as Specialist Nurse representative from NHS Borders and a GP representative from NHS Fife – communication will be sent out to relevant colleagues across the East region, with new committee members appointed in due course. Confirmation of a representative from the NHS Lothian Renal team is currently in progress.

1.3 Matters arising

- **1.3.1** ERFC August 2024 Item 3.1.1 FAF1 Dupilumab: Dupixent (SMC2598) was reviewed at the ERFC August meeting. The ERFC requested clarification on whether the guideline provided with the submission is being adopted by NHS Borders. It was noted that feedback has been received to confirm that the treatment pathway included in the application is appropriate for use in NHS Borders. Action completed.
- **1.3.2** ERFC August 2024 Item 3.1.7 FAF1 Conestat-alfa: Ruconest (SMC745/11) was reviewed at the ERFC August meeting. The ERFC requested a revised submission with corrected costings for the planned model of care, a revised guideline with further information regarding treatment choices used within the pathway, and the order of preference with subsequent reasoning, i.e., safety, efficacy, and cost-effectiveness. The ERFC further requested the submission of a formulary application for Icatibant alongside the resubmission.

It was noted that a revised submission has been received with confirmation that patients will be reviewed after three months by their Immunologist and Immunology Nurse when initiated on Ruconest, or sooner if the patient is experiencing frequent angioedema attacks that do not improve with treatments; further reviews are carried out every three- to six-months. It was further noted that whilst exact costings are difficult to predict, patients who require regular use of Berinert, Cinryze, or Ruconest will be considered for prophylactic treatment. The revised submission also includes an amended finance section to reflect service delivery via Homecare.

The committee noted that further information was received regarding the number and order of treatment choices used within the pathway.

The ERFC noted that the request for a FAF1 Icatibant application is still outstanding, however, the applicants confirmed that a submission is expected for the next ERFC meeting in December, and building of the relevant ERF pathway will commence thereafter.

The ERFC agreed to classify Conestat-alfa: Ruconest (SMC745/11) as Routinely available in line with national guidance. Included in the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

1.3.3 ERFC August 2024 Item 3.1.11 FAF1 Avatrombopag: Doptelet (SMC2345) was reviewed at the ERFC August meeting. The ERFC requested the submission of a revised application with further information regarding the comparable clinical efficacy of Avatrombopag to Eltrombopag; confirmation of the treatment choices used and order of preference, and the revision of clinical guidance to reflect, with the potential to streamline the number of medicine options within the treatment pathway; a revision of costs accounting for replacement therapy costings, and for the planned model of care; as well as evidence of the incremental costs for the use of the medicine, and confirmation that budget holders and medical managers are supportive of additional costs related to yearly growth in patient numbers.

It was noted that a revised application has been received with confirmation from the applicants that there is no direct clinical evidence available to highlight the comparable clinical efficacy of Avatrombopag to Eltrombopag; patients are currently started on Eltrombopag and then switched to Avatrombopag if ineffective or not tolerated due to adverse or side effects. The applicants have advised that data will be provided to the ERFC in one year to indicate the number of patients that tolerate and are treated effectively with Avatrombopag as the initial TPO mimetic, and how many require alternative treatment. If Avatrombopag clearly shows to be more effective and well tolerated

compared with Eltrombopag, Eltrombopag could be removed from the formulary to streamline number of medicine options in the treatment pathway.

The committee noted that further information was received regarding the number and order of treatment choices used within the Adult 'Treatment of idiopathic thrombocytopenic purpura (ITP)' pathway; medicine choice will be made based on interactions with other medication, side-effect profile, route of administration and efficacy. Clinical guidance has been updated to reflect the changes, with support from haematology consultants and Clinical Directors across the East region.

It was noted that patients that are currently receiving stable treatment on Eltrombopag will not be actively switched over to Avatrombopag. Further information regarding the incremental costs of Avatrombopag was provided in the revised application,. The ERFC noted that confirmation has been received that budget holders and medical managers are supportive of the application.

The ERFC agreed to classify Avatrombopag: Doptelet (SMC2345) as Routinely available in line with national guidance. Included in the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

1.3.4 ERFC August 2024 Item 3.1.12 FAF1 Lanadelumab: Takhzyro (SMC2206) was reviewed at the ERFC August meeting. The ERFC requested a revised submission with further information as to how patient numbers are derived, and a revision of costs accounting for the planned model of care. The ERFC further requested clarity from the clinical team regarding whether the proposed indicated use is for both adults and adolescents in line with the SMC advice statement, or whether it is for use in adults only, as well as 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.

It was noted that a revised application has been received with confirmation provided that the patient numbers stated in the application are based on current prescribing trends. The ERFC acknowledged that patients in all three Boards will be managed by the NHS Lothian Immunology service which has a regional remit. It was further noted that the revised application provides confirmation that there is no formal implementation plan, however, there is a robust process in place regarding patient selection criteria with the requirement for treatment assessed on a case-by-case basis and consensus reached through discussion at the monthly Scottish Immunology MDT meeting.

The applicants provided further confirmation that current prescribing is primarily in adults due to the clinical nature of hereditary angioedema with symptoms largely manifesting in adulthood and later adolescence. All prescribing is envisaged to be in patients aged 12 years and older, and, therefore, in line with SMC advice statement.

It was noted that a new pathway is required on the ERF for prophylaxis of hereditary angioedema attacks, with Lanadelumab as first-line treatment option, followed by Cinryze.

The ERFC agreed to classify Lanadelumab: Takhzyro (SMC2206) as Routinely available in line with national guidance. Included in the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

1.3.5 ERFC August 2024 Item 3.1.13 Tirzepatide: Mounjaro (<u>SMC2633</u>) was reviewed at the ERFC August meeting.

The ERFC acknowledged the inclusion of a post-meeting note in the minutes of the ERFC August meeting to record that the ERFC co-Chairs had received confirmation that primary care budget holders in all three Boards are aware of the financial impact of Tirzepatide, and, agreed that there is sufficient evidence to support the inclusion of Tirzepatide: Mounjaro on the ERF.

The committee discussed the potential requirement for additional messaging on respective

prescribing software across the three Boards to minimize the risk of prescribing similarly named medicines i.e. Teriparatide. It was noted that pop-ups on prescribing software is managed nationally by the provider and linked with the dictionary of medicines + devices (dm+d), and, as a result, the requirement for local action at Board level is unlikely. Committee members in the respective Boards will investigate the need for additional prescribing messaging, and report back at the ERFC December meeting, if required. Action complete.

1.3.6 ERFC August 2024 Item 3.1.15 FAF2 Flamigel RT was reviewed at the ERFC August meeting. The ERFC requested further information from the applicants as to why Flamigel RT is preferred to Flamigel.

It was noted that the Flamigel RT is specifically indicated for use within radiotherapy settings for the treatment of radiotherapy-induced skin reactions, whereas Flamigel has a more extensive range of indications such as minor or superficial burns, cuts, grazes, and dermatitis. The applicants confirmed that Flamigel RT is currently on the drug tariff, and, therefore, reimbursable, whilst Flamigel is not on the drug tariff.

The applicants further confirmed that the intention is to replace their current use of Flamazine with Flamigel RT to be in line with the other cancer centres across the UK, with Flamigel RT to be initiated by clinical oncologists only for patients undergoing radiotherapy.

Flamigel RT will be included in the Formulary Decisions section of the ERF only, under Specialist Use Only formulary flagging.

The ERFC agreed to classify Flamigel RT 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

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 07 August 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 11 September 2024

The minutes of the ERWG meeting on 11 September 2024 were noted for information.

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

2.3.1 ERF Adult - Angina - Regular treatment of angina

The ERFC discussed the updated ERF pathway – 'Regular treatment of angina'.

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

ACTION: NHS Lothian Admin Team

2.3.2 ERF Adult - Bipolar disorder - Valproate use in men

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

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

ACTION: NHS Lothian Admin Team

2.3.3 ERF Adult - Crohn's disease - Addition of Ustekinumab

The ERFC discussed the updated ERF adult pathway – 'Severe active or active fistulising Crohn's disease'

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

ACTION: NHS Lothian Admin Team

2.3.4 ERF Adult – Epilepsy Conditions - Valproate use in men

The ERFC discussed the updated pathways and prescribing notes for all relevant adult pathways.

The committee noted that, when circulated for comment, chapter experts responded to advise they felt there was somewhat of an imbalance of information between the prescribing notes for males and the prescribing notes for females. The committee agreed to review a revised version of the amendment with the removal of detailed information statements; alternatively signposting to MHRA links directly, and return comments by 17th of October 2024.

Post-meeting note: Committee members have returned comments and confirmed their approval of the revised version of the amendment.

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

ACTION: NHS Lothian Admin Team

2.3.5 ERF Adult - Hepatic Encephalopathy - Prophylaxis of hepatic encephalopathy

The ERFC discussed the new ERF adult pathway – 'Prophylaxis of hepatic encephalopathy'.

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

ACTION: NHS Lothian Admin Team

2.3.6 ERF Adult - Psoriasis - Addition of Ustekinumab

The ERFC discussed the updated ERF adult pathways – 'Biologic treatment of chronic plaque psoriasis', 'Biologic treatment of psoriasis with psoriatic arthritis', and 'Biologic treatment of chronic plaque psoriasis with inflammatory bowel disease'.

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

ACTION: NHS Lothian Admin Team

2.3.7 ERF Adult - Psoriatic Arthritis - Addition of Ustekinumab

The ERFC discussed the updated ERF adult pathway – 'Treatment of Psoriatic arthritis with biologics and targeted synthetic DMARDs'.

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

ACTION: NHS Lothian Admin Team

2.3.8 ERF Child - Crohn's disease - Addition of Ustekinumab

The ERFC discussed the updated ERF child pathway - '(C) Severe active or active fistulising Crohn's disease'.

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

ACTION: NHS Lothian Admin Team

2.3.9 ERF Child - Epilepsy syndromes and epilepsy conditions - Valproate use in men

The ERFC discussed the updated ERF child pathways – 'Epilepsy (all pathways with valproate in choices or prescribing notes', 'Dravet syndrome: Treatment of Dravet Syndrome', and 'Lennox-Gastaut syndrome: Treatment of Lennox-Gastaut Syndrome'.

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

ACTION: NHS Lothian Admin Team

2.3.10 ERF Child - Psoriasis - Addition of Ustekinumab

The ERFC discussed the updated ERF child pathway - 'Biologic treatment of chronic plaque psoriasis'.

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

ACTION: NHS Lothian Admin Team

2.3.11 ERF Adult & Child - Asthma - Addition of Omalizumab

The ERFC discussed the updated adult and child pathway – Adult 'Immunotherapy in asthma', and Child 'Biological medicines in asthma'.

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

ACTION: NHS Lothian Admin Team

2.3.12 ERF Adult & Child - Urticaria - Addition of Omalizumab

The ERFC discussed the updated adult and child pathways – 'Treatment of chronic spontaneous urticaria'.

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

ACTION: NHS Lothian Admin Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Glycopyrronium/formoterol fumarate pressurised inhalation, suspension: Bevespi Aerosphere (SMC2652)

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 a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

The finance budget template was included with the FAF.

The ERFC discussed the submission, noting that there is currently no LAMA/LABA bronchodilators in a pressurised metered dose inhaler (pMDI) available on the Formulary, with current patients requiring this combination given triple therapy, and, therefore, given an unnecessary inhaled corticosteroid. It was noted that the inclusion of Bevespi Aerosphere removes the need for inhaled corticosteroids and is a cost-effective addition to the Formulary.

The committee acknowledged and discussed the environmental impact of the inclusion of another pressurised pMDI on the Formulary. It was noted that similar concerns have been raised in health boards across NHS Scotland, with confirmation received from the NHS Lothian Respiratory team that the propeller within the device is due to be changed within the next year to become more environmentally friendly. It was also noted that relevant posters and leaflets provided by NHS Scotland's National Procurement Service offer additional information and emphasise the importance of environmentally-friendly, sustainable prescribing.

The ERFC agreed to classify FAF1 Glycopyrronium/formoterol fumarate pressurised inhalation, suspension: Bevespi Aerosphere (SMC2652) as Routinely available in line with national guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2 Formulary Amendment Form

3.2.1 Molnupiravir: Lagevrio

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: Treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19 – second choice where Paxlovid is not an option – in line with local guidelines and prescribing while SMC advice is awaited (due January 2025).

Application for amendments due to evolving evidence for the treatment of COVID-19, and to be in line with new NICE guidance.

The ERFC discussed the supporting evidence, noting that Molnupiravir is not included in any treatment pathways due to the complex evolving nature of the treatment, and will remain in the Formulary Decisions section only.

The committee noted the relevant guidelines provided from each Board, and noted the differing preferences for the order of medicine choices within each guideline provided.

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

ACTION: NHS Lothian Admin Team

3.2.2 Nirmatrelvir and Ritonavir: Paxlovid

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 COVID-19 in adults who do not require supplemental oxygen and who are at high risk for progression to severe COVID-19 – in line with local guidelines for prescribing and SMC advice following collaboration with NICE MTA TA878.

Application for amendments due to evolving evidence for the treatment of COVID-19, and to be in line with new NICE guidance.

The ERFC discussed the supporting evidence, noting that Paxlovid is not included in any treatment pathways due to the complex evolving nature of the treatment, and will remain in the Formulary Decisions section only.

The committee noted the relevant guidelines provided from each Board, and noted the differing preferences for the order of medicine choices within each guideline provided.

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

ACTION: NHS Lothian Admin Team

3.2.3 Remdesivir: Veklury

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 COVID-19 in:

- adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment).
- adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

Application for amendments due to evolving evidence for the treatment of COVID-19, and to be in line with new NICE guidance.

The ERFC discussed the supporting evidence, noting that Remdesivir is not included in any treatment pathways due to the complex evolving nature of the treatment, and will remain in the Formulary Decisions section only.

The committee noted the relevant guidelines provided from each Board, and noted the differing preferences for the order of medicine choices within each guideline provided.

The ERFC agreed to classify Remdesivir 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

3.2.4 Tocilizumab: RoActerma

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 COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation in line with local guidelines for prescribing and SMC advice following collaboration with NICE MTA TA878.

Application for amendments due to evolving evidence for the treatment of COVID-19, and to be in line with new NICE guidance.

The ERFC discussed the supporting evidence, noting that Tocilizumab is not included in any treatment pathways due to the complex evolving nature of the treatment, and will remain in the Formulary Decisions section only.

The committee noted the relevant guidelines provided from each Board, and noted the differing preferences for the order of medicine choices within each guideline provided.

The ERFC agreed to classify Tocilizumab 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

The other IL6 inhibitor Sarilumab: Kevzara was not mentioned in any of the guidelines. All 3 boards were in agreement to make Sarilumab as 'Not routinely available' as Tocilizumab has a licence and use of Sarilumab would only be indicated if there was a national shortage, as an off-label alternative.

The ERFC agreed to classify Sarilumab: Kevzara 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.

ACTION: NHS Lothian Admin Team

3.2.5 Sotrovimab: Xevudy

The ERFC noted the additional inclusion of Sotrovimab: Xevudy within the collective review of COVID-19 medicines on the East Region Formulary.

Indication: Sotrovimab is accepted for restricted use in the treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection. Refer to local guidelines.

The ERFC noted that Sotrovimab: Xevudy will retain the Specialist Use Only formulary flagging.

The ERFC agreed to classify Sotrovimab: Xevudy 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

3.2.6 Ustekinumab Biosimilars – Pyzchiva: Sandoz and Wezenla: Amgen

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

Indication: For treatment of Crohn's disease, Psoriatic arthritis (PsA), and Plaque psoriasis.

Application for the amendment to enable the biosimilar switch of medicines.

The ERFC discussed the supporting evidence. It was noted that the application was approved by Chair's action on the 24th of September 2024 to allow respective clinical teams across the East region to undertake the necessary preparation and ensure readiness prior to the new contract start date.

The ERFC agreed to classify Pyzchiva: Sandoz and Wezenla: Amgen 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

3.2.7 Teriparatide: Sondelbay

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

Indication: Treatment of severe spinal osteoporosis

Application for the amendment to enable the biosimilar switch of medicines.

The ERFC discussed the supporting evidence, and noted that whilst specialist Rheumatology pharmacists and Clinical Directors from NHS Fife and NHS Borders are in support of this amendment, the necessary resource to action immediately may not be available. As a result, the Movymia brand will remain on the Formulary until relevant changes have occurred in all three Boards.

The ERFC agreed to classify Teriparatide: Sondelbay 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

3.2.8 FreeStyle Libre 2 Plus

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: Continuous monitoring of blood glucose in Type 1 diabetes.

Application for amendment as the new Libre 2PLUS sensor is able to deliver "Hybrid Closed Loop" in conjunction with Omnipod 5 insulin pump.

The ERFC discussed the supporting evidence, noting that the company plan to cease FreeStyle Libre 2 and replace with FreeStyle Libre 2 Plus, allowing one year for the transition. It was noted that FreeStyle Libre 2 will be phased out and replaced with FreeStyle Libre 2 Plus, and will be removed from the ERF once all three Boards confirm that only FreeStyle Libre 2 Plus is in use.

The ERFC agreed to classify FreeStyle Libre 2 Plus as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.9 Diroximel Fumarate

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 MS

Application to move medicine from first-line treatment option in the 'Treatment of active relapsing remitting multiple sclerosis' pathway to second-line due to the high cost of the medicine.

The ERFC discussed the supporting evidence.

The ERFC agreed to move Diroximel Fumarate to second-line treatment option within the relevant pathway. 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** Fezolinetant film-coated tablets: Veoza (SMC2702)
- **3.4.2** Nivolumab concentrate for solution for infusion: Opdivo (SMC2704)
- 3.4.3 Talquetamab solution for injection: Talvey (SMC2705)
- 3.4.4 Trastuzumab deruxtecan powder for concentrate for solution for infusion: Enhertu (SMC2706)
- **3.4.5** Pegcetacoplan: Aspaveli (SMC2715)
- **3.4.6** Volanesorsen: Waylivra (SMC2716)
- **3.4.7** Zilucoplan: Zilbrysq (SMC2717)

ACTION: NHS Lothian Admin Team

- 3.5 Abbreviated submissions
- **3.5.1** None noted.
- 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 Etranacogene dezaparvovec concentrate for solution for infusion: Hemgenix (SMC2649)
- **3.7.2** Trifluridine/tipiracil film-coated tablets: Lonsurf (SMC2654)
- 3.7.3 Ivacaftor-tezacaftor-elexacaftor: Kaftrio (SMC2713)
- **3.7.4** Tezacaftor-ivacaftor: Symkevi (SMC2711)
- **3.7.5** Lumacaftor-ivacaftor: Orkambi (SMC2712)
- 3.7.6 Teclistamab: Tecvayli (SMC2668)
- **3.7.7** Dabrafenib: Finlee (SMC2667)
- 3.7.8 Elranatamab: Elrexfio (SMC2669)
- 3.7.9 Ivosidenib: Tibsovo (SMC2664)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, 3.7.6, 3.7.7, 3.7.8, and 3.7.9 as Not Routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.8 National Cancer Medicines Advisory Group

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 04 December 2024 at 1400 - 1630 hours via MS Teams. NHS Borders will be hosting the meeting.

FAF3s should be submitted by 23 October 2024 (for discussion at the ERFC pre-panel meeting on 30 October 2024).

FAF1s for consideration by the ERFC pre-panel should be submitted by 23 October 2024 (for discussion at the ERFC pre-panel meeting on 30 October 2024).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 19 November 2024.

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 loth.prescribing@nhs.scot.