East Region Formulary

East Region Formulary Committee
Minutes

Date: 29 May 2024
Time: 2.00pm – 5.00pm
Location: MS Teams

Present:

Jane Browning	Associate Director of Pharmacy, NHS Lothian
Ruth Cameron	Advanced Clinical Nurse Specialist - Urology, NHS Fife
Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Malcolm Clubb	Director of Pharmacy (Co-chair), NHS Borders
Steven Fenton	Project Manager, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife – in the Chair
Nikki Gilluley	Lead Pharmacist - Regional Formulary Development, 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

In attendance:
Clare Colligan, Lead Pharmacist, NHS Forth Valley *(observer)*
Stephen O'Neill, Lead Pharmacist, NHS Forth Valley *(observer)*
Moira Ross, Information Officer, NHS Lothian *(minutes)*

Apologies:
Nicole Cromar, Pharmacist – Neurology, NHS Lothian
Gillian Donaldson, Nurse – Cardiology, NHS Borders
Carol Holmes, Pharmacist - Primary Care, NHS Lothian
Cathryn Park, Deputy Director of Pharmacy, NHS Borders
Dr Andrew Watson, Consultant – Psychiatry (Co-chair), NHS Lothian

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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 - Nikki Gilluley, NHS Lothian and Jane Goddard, NHS Lothian; the Chair noted Nikki Gilluley and Dr Jane Goddard's resignation from the ERFC. On behalf of the ERFC, the Chair thanked Nikki and Jane for their work and contribution to the committee.

1.2 Update on 'Stop and Assess' ERFC Pre-Panel

The ERFC received an update on the new 'Stop and Assess: Medicine' Pre-ERFC Panel.

The Pre-ERFC Panel is a process being tested as part of Stop & Assess in NHS Lothian. It is expected to be a temporary measure for 6 months. The Terms of Reference and further communications will be sent out once the process has been tested, and findings will be shared by NHS Lothian with NHS Fife and NHS Borders in due course.

The panel, which is being considered as an external peer review, will look at formulary application forms where finance has a net impact of £150,000 and above across the East region; all biologic medicines; applications where there is a discrepancy in patient number estimates in comparison to data provided in SMC advice; applications where there is an additional resourcing implication for the implementation of that medicine; and all FAF3 applications.

Three formulary applications submitted to this ERFC meeting were selected for review by the panel. The outcomes of the review were discussed by the ERFC, and action points were raised to inform the next review and discuss with Scottish Government and the SMC.

ACTION: Jane Browning, Associate Director of Pharmacy, NHS Lothian

1.3 Matters arising

1.3.1 ERFC 07 February 2024 Item 3.1.2 FAF1 Dostarlimab: Jemperli (SMC2404) was reviewed at the ERFC February meeting. The ERFC requested further evidence from the clinical team regarding the duration of treatment for this medicine and the subsequent costings. The ERFC noted that the requested information had been received, with costings provided based on a 6-month duration of treatment. However, the committee noted that there is the possibility for the duration of treatment to be significantly longer, with the potential for treatment to continue for up to three years, thus incurring exponential additional costs.

Consequently, the ERFC agreed for Dostarlimab: Jemperli (SMC2404) to remain as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The ERFC agreed for treatment decisions to be made on a case-by-case basis until SMC issues a reassessment of the medicine. Action completed.

ACTION: NHS Lothian Admin Team

1.3.2 ERFC 27 March 2024 Item 3.1.1 FAF1 Bimekizumab: Bimzelx (SMC2605) was reviewed at the ERFC March meeting. The ERFC requested further evidence from the clinical teams to demonstrate Bimekizumab: Bimzelx has higher efficacy compared to the other medicines within the pathway, as well as a review of patient numbers and replacement therapy costs.

The ERFC noted that the requested information had been received, with confirmation from the clinical team that there are no comparative studies available, and that the inclusion of Bimekizumab is an additional medicine option within the treatment pathway rather than a replacement medicine for Secukinumab.

The ERFC discussed and agreed that the addition of Bimekizumab would replace Secukinumab within the treatment pathway. The ERFC recommended further review of the existing formulary options for biologics and synthetic DMARDS for psoriatic arthritis by local experts to reach an agreement on the proposed ERF order of choices to reflect cost-effectiveness and current acquisition costs; the remaining medicine choices will cover options suitable for the initial treatment of most patients. The ERFC further recommended that the chapter experts advise on the removal of items that are less commonly used as they are not considered cost-effective in comparison to alternative formulary options.

Prescribers are reminded that non formulary options may be accessed for individual patients on a case- by-case basis through local Board non-formulary routes. The ERFC, however, stressed that access through Board non-formulary procedures will apply to new initiations of treatment only. The ERFC recommend local Board guidelines and treatment protocols are updated to reflect the revised order of

choices on the formulary when agreed by experts from the region.

The ERFC requested the applicants collaborate with chapter experts across the region to review the existing formulary choices for biologic and synthetic DMARDs in the formulary pathway, agree a revised order of choices, and identify less commonly used items to be removed in a revised application. The ERFC recommend the revised application is accompanied with copies of each boards revised treatment protocol(s) and/or updated local guidelines reflecting the agreed changes. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed for Bimekizumab: Bimzelx (SMC2605) to remain 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

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 27 March 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 08 May 2024

The minutes of the ERWG meeting on 06 March 2024 were noted for information.

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

- **Skin (Paediatric)**

The ERFC discussed the key points in the ERF Skin (Paediatric) chapter.

It was noted that there was positive engagement with chapter experts across the region, with the main aim of aligning Paediatric content with Adult pathways. Considerations have been made regarding the BNF for Children recommendations that varied from Adult recommendations, and Paediatric Licence Extensions that are now available for products that are used in adults and which the SMC now permit local Board decision-making.

The following comments were made:

- The guidance for up-dosing antihistamines for the treatment of urticaria in children advises to seek specialist dermatology advice.
- For the Treatment of Cradle Cap, it was noted that the evidence base is inconclusive and that some health professionals and guidelines, including NHS Inform and eczema.org, now advise avoiding the use of olive oil for cradle cap. It was, therefore, agreed to remove olive oil from the formulary. After the section review is concluded, Pharmacy First Scotland will be contacted to review the inclusion of olive oil on the Pharmacy First Approved List for this indication.
- There have been updates to skin disinfectants – unlicensed medicine flag added to Chlorhexidine Gluconate 0.5% solution, and Videne 10% antiseptic solution changed to the generic description 'povidine-iodine 10% antiseptic solution'.
- Anthelios sunscreen lotion SPF 50+ included post-ACBS approval; will also be included in the Adult pathway.
- In regard to the systemic treatment of fungal nail, skin, and scalp infections, it was agreed for no immediate treatment to be sought for fungal nail infections, but to seek prompt treatment for fungal scalp infections, and dermatology advice for fungal skin infections.
- There have been updates to the Scabies recommendations: MSAN links to Permethrin deleted and a password-protected link (for NHS Fife users only) included to access the NHS Fife guideline

for off-label dosing of Permethrin prior to starting Ivermectin - other Boards recommended to seek specialist advice.

- It was noted that the formulary recommendations (for both adults and children) differ from current BNF guidance on contraceptives for individuals using topical retinoids. It was agreed to align to the BNF in both the adult and child recommendations by deleting the text *"(oral progestogen-only contraceptives not considered* effective)", with changes approved by local experts.

The ERFC approved the new chapter content with the requested revision. The formulary website will be updated.

ACTION: ERF Project Manager

2.3.1 ERF Adult – Bipolar Disorder – Valproate MHRA DSU

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

2.3.2 ERF Adult – Epilepsy – Valproate MHRA DSU

The ERFC discussed the updates to a number of ERF adult pathways within 'Epilepsy Conditions'.

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

ACTION: NHS Lothian Admin Team

2.3.3 ERF Child – Epilepsy Conditions – Valproate MHRA DSU

The ERFC discussed the updates to a number of ERF child pathways within 'Epilepsy Conditions'.

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

ACTION: NHS Lothian Admin Team

2.3.4 ERF Child Amendment - Epilepsy Syndromes - Dravet and Lennox-Gastaut

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

2.3.5 ERF Adult & Child - Scabies - Ivermectin: Ivermectin

The ERFC discussed the updated Adult & Child pathways - 'Treatment of scabies'.

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 Conestat-alfa: Ruconest (SMC745/11)

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

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The ERFC noted that the SMC advice refers to both adolescents and adults, but the application mentions adults only. The product is available as powder for solution for injection with or without solvent. Further clarification is required to confirm whether one or both available formulations are proposed for formulary inclusion.

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, and the formulation to be included. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted the potential risk for hypersensitivity for patients with cow's milk protein allergies with Conestat-alfa: Ruconest containing traces of rabbit proteins; the SPC states that although unlikely, the possibility of cross-reactivity in a patient who has a clinical allergy to cow milk cannot be excluded. The ERFC recommend that this is added as a caution in the local patient letter.

It was noted that the use of Icatibant is mentioned within the supporting information, however, is not on the East Region Formulary currently. The ERFC agreed that a cost comparison of the products using current pricing information within the adult and child 'Acute attacks of hereditary angioedema' treatment pathway, as well as Conestat-alfa: Ruconest and Icatibant, is required to agree the formulary products for this indication, and to review and revise the product choices and order of choices with regard to cost-effectiveness. A submission for Icatibant is recommended if there is an intention to use this product in the East region.

The ERFC requested clarification on whether treatment with Ruconest would be provided to patients as stock only via Home Care or whether stock would also be held in emergency departments. If stock is to be held in emergency departments, the costs will require revision to account for stock holding and consideration to expired stock. If all stock is to be delivered via Home Care, the costs in the table should be amended to reflect. The ERFC noted in the application that Ruconest may be considered during supply shortages of alternative medicines, if attacks are infrequent, and/or the long shelf-life offers cost benefits in comparison to the alternatives (comparing against cost to replace expired stock).

The ERFC requested an amended application to be submitted with revised costings and 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 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 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted that a patient letter, but no national, regional, or local guideline or treatment protocol was presented with the application. The ERFC noted that additional costs and staffing resources are associated with this medicine in relation to implementation.

The ERFC 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 applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: 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

3.1.2 FAF1 Dupilumab: Dupixent (SMC2598)

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 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 supporting evidence. The committee noted the applicants cited short-term data; therefore, it is unclear whether the treatment response would tail off in the longer term. The protocol (NHS Fife) provided with the application states that treatment will cease after 16 weeks if there is no response - if there is a partial response, a review will occur at 52 weeks. The ERFC requested that information is added regarding the review of treatment thereafter, with clear stopping criteria. The ERFC request clarification on the availability of guidelines for NHS Lothian and NHS Borders, or if these boards intend to adopt the NHS Fife guidance, or whether there is national guidance. The ERFC agreed that this medicine, when approved, would be appropriate to note in formulary decisions only, due to the highly specialised management with initial treatment options dependant on underlying cause.

The ERFC requested further information from the applicants regarding plans for patient reviews at further timepoints and stopping criteria for loss of response. The ERFC request clarification on guidelines for use in the other Boards or confirmation that the guideline with the submission is being adopted by the other Boards. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC raised concerns regarding the low number of proposed patients. The patient numbers in the application are lower than those is in the SMC detailed advice document. The SMC further noted that the experts consulted advised that company estimates could be underestimated.

The ERFC requested further information as to how patient numbers are derived. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Dupilumab: Dupixent (SMC2598) 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 Mavacamtem: Camzyos (SMC2618)

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 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 supporting evidence, with primary evidence provided by the EXPLORER-HCM study. It was noted that the costings provided in the application account are for the acquisition cost of Mavacamtem in the incident population. It was agreed that costings should be amended to reflect the use of the medicine as treatment for the incident population and prevalent population for one year, and that the cost should be revised to account for 13 packs of 28 tablets per annum. The ERFC noted that additional costs will be incurred through genetic testing and follow up treatment, and requested that the applicants confirm that budget holders and medical mangers are supportive of the additional costs/resources implications.

The ERFC requested an amended application to be submitted with revised patient numbers and costings, and confirmation that budget holders and medical managers are supportive of additional costs related to yearly growth in patient numbers and associated testing. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted the proposed 'Specialist Use Only' formulary flag, and highlighted the importance of including advice for GPs in the guidance; noting the need to include contraceptive advice, and the impact of Mavacamtem on the other medicines a patient may be given.

The ERFC requested that the applicants liaise with a GP and include the required advice within their guidance. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The proposed place in therapy is as the third-line treatment option. The ERFC, however, noted the recommendation from the European Society of Cardiology, and agreed that Mavacamtem: Camzyos would be more suitably used after treatment failure or tolerability of the first-line treatment options as an adjunct to individually optimised standard care, where standard care comprises of either non-vasodilating beta-blockers or non-dihydropyridine calcium channel blockers as monotherapy in line with the licensed indication. It was further noted that the proposed use the medicine is alongside Disopyramide, however, it is not on the ERF currently - it is not always available and less favourable for new initiations due to tolerability. There is no ERF treatment pathway for oHCM, therefore, due to highly specialised management, this medicine would be appropriate for inclusion in formulary decisions section.

The ERFC requested further clarity regarding the positioning of Mavacamtem in relation to first- and second-line treatment options, and the revision of local guidance to reflect. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Mavacamtem: Camzyos (SMC2618) 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 Mirikizumab: Omvoh (SMC2650)

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 adult patients with moderately to severely active Ulcerative Colitis (UC) 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 supporting evidence and noted a discrepancy between the Lothian UC pathway referenced in the application and the current ERF treatment pathway; anti-TNF medicines (Infliximab or Adalimumab) noted as first-line treatment options on ERF, whereas Infliximab, Filgotinib, and Vedolizumab are noted as first-line within the Lothian guideline. No other board guidelines were presented in support of the application.

The ERFC recommend further review of the existing formulary options for biologics and synthetic DMARDS for ulcerative colitis by collaboration between local experts from the region to reach an agreement on the proposed ERF order of choices. The ERF order of choices is to reflect safety, efficacy, cost-effectiveness, and current acquisition costs. The remaining choices on the formulary are to cover those options suitable for initial treatment of most patients. The ERFC agreed that the addition of Mirikizumab should be to replace an alternative formulary drug in the same class that is considered to be less cost-effective. The ERFC recommend the chapter experts advise on the removal of any items that are less commonly used because they are not considered cost-effective in comparison to alternative formulary options. Prescribers are reminded that non-formulary options for new initiations may be accessed for individual patients on a case-by-case basis through local Board non-formulary routes (this process does not apply to patients already established on treatment). The ERFC recommend local Board guidelines and treatment protocols are updated to reflect the revised order of choices on the formulary when agreed by experts from the region.

The ERFC requested guidelines for the other Boards or if no Board guideline, confirmation of the treatment choices used, and the order of preference and reasoning i.e., safety, efficacy, cost-effectiveness. Where there is variation in practice between the Boards, the ERFC request supporting evidence regarding efficacy, safety, and cost-effectiveness. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC seek 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 applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The SMC approval of this medicine is an addition of a new treatment in the drug class via the Abbreviated Submission process, therefore, the ERFC agreed that Ustekinumab is the relevant comparator medicine rather than Vedolizumab.

The ERFC requested the submission of a revised application for Mirikizumab as a replacement medicine within the treatment pathway, not as an additional medicine, and revised medicine choices in the pathway 'Treatment of ulcerative colitis with biologic and targeted synthetic DMARDs'. The revised application is also required to provide financial evidence with Ustekinumab as the comparator medicine rather than Vedolizumab. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

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

3.1.5 FAF1 Nivolumab: Opdivo (SMC2619)

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: In combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable (tumours ≥4 cm or node positive) non-small cell lung cancer in adults.

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

The ERFC discussed the supporting evidence, noting the immunotherapy trial evidence provided which states that patients who have PD-L1 receptors received no additional benefit from Nivolumab.

The ERFC requested a protocol to be written with instruction that the medicine should not be given to all patients who are PD-L1 unless the clinical team can provide justifiable reasoning. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Nivolumab: Opdivo (SMC2619) 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 Regorafenib: Stivarga (SMC2562)

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 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 ERFC discussed the supporting evidence and the additional information provided from the ERFC pre-panel meeting. The committee noted and discussed the recent developments in the treatment of the disease and on-going discussions regarding the use of Regorafenib, with the positioning of the medicine within treatment pathways currently under national discussion.

The ERFC noted the toxicity profile of the medicine, with common side-effects that the SACT teams are experienced in dealing with and have policies in place to manage. Non-medical prescribers will be trained to prescribe the drug, and it was noted that the medicine is not suitable for Shared Care.

It was noted that the formulary application states that the medicine will be administered in NHS Lothian, however, the committee noted that the medicine will, in fact, be administered in all three Boards. Further concerns were raised regarding the financial information provided; there is the potential for an additional financial impact incurred as a result of the high toxicity of the medicine which will potentially result in increased hospital admissions, as well as the medicine being

administered via the chemotherapy unit rather than out of clinics. Neither have been included in the costings provided.

The ERFC requested confirmation that budget holders and medical managers have noted and supported the additional costs in relation to treatment of toxicity and resources for delivery in all three Boards. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC noted the marginal clinical benefit and high cost of this medication, and were advised that prior to decision to start a new treatment in an individual, as well as at the beginning of each administration of SACT, shared decision making between health professionals and patients is considered and documented.

The ERFC agreed to classify Regorafenib: Stivarga (SMC2562) as Not Routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.7 FAF1 Ritlecitinib: Litfulo (SMC2610)

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: 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.

The ERFC discussed the supporting evidence. The ERFC noted the lack of treatment protocol and accompanying implementation plan. It was noted that the patient numbers provided in the formulary application are not reflective of the information provided by the SMC who state that there will be an escalating number of patients.

For each Board, further detail is required on the assessment of response, stopping criteria, and safety considerations in relation to MHRA guidance on JAK Inhibitors with a shared decision-making framework. It was further noted that as a JAK Inhibitor medicine, hepatitis and TB screening will be required prior to starting treatment.

The ERFC request confirmation that additional costs and resource implications as well as the anticipated growth in use over time are noted and supported by medical managers and budget holders.

The ERFC requested 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 applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

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

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific and two personal non-specific declarations of interest were noted. 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 supporting evidence, and the additional information provided from the ERFC pre-panel meeting.

The ERFC acknowledged the error noted in the Declarations of Interest section of the application and requested a re-submission of the form with corrected DOIs.

The ERFC noted that Secukinumab will be an additional cost, not a replacement medicine, as it will be used second-line after Adalimumab if treatment has not been successful or if treatment effect has waned. Therefore, it was agreed that Adalimumab should not be used as a cost-comparator medicine for Secukinumab. The ERFC further discussed the discrepancies in the finance section due to variable dosing schedules.

The ERFC requested the submission of a revised application with Adalimumab removed as the cost-comparator medicine and a review of the finance section to account for variable dosing schedules. With the resubmission, the committee require 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 DOI section of the application will also need corrected. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Secukinumab: Cosentyx (SMC2592) 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

3.1.9 FAF1 Selpercatinib: Retsevmo (SMC2573)

The ERFC noted and discussed the previously circulated FAF1 submission. 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 noted that the guideline and protocol is in early draft form with comments, clarifications, and approval outstanding.

The ERFC noted that the pricing used in the calculation was incorrect and requires revision.

The ERFC requested the submission of a revised application with corrected costings. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC discussed the supporting evidence and the additional information provided from the ERFC pre-panel meeting. The committee noted that positive phase III trial data has been reported since the SMC interim advice was issued.

The ERFC agreed to classify Selpercatinib: Retsevmo (SMC2573) 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

3.1.10 FAF2 Cationorm Eye Drops

The ERFC noted and discussed the previously circulated FAF2 submission. One personal non-specific declaration of interest was noted. Named CD support was received from all three Boards.

Indication: For the treatment of Moderate to Severe dry eye – indicated to provide relief of dry eye symptoms, such as stinging, itching or burning eyes, or foreign-body sensation in the eyes.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The proposed place in therapy is third-line treatment for severe dry eye where it is refractory to other treatments or for those on multiple drop types.

The ERFC queried the requirement to commence treatment within hospital, noting the potential cost-saving if prescription can be granted via GPs.

The ERFC agreed to classify Cationorm Eye Drops 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

3.1.11 FAF2 Insulin Aspart: Trurapi

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were noted. The same individual has completed the clinician and pharmacist applicant sections. Email support given by two other pharmacists. Named CD support was received from all three Boards.

Indication: For the treatment of diabetes in adults, adolescents and children aged 1 year and above requiring a Rapid Acting Insulin.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence.

The ERFC requested the application form to be re-submitted with the signature section correctly co-signed with completed declaration of interests by a supporting pharmacist. The applicant is requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Insulin Aspart: Trurapi, subject to revised application, as Routinely available in line with local or regional guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.12 FAF2 Mexiletine

The ERFC noted and discussed the previously circulated FAF2 submission. 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 supporting evidence.

The ERFC noted that there is a lack of clear information regarding which anti-arrhythmic medicines would be used prior to Mexiletine, and requested further clarity as there is not currently a treatment pathway.

The ERFC further noted that the finance section only accounts for new patients treated in secondary care, and does not account for the existing fifteen patients who are currently being treated across the East Region.

The ERFC requested the submission of an amended application with revised costings to account for existing patients, as well as information regarding the anti-arrhythmic medicines used prior to Mexiletine. The applicants are requested to respond with information on the recommended action by 23 July 2024.

The committee would like further information from the clinical team to understand what discussions have occurred already with colleagues concerning the transition from secondary to primary care, taking into account that Shared Care might not occur. The ERFC agree that the medicine is appropriate for shared care and request a draft shared care agreement is developed before the medicine can be considered for classification as for “specialist initiation”. The ERFC agreed to flag this drug as “Specialist Use Only” and for the applicants to resubmit an amendment request along with a draft Shared Care Agreement in support of the proposal.

The ERFC agreed to classify Mexiletine 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 FAF3 Neomycin

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were noted. Named CD support was received from all three Boards.

Indication: Antibiotic prophylaxis in left-sided colonic or rectal resection with planned anastomosis.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence and noted differences in dosing. It was noted that the applicants intend to follow a protocol from another health board out with the East Region. To ensure governance adherence, the committee recommend the use of a protocol that has gone through the ADTC for one of the three ERF Boards and to the Antimicrobial Team.

The ERFC also queried why Neomycin (which is unlicensed) was chosen when there are licensed products available.

The ERFC requested further information to provide positive evidence for the unlicensed use of Neomycin for the proposed indication. The ERFC also require a protocol which has been ratified by local Boards' governance processes and respective antimicrobial teams. The applicants are requested to respond with information on the recommended action by 23 July 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Neomycin 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 Forms

3.2.1 LaRoche-Posay Anthelios SPF50+ Suncream

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: Sun protection.

Application for the addition of LaRoche-Posay Anthelios SPF50+ Suncream to 'Prescribable sunscreens for ACBS conditions' following discontinuation of other sunscreen products.

The ERFC discussed the supporting evidence.

The ERFC agreed to add LaRoche-Posay Anthelios SPF50+ Suncream to the treatment pathway. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Travoprost PF

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

Indication: For the treatment of Glaucomas.

Application for the addition of Travoprost PF to allow for a preservative-free option for those with sensitivities to preservatives.

The ERFC discussed the supporting evidence.

The ERFC requested named CD support from all three Boards prior to inclusion on the ERF.

ACTION: NHS Lothian Admin Team

The ERFC agreed to add Travoprost PF to the treatment pathway. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra-Orphan Medicines

None noted.

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Ruxolitinib topical: Opzelura (SMC2634)
3.4.2 Zanubrutinib: Brukinsa (SMC2671)

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

The ERFC noted the SMC abbreviated submission for Glycopyrronium/formoterol fumarate pressurised inhalation, suspension: Bevespi Aerosphere (SMC2652).

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

The ERFC agreed to classify Glycopyrronium/formoterol fumarate pressurised inhalation, suspension: Bevespi Aerosphere (SMC2652) 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 Daridorexant film-coated tablets: Quviviq (SMC2611)
3.7.2 Tirzepatide solution for injection in pre-filled pen: Mounjaro (SMC2633)
3.7.3 Dostarlimab concentrate for solution for infusion: Jemperli (SMC2635)
3.7.4 Budesonide/formoterol: Symbicort Turbohaler (SMC2622)
3.7.5 Remdesivir: Veklury (SMC2550)

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

ACTION: NHS Lothian Admin Team

3.8 National Cancer Medicines Advisory Group

None noted.

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

None raised.

4.3 NHS Lothian

None raised.

5 Any other competent business

The Chair and committee members acknowledged that Alison Casey will be leaving the committee as she embarks on her maternity leave, and will rejoin the committee upon her return. The committee wished Alison all the best for her upcoming maternity leave.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 07 August 2024 at 1400 - 1630 hours via MS Teams. NHS Borders will be hosting the meeting.

FAF3s should be submitted by 02 July 2024 (for discussion at the ERWG meeting on 17 July 2024).

FAF1s and FAF2s should be submitted by 23 July 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.