East Region Formulary

East Region Formulary Committee
Minutes

Date: 07 August 2024
Time: 2.00pm – 4.45pm
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
Dr David Griffith	Consultant – Microbiologist, NHS Fife
Carol Holmes	Pharmacist - Primary Care, NHS Lothian
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist - Medicines Governance and Guidance, NHS Lothian
Alice Mathew	Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant – Cardiology, NHS Borders
Fraser Notman	Senior Pharmacist – Medicines Management, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian

In attendance: 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
Cathryn Park, Deputy Director of Pharmacy, NHS Borders

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1 Project update

1.1 Welcome and Apologies

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

- ERFC noted that the meeting is being recorded
- Leaving – Steven Fenton; the Chair noted the departure of Steven Fenton, ERF Project Manager, as he embarks on the West Region Formulary project development. On behalf of the East Region Formulary Committee, the Chair thanked Steven for his invaluable work in the establishment and continued development of the East Region Formulary.
- The Chair further noted that David Griffith has stepped down as NHS Fife Chair after his three-year tenure, but will remain on as a member of the East Region Formulary Committee. On behalf of the ERFC, the Chair thanked David for his time and contribution to the East Region Formulary as co-Chair.

1.3 Matters arising

1.3.1 ERFC May 2024 Item 3.1.5 FAF1 Nivolumab: Opdivo (SMC2619) was reviewed at the ERFC May meeting. The ERFC requested a protocol to be written with stated instruction that the medicine should not be given to all patients who are PD-L1 unless the clinical team can provide justifiable reasoning. It was noted that a response has been received from the applicants to confirm that the protocol now includes the requested information. Action completed.

ACTION: NHS Lothian Admin Team

1.3.2 ERFC May 2024 Item 3.1.11 FAF2 Insulin Aspart: Trurapi was reviewed at the ERFC May meeting. The ERFC requested that the application form be re-submitted with the signature section correctly co-signed. It was noted that a revised application has been received with a corrected signature section. Action completed.

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 29 May 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 17 July 2024

The minutes of the ERWG meeting on 17 July 2024 were noted for information.

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

2.3.1 ERF Adult - Respiratory - COPD Pathway 1-5 Amendments

The ERFC discussed the updates to a number of ERF adult pathways within 'Chronic Obstructive Pulmonary Disease (COPD)'.

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

ACTION: NHS Lothian Admin Team

2.3.2 ERF Adult - Epilepsy Conditions – Topiramate MHRA DSU June 2024

The ERFC discussed the updated ERF adult pathways – 'Epilepsy treatments – Specialist list' and 'Treatment of epilepsy in pregnancy - general notes'.

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

ACTION: NHS Lothian Admin Team

2.3.3 ERF Adult & Child - Migraine - Topiramate MHRA DSU June 2024

The ERFC discussed the updated ERF adult pathway – 'Prophylaxis of migraine', and child pathway – 'Prophylaxis of migraine'.

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

ACTION: NHS Lothian Admin Team

2.3.4 ERF Child - Epilepsy Conditions – Topiramate MHRA DSU June 2024

The ERFC discussed the updated prescribing notes for all relevant paediatric pathways, and the updated ERF child pathway – 'Epilepsy treatments – additional treatments'.

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

ACTION: NHS Lothian Admin Team

2.3.5 ERF Child – Epilepsy Syndromes - Topiramate MHRA DSU June 2024

The ERFC discussed the updated ERF child pathways – 'Treatment of Dravet syndrome' and 'Treatment of Lennox-Gastaut syndrome'.

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 Dupilumab: Dupixent (SMC2598) - *resubmission*

The ERFC noted and discussed the FAF1 re-submission for Dupilumab: Dupixent, previously reviewed at the May ERFC meeting. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: For the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.

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

The ERFC discussed the revised submission, acknowledging the committee's request from the May meeting for additional information regarding plans for patient reviews at further timepoints and stopping criteria for loss of response, as well as clarification on current guidelines used in the respective Boards, or confirmation that the guideline provided with the submission is being adopted by the other Boards.

The committee noted the revised guideline provided which details further information regarding timelines for patient reviews – a revision is recommended to clarify subsequent review of treatment for patients who experience a good response to the medicine at 24 weeks. In regard to regional guidelines, it was noted that the clinical team in NHS Lothian intends to adopt the NHS Fife guideline once approval has been sought through their local review group. No response from the NHS Borders dermatology team has been received.

The ERFC requested clarification on whether the guideline provided with the submission is being adopted by NHS Borders. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: Malcolm Clubb, Director of Pharmacy (Co-chair), NHS Borders/ NHS Lothian Admin Team

At the May ERFC meeting, the committee requested further information as to how patient numbers were derived. The ERFC acknowledged the additional information provided by the applicants which confirmed that the estimated patient numbers provided in the SMC Detailed Advice Document (DAD) did not account for the atopic eczema patient population, and, therefore, the patient numbers noted in the application provide a more accurate representation of the number of patients who would receive Dupilumab for the proposed indication.

The ERFC agreed that Dupilumab: Dupixent is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify Dupilumab: Dupixent (SMC2598) 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 Mirikizumab: Omvoh (SMC2650) - *resubmission*

The ERFC noted and discussed the FAF1 re-submission for Mirikizumab: Omvoh, previously reviewed at the May ERFC meeting. No declarations of interest were received. Named CD support was received from all three Boards.

Indication: For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment. Mirikizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.

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

The ERFC discussed the revised submission, acknowledging the committee's request from the May meeting for guidelines from the respective Boards, or if no Board guideline is available, then confirmation of the treatment choices used, and the order of preference with subsequent reasoning, i.e., safety, efficacy, and cost-effectiveness; where there is variation in practice between the Boards, the committee requested supporting evidence regarding efficacy, safety, and cost-effectiveness. The committee further sought agreement on the order of choices for biologics and synthetic DMARDS for ulcerative colitis from specialists in the region, along with supporting evidence where there is variance on proposed formulary positioning and order of choices in Board guidelines.

The ERFC acknowledged the revised NHS Lothian guideline provided which notes Adalimumab or Infliximab and Filgotinib as first-line treatment options, with Vedolizumab, Upadacitinib, Mirikizumab or Etrasimod as second-line, and Ustekinumab, Tofacitinib, and Ozanimod as third-line. The committee noted that there is continued disparity regarding the order of medicine choices between the NHS Lothian guideline and the 'Treatment of ulcerative colitis with biologic and targeted synthetic DMARDs' pathway on the ERF – Filgotinib is reasoned as a second-line treatment option on the ERF due to the MHRAs advice on use of JAK inhibitors and in order to align with the approved SMC indication of only using the medicine if there is an inadequate response or lost response to either conventional therapy or after a biological agent. The committee further noted that clinical teams in NHS Fife and NHS Borders intend to adhere to the order of medicine choices on the ERF, with all three Boards in agreement to remove Golimumab entirely.

The revised application adheres to the committee's request at the May ERFC meeting, with the amended application providing financial evidence with Ustekinumab as the comparator medicine to Mirikizumab rather than Vedolizumab. The committee acknowledged that Mirikizumab is the more cost-effective medicine option, with all three Boards providing confirmation that there is service capacity at the infusion sites and that Home Care will be set up.

The ERFC discussed the forthcoming availability of biosimilar Ustekinumab, noting that any changes in pricing of the originator and competitor products may impact the order of medicine choices in relevant treatment pathways. The committee noted that contract reviews are expected prior to the October ERFC meeting, and, as a result, the ERFC agreed to recommend that the team review the formulary application when details are available, and then decide whether to resubmit with revised costings.

The ERFC agreed to classify Mirikizumab: Omvoh (SMC2650) 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

3.1.3 FAF1 Etrasimod: Velsipity (SMC2655)

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: For the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

The local treatment protocol was included with the FAF. It was noted that Etrasimod: Velsipity (SMC2655) is an abbreviated submission, and, therefore, there is no available SMC budget impact information or comparative evidence.

The ERFC discussed the supporting evidence, noting that Etrasimod offers as additional treatment choice in the therapeutic class of sphingosine 1-phosphate receptor modulators.

The committee noted that clinical teams in NHS Fife and NHS Borders have no intention of starting new patients on Etrasimod as they do not have the capacity to commit to the extensive additional testing with patients initiated on Etrasimod and Ozanimod requiring a baseline ECG prior to starting the medicine; first-dose monitoring must be arranged for patients to determine signs and symptoms of bradycardia, and patients initiating both drugs will require ophthalmological evaluation.

In regard to the financial forecasting provided, the committee noted the comparative use of Ozanimod as the replaced therapy medicine to highlight the cost-saving benefit of Etrasimod. However, the committee further noted the recently revised PAS for Ozanimod, published in August 2024. The finance section of the application requires revision to account for the new Ozanimod PAS price.

The ERFC requested the submission of a revised application with a review of the finance section to account for the new Ozanimod PAS price. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The committee queried the low patient numbers, and discussed the efficacy of having both Etrasimod and Ozanimod, two medicines of the same class, within a singular pathway. It was noted that whilst there are some benefits of having a variation of medicines within the same class available within a pathway i.e. adherence to formulary governance processes to subsequently allow Home Care service delivery to be set up or to allow for variable treatment options for patients who may not be able to tolerate one medicine or the other, the committee noted that it may be more appropriate, in this instance, for non-formulary routes to be pursued. The ERFC, therefore, agreed that further information is required from the applicants regarding the evidence base for Etrasimod compared to Ozanimod.

The ERFC requested the submission of a revised application including evidence comparing Ozanimod and Etrasimod. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Etrasimod: Velsipity (SMC2655) 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

3.1.4 FAF1 Secukinumab: Cosentyx (SMC2592) - *resubmission*

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

Indication: For use in adult patients with active moderate to severe hidradenitis suppurativa (HS) (acne inversa) for whom Adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior Adalimumab treatment.

The finance budget template was included with the FAF.

The ERFC discussed the revised submission, acknowledging the committee's request from the May meeting for the submission of an amended application with Adalimumab removed as the cost-comparator medicine and a review of the finance section to account for variable dosing schedules. The committee noted that Adalimumab has been removed as the cost-comparator medicine, and that the finances presented in the revised submission now reflect the correct PAS price for the proposed Secukinumab indication. The committee further acknowledged that the patient numbers provided now account for a more accurate reflection of current and expected patient numbers per annum across the East Region.

With the resubmission, the committee requested a copy of the protocol or guideline that is planned for use in each of the Boards, or if this cannot be provided, confirmation that a protocol or guideline will be developed and approved via local Board governance processes. The committee noted that a protocol has been included with the revised submission, with confirmation that NHS Fife and NHS Borders will use an adapted version in their respective Boards. It was further noted that the protocol provides additional information regarding patient review schedules and stopping criteria.

The ERFC noted the personal non-specific declaration of interest from the applicant; however, upon discussion, the committee are satisfied that as an SMC-approved medicine with CD support from across the region, there is sufficient compliance with the formulary governance process and no further action is required.

The ERFC agreed to classify Secukinumab: Cosentyx (SMC2592) 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 Ritlecitinib: Litfulo (SMC2610) - *resubmission*

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

Indication: For the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

The finance budget template was included with the FAF.

FAF1 Ritlecitinib: Litfulo was discussed at the May ERFC meeting, with the committee requesting the submission of a revised application providing clarification on patient numbers per annum, and an

accompanying treatment protocol and implementation plan for use in the region or Board-specific prescribing guidance for each Board.

The committee noted that the patient numbers presented in the revised submission are a more accurate reflection of current and expected patient numbers per annum across the East Region. The committee further noted that a guideline has been received from both NHS Fife and NHS Lothian, detailing eligibility and response criteria. No response from the NHS Borders dermatology team has been received.

The ERFC requested clarification on whether either of the guidelines provided with the submission is being adopted by NHS Borders The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: Malcolm Clubb, Director of Pharmacy (Co-chair), NHS Borders/ NHS Lothian Admin Team

The committee noted that the revised submission includes further information regarding the associated costs attached to the number of tests required in pre-treatment screening.

The ERFC agreed to classify Ritlecitinib: Litfulo (SMC2610) 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 FAF1 Budesonide/Formoterol: Symbicort (SMC2622)

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

Indication: Anti-inflammatory reliever therapy for patients with mild asthma who would have otherwise received inhaled corticosteroid (ICS) maintenance therapy plus short-acting beta-2 adrenoceptor agonist (SABA) as needed.

The local treatment protocol and finance budget template were included with the FAF. The ERFC recognised the difficulties in estimating predicted patient numbers per annum and the associated financial impact.

The ERFC discussed the supporting evidence, with the application noting the forthcoming new guidance from SIGN/NICE/BTS which will promote increased prescribing of anti-inflammatory reliever (AIR) and maintenance and reliever therapy (MART) to be more in line with the Global Initiative for Asthma (GINA) guidelines.

The committee acknowledged the additional information provided showcasing Symbicort versus other formulary ICS-formoterol inhalers, with Symbicort noted to have a beneficial 3-year expiry compared to the other ICS-formoterol inhalers detailed.

The committee discussed the appropriate place in therapy, noting the expected future licencing of other AIR inhaled corticosteroid (ICS)-formoterol devices. The ERFC discussed and agreed to include Budesonide/Formoterol: Symbicort in both the Adult and Child 'Intermittent reliever therapy' pathway as a first-line alternative to (SABA) salbutamol as intermittent reliever therapy AIR-anti-inflammatory reliever, with Salbutamol/terbutaline retained on formulary for prescribing alongside regular preventer therapy for patients unsuitable for AIR/MART, with confirmation from the clinical team that local asthma pathways and guidance will be reviewed in line with the NICE/BTS/SIGN asthma guidance upon publication in November.

The ERFC agreed to classify Budesonide/Formoterol: Symbicort (SMC2622) as Routinely available in line with national guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.7 FAF1 Conestat-alfa: Ruconest (SMC745/11) - *resubmission*

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

Indication: Acute angioedema attack in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.

The finance budget template was included with the FAF.

The ERFC discussed the revised submission which provides confirmation that the proposed indicated use is via powder and solvent for injection, and for use in both adults and adolescents in line with the SMC advice statement.

At the May ERFC meeting, the committee requested a revision to the finance section accounting for the planned model of care as well as supporting information detailing a whole cost comparison of treatment options (Berinert, Cynryze, Icatibant, and Ruconest), and the proposed order of choices and restrictions on use in both the Adult and Child pathways. The committee also requested information on guidelines or treatment protocol to support local implementation, and confirmation that additional costs noted in the application in relation to implementation are supported by medical managers and budget holders.

The committee noted that as Home Care is the proposed delivery route for medicine, the associated costings will need to be included in the finance section.

The ERFC requested the revision of the finance section to include Home Care costings. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

It was further noted that the NHS Lothian Adult Acute Hereditary Angioedema Treatment Guideline has been included in the resubmission, detailing Berinert and Cinryze as first-line treatment options with Ruconest as alternative first-line treatment or second-line alongside Icatibant. The committee agreed that a formulary application for Icatibant is required prior to its inclusion within the treatment pathway.

The ERFC further acknowledged that the inclusion of all four licensed medicines is due to the availability of each medicine in the respective Boards during the development of the regional formulary, however, agreed that the pathway can now potentially undergo revision and that further discussion is required to streamline the number of medicine options available.

The ERFC requested a revised submission with correcting 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 request the submission of a formulary application for Icatibant alongside the resubmission. The applicants are requested to respond with information on the recommended action by 17 September 2024.

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

The ERFC agreed to classify Conestat-alfa: Ruconest (SMC745/11) 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

3.1.8 FAF1 Mavacamtem: Camzyos (SMC2618) - *resubmission*

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

Indication: For the treatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients.

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

The ERFC discussed the re-submission, acknowledging the committee's request from the May meeting for a revised application with amended patient numbers and costings, and confirmation that budget holders and medical managers are supportive of additional costs related to the yearly growth in patient numbers and associated testing. The committee noted the modified patient numbers and costings provided, with the applicants documenting that the number of new patients commenced per year is projected to decrease over time to become more in line with the SMC estimates, but the initial increase in the number of patients and initial usage will likely be higher than predicted due to an existing cohort of patients that are being treated sub-optimally. The applicants also provided information regarding associated costings for genotype testing carried out prior to and throughout treatment.

At the May ERFC meeting, the committee further requested that the applicants liaise with a GP and include the required advice within their guidance. The committee noted the inclusion of both a standardised GP letter which provides guidance and recommended actions for GPs to support primary care prescribing, and a guideline which provides information regarding eligibility criteria and monitoring instructions.

The committee discussed the positioning of Mavacamtem within the treatment pathway, and agreed that due to the small number of patients who will be under the care of specialist cardiologists, this medicine would be more appropriate for inclusion in the Formulary Decisions section, and no further information regarding a pathway is required.

The ERFC agreed to classify Mavacamtem: Camzyos (SMC2618) 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

3.1.9 FAF1 Selpercatinib: Retsevmo (SMC2573) - resubmission

The ERFC noted and discussed the FAF1 submission, previously reviewed at the May ERFC meeting. One personal non-specific and one non-personal non-specific declaration of interest was noted. Named CD support was received from all three Boards.

Indication: As monotherapy for the treatment of adults with advanced rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

SMC restriction: for use in treatment-naïve patients who have not previously received a RET-inhibitor or any other systemic treatments for their advanced stage of disease.

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

The ERFC discussed the revised submission, noting the committee's request from the May meeting for a revision of the finance section with use of the correct PAS price. The ERFC agreed that all prior requests have been satisfied, with corrected costings provided, as well as the further information regarding duration of treatment due to new phase III trial data published post-SMC approval.

The ERFC agreed to classify Selpercatinib: Retsevmo (SMC2573) 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

3.1.10 FAF1 Regorafenib: Stivarga (SMC2562) - *resubmission*

The ERFC noted and discussed the FAF1 submission, previously reviewed at the May ERFC meeting. No declarations of interest were received. Named CD support was received from NHS Lothian and NHS Borders, with NHS Fife noting further support.

Indication: As monotherapy for the treatment of adult patients with metastatic colorectal cancer who have previously been treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.

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

The committee discussed the re-submission and agreed that concerns raised at the May ERFC meeting have been resolved, with confirmation provided that budget holders and medical managers have noted and are in support of the additional costs in relation to the treatment of toxicity. Further confirmation has been provided that are sufficient resources for delivery in all four Boards (NHS Dumfries & Galloway, included).

The ERFC agreed to classify Regorafenib: Stivarga (SMC2562) 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

3.1.11 FAF1 Avatrombopag: Doptelet (SMC2345) – *pre-ERFC panel review*

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

Indication: For the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins), in patients with severe symptomatic ITP or a high risk of bleeding.

SMC restriction: to use in patients with severe symptomatic ITP or a high risk of bleeding.

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

The ERFC discussed the supporting evidence, with phase III international randomised double-blind trial data determining that Avatrombopag was more effective than the placebo medicine in raising and maintaining platelet counts at (or above) a minimum target level in previously-treated patients with ITP.

The committee acknowledged the concerns raised at the pre-ERFC panel meeting regarding stopping criteria and treatment holidays, with the NHS Lothian ITP Clinical Management Guideline included in the application noting that reviews will be carried out within the two-to-four-week period after initiation of the medicine to re-measure effectiveness and monitor platelet levels.

In regard to the proposed place in therapy, it was noted that the 'Treatment of idiopathic thrombocytopenic purpura (ITP)' pathway currently lists Immunosuppressants/Corticosteroids as the first-line treatment option, with Eltrombopag as second-line, and Romiplostim and Rituximab as third-line. The committee noted that the treatment flowchart for Persistent ITP provided recommends the initial use of Rituximab for 4 weeks prior to commencing use of Avatrombopag, Romiplostim, or Eltrombopag unless the patient desires otherwise or there are contraindications. It was further noted that the SMC DAD states that clinical experts agreed place in therapy as an additional orally-administered TP-RO treatment alongside other respective treatments, whilst information from the Patient and Clinician Engagement (PACE) meeting and patient feedback favour the use of Avatrombopag as there is no requirement to fast or make any dietary modifications.

The committee also noted that the approved SMC indication for Eltrombopag is for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments, whilst the clinical trial evidence provided in the Avatrombopag application is for patients with and without spleens. The ERFC agreed that the clinical guideline provided requires peer-review prior to approval, as well as additional information to highlight the clinical effectiveness of Avatrombopag in comparison to Eltrombopag, and reasoning as to why Avatrombopag is not considered first-line treatment option within the pathway.

The ERFC request the submission of a revised application with further information regarding the comparable clinical efficacy of Avatrombopag to Eltrombopag. The ERFC also request 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. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted that the costings provided required revision to account for replacement therapy costs and for service delivery via Home Care. The committee further noted that the costings provided only account for one year of treatment.

The ERFC requested a revision of costs accounting for replacement therapy costings, and for the planned model of care. The ERFC also request 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. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Avatrombopag: Doptelet (SMC2345) 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

3.1.12 FAF1 Lanadelumab: Takhzyro (SMC2206) - *pre-ERFC panel review*

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

Indication: Prevention of recurrent attacks of hereditary angioedema

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

The ERFC discussed the supporting evidence, and the additional information provided from the ERFC pre-panel meeting. The committee noted that the proposed indication of Lanadelumab is a prophylactic injection for people who have C1 esterase inhibitor deficiency (C1ID); patients experiencing frequent

attacks and, therefore, requiring frequent acute treatment would be considered for long-term prophylactic treatment.

The ERFC noted the high cost of the treatment and acknowledged that use of the medicine would be selectively determined by an immunology national multi-disciplinary team. It was further noted that use of Lanadelumab does not completely eliminate episodes of acute angioedema, but does significantly reduce the number of attacks.

The ERFC queried the patient numbers provided, with an estimated 25-30 patients with the condition across the East Region, but costings provided for only four eligible patients per annum. The committee agreed that further confirmation of patient numbers per annum is necessary in order to determine if inclusion in the 'Acute attacks of hereditary angioedema' treatment pathway is required, or whether the proposed medicine would be more appropriate for inclusion in Formulary Decisions section only.

The ERFC requested a revised submission with further information as to how patient numbers are derived. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The committee raised concerns regarding the NHS Lothian Acute Hereditary Angioedema Treatment Guideline provided which accounts for the treatment in adults, however, the proposed indication for Lanadelumab is licensed for use in patients 2-years and above. It was noted that the hereditary nature of the condition may result in the treatment of entire families. The ERFC also queried the intended use of the NHS Lothian guideline in NHS Fife and NHS Borders.

The ERFC requested further 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. The ERFC also 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 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted that the costings provided required revision to account for service delivery via Home Care.

The ERFC requested a revision of costs accounting for the planned model of care. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Lanadelumab: Takhzyro (SMC2206) 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

3.1.13 Tirzepatide: Mounjaro (SMC2633) - *pre-ERFC panel review*

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

Indication: for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.

SMC restriction: in addition to other oral anti-diabetic medicines as an option when glucagon-like peptide-1 (GLP-1) receptor agonists would be considered.

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

The ERFC discussed the supporting evidence, and the additional information provided from the pre-ERFC panel meeting. The committee noted that "insufficiently controlled" type 2 diabetes mellitus refers to patients who have a HbA1c level greater than 58. Supporting evidence for Tirzepatide is provided from three trials: SURPASS-2 with comparable evidence versus Semaglutide, SURPASS-3 versus Insulin Degludec, and SURPASS-4 versus Insulin Glargine, with all three trials demonstrating statistically significant reductions in HbA1c, both at week 40 and week 52 in the trials.

It was noted that Tirzepatide has a safety profile similar to most GLP-1 receptor agonists, with a low number of hypoglycaemic events and discontinuation primarily due to adverse gastrointestinal effects. The proposed place in therapy is fourth-line, with patients required to be treated with a SGLT-2 inhibitor, or Metformin, or a GLP-1 prior to commencing treatment with Tirzepatide, unless there are other contraindications. The applicants also provided confirmation that current fourth-line treatment options, Pioglitazone and Sitagliptin, will be moved to fifth-line in the 'Diabetes Mellitus – type 2' treatment pathway. The ERFC emphasised the importance of separating the proposed indicated use for Tirzepatide as a treatment for adults with insufficiently controlled type 2 diabetes from the weight management indication of the medicine on the ERF, noting concerns of exponentially increased prescribing of Tirzepatide due to frequent NPSA alerts and stock control issues for GLP-1s.

The committee noted that the patient numbers provided account for a percentage of all type 2 diabetic patients in the East Region who would have a HbA1c greater than 58, and, therefore, the numbers provided are likely to be an overestimation as the majority of the type 2 diabetic population will be treated satisfactorily with a GLP-1.

The ERFC noted that upon review at the pre-ERFC panel meeting, a request was made for the treatment flowchart to include targets for each stage of treatment escalation. However, the applicants have confirmed that this is not possible as it goes against national and international guidance from NICE, SIGN, and the ADA; it was noted that treatment targets are individualised to the patient based on several factors including age, frailty, comorbidities, and hypoglycaemia risk, therefore, the wording on the treatment algorithm is very specific regarding achieving individualised targets and should not be changed. The pre-ERFC panel also requested further information as to how patient reviews at six months will be managed and stopping information based on HbA1c, as well as whether weight loss alone will be considered a successful treatment. The applicants provided confirmation that the decision to continue or discontinue Tirzepatide is individualised to the patient and will likely include both tolerability, initial HbA1c, weight change, HbA1c change, cardiovascular risk profile, and individualised HbA1c target; patients who do not demonstrate weight loss or HbA1c improvement will be counselled on treatment discontinuation. It was noted that Tirzepatide will be prescribed Specialist Initiation by secondary care in the first instance, however, the ERFC queried whether six-month reviews for patients will be carried out in primary or secondary care, with further guidance required to support prescribing across the interface.

The ERFC discussed the affordability of the medicine, with confirmation from the applicants that there is currently no framework for discussion between secondary care specialists and primary care budget holders. Upon discussion, the ERFC agreed that there are no clinical concerns regarding the use of Tirzepatide across the region, however, the committee noted the significant financial impact on HSCPs across the East Region, and stressed that primary care prescribing forums need to be sighted to ensure effective planning and budgeting.

Post-meeting note: The ERFC co-Chairs noted that confirmation has been received 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 ERFC agreed to classify Tirzepatide: Mounjaro (SMC2633) as Routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.14 FAF2 Mexiletine - *resubmission*

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

Indication: For the treatment of Ventricular Arrhythmias.

The finance budget template was included with the FAF.

The ERFC discussed the re-submission, acknowledging the committee's request from the May meeting for a revised application with amended costings to account for existing patients, as well as information regarding the anti-arrhythmic medicines used prior to Mexiletine. The committee noted the revised costings provided as well as the further information to confirm that Mexiletine is used for the treatment of ventricular arrhythmias unresponsive to other antiarrhythmic agents (Beta blockers, Digoxin, Amiodarone, and Flecainide).

The ERFC noted and confirmed their satisfaction with the Shared Care protocol included to support the use of Mexiletine in both primary and secondary care. The committee noted that Mexiletine would be more appropriate for inclusion in Formulary Decisions section of the formulary.

The ERFC agreed to classify Mexiletine 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

3.1.15 FAF2 Flamigel RT

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were noted. Named CD support was received from NHS Lothian, with the medicine used only in the Edinburgh Cancer Centre, the tertiary oncology centre for the East Region.

Indication: Symptomatic treatment of low-grade radiotherapy-induced skin reactions such as red, dry, itching, flaking, peeling or irritated skin (dry desquamation). It can also be used to treat more severe skin reactions that can develop at a later stage of radiotherapy as partial skin breakdown and appearance of oozing blisters (moist desquamation).

The finance budget template was included with the FAF.

The ERFC noted the intended use of Flamigel RT as a replacement for Flamazine due to ongoing stock control issues with the medicine and as a cost-saving alternative. The committee queried the preferred use of Flamigel RT in comparison to Flamigel which is significantly cheaper and contains the same ingredients.

Post-meeting note: If the clinical team after review wish to change the product to Flamigel, please submit a FAF3; if not, please resubmit the FAF2 with reasoning on why Flamigel RT is preferred.

The ERFC request further information from the applicants as to why Flamigel RT is preferred to Flamigel. The applicants are requested to respond with information on the recommended action by 17 September 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Flamigel RT 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

3.2 Formulary Amendment Form

3.2.1 Acetylcysteine

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Clinical team support received from NHS Lothian and NHS Borders.

Indication: Reduce the viscosity and tenacity of mucus in the eye

Application for amendments to the Adult 'Treatment of severe dry eye', Adult 'Treatment of moderate dry eye', Child 'Treating mild dry eye', Child 'Treating moderate dry eye', and Child 'Treating severe dry eye' ERF pathways.

The ERFC discussed the supporting evidence. The committee noted the prescribing enquiry received regarding the high cost of ILUBE Acetylcysteine 5% Eye Drops, with the medicine noted as Specialist Initiation in other NHS Scotland Health Boards. Ophthalmology specialists within NHS Lothian have confirmed that despite the high cost, the medicine provides treatment for a specific patient group where there are no alternative cost-saving treatments.

The ERFC noted the draft formulary amendment provided, and approved the addition of Specialist Initiation formulary flagging to ILUBE Acetylcysteine 5% Eye Drops throughout the relevant treatment pathways, as well as revised prescribing notes to provide further clarity that the SI flagging allows for prescribing by both community optometrists with the independent prescriber qualification and ophthalmologists.

The ERFC agreed to add Specialist Initiation formulary flagging to ILUBE Acetylcysteine 5% Eye Drops throughout the relevant treatment pathways, as well as amendments to the relevant prescribing notes. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Atogepant

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: Preventative treatment of chronic and episodic migraine

Application for the removal of the 'Specialist Initiation' formulary flagging from Atogepant within the Migraine 'Advanced therapies for treatment of chronic and episodic migraine' pathway.

The ERFC discussed the supporting evidence, raising concerns regarding the additional support required for prescribers. It was noted that the Migraine/Chronic Migraine RefHelp guideline will be amended to include prescribing guidance for Atogepant, with a link to the Centre for Sustainable Delivery's National Headache Pathway included in the RefHelp guideline. The committee noted that the amended RefHelp guideline will provide support for secondary care prescribing, and agreed that an article in an upcoming edition of the East Region Prescribing Bulletin will be beneficial to support prescribing in primary care.

The ERFC agreed to remove the Specialist Initiation formulary flagging from Atogepant within the Migraine 'Advanced therapies for treatment of chronic and episodic migraine' pathway. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Rimegepant

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: Preventative treatment of episodic migraine

Application for the removal of the 'Specialist Initiation' formulary flagging from Rimegepant within the Migraine 'Advanced therapies for treatment of chronic and episodic migraine' pathway.

The ERFC discussed the supporting evidence, raising concerns regarding the additional support required for prescribers. It was noted that the Migraine/Chronic Migraine RefHelp guideline will be amended to include prescribing guidance for Rimegepant, with a link to the Centre for Sustainable Delivery's National Headache Pathway included in the RefHelp guideline. The committee noted that the amended RefHelp guideline will provide support for secondary care prescribing, and agreed that an article in an upcoming edition of the East Region Prescribing Bulletin will be beneficial to support prescribing in primary care.

The ERFC agreed to remove the Specialist Initiation formulary flagging from Rimegepant within the Migraine 'Advanced therapies for treatment of chronic and episodic migraine' pathway. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.4 Pivmecillinam

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: Lower UTI (LUTI) in women and men, LUTI due to confirmed multidrug resistant Enterobacteriaceae.

Application for amendments to the 'Lower UTI in non-pregnant women' and 'Lower UTI in men' pathways due to changes in microbiology laboratory testing now permitting routine testing of urine samples for sensitivities to Pivmecillinam.

The ERFC discussed the supporting evidence.

The ERFC agreed to include Pivmecillinam in the relevant treatment pathways. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.5 Erythromycin

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: Penicillin allergy in pregnancy.

Application for the amendment of the 'Treatment of acute cough and bronchitis' pathway and community acquired pneumonia as an alternative medicine option for penicillin allergy in pregnancy.

The ERFC discussed the supporting evidence and accepted the proposed changes with additional input required to agree the proposed changes are presented consistently in line with other formulary content and to incorporate suggestions for the treatment of pertussis. The ERFC agreed that following chapter expert input the changes can be approved by the ERWG.

The ERFC agreed to include Erythromycin in the relevant treatment pathway. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra Orphan Medicines Initial Assessment – *for information*

Birch bark extract: Filsuvez (SMC2651) **Ultra-Orphan Initial Assessment**

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Clostridium botulinum neurotoxin type A powder for solution for injection: Xeomin (SMC2680)
3.4.2 Decitabine/cedazuridine film-coated tablets: Inaqovi (SMC2681)
3.4.3 Dupilumab solution for injection in pre-filled pen and syringe: Dupixent (SMC2682)
3.4.4 Pembrolizumab concentrate for solution for infusion: Keytruda (SMC2683)
3.4.5 Lenacapavir film-coated tablets and solution for injection: Sunlenca (SMC2691)
3.4.6 Remimazolam: Byfavo (SMC2692)
3.4.7 Trastuzumab deruxtecan: Enhertu (SMC2693)
3.4.8 Pembrolizumab concentrate for solution for infusion: Keytruda (MGC) (SMC2644)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Momelotinib film coated tablet: Omjjara (SMC2636)

The ERFC noted the SMC abbreviated submission for Momelotinib film coated tablet: Omjjara (SMC2636).

Indication: Treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

The ERFC agreed to classify Momelotinib film coated tablet: Omjjara (SMC2636) as Not Routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5.2 Follitropin delta: Rekovelle (SMC2670)

The ERFC noted the SMC abbreviated submission for Follitropin delta: Rekovelle (SMC2670).

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

SMC restriction: for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L).

The ERFC noted the information received from NHS Fife to confirm that the medicine is only used in their tertiary centre at Ninewells, and a formulary application will not be required.

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

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 Glofitamab concentrate for solution for infusion: Columvi (SMC2614)
3.7.2 Voxelotor film-coated tablets: Oxbryta (SMC2626)
3.7.3 Epcoritamab concentrate for solution for injection and solution for injection: Tepkinly (SMC2632)
3.7.4 Tirzepatide solution for injection in pre-filled pen: Mounjaro (Obesity) (SMC2653)
3.7.5 Empagliflozin film-coated tablets: Jardiance (SMC2642)
3.7.6 Nivolumab, relatlimab concentrate for solution for infusion: Opdualag (SMC2645)
3.7.7 Pembrolizumab: Keytruda (SMC2660)
3.7.8 Pegunigalsidase alfa: Elfabrio (SMC2665)
3.7.9 voretigene neparvovec 5 x 1012 vector genomes/mL concentrate and solvent for solution for injection: Luxturna (SMC2641) **Ultra-Orphan Reassessment**

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

NCMAG Programme Quarterly Update – *for noting*.

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

FAF3s should be submitted by 21 August 2024 (for discussion at the ERFC pre-panel meeting on 28 August 2024).

FAF1s for consideration by the ERFC pre-panel should be submitted by 21 August 2024 (for discussion at the ERFC pre-panel meeting on 28 August 2024).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 17 September 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 prescribing@nhslothian.scot.nhs.uk.