East Region Formulary

East Region Formulary Committee
Minutes

Date: 13 December 2023
Time: 2.00pm – 4.51pm
Location: MS Teams

Present:

Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Malcolm Clubb	Director of Pharmacy (Co-chair), NHS Borders
Steven Fenton	Project Manager, NHS National Services Scotland
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiology (Co-chair), NHS Fife
Nikki Gilluley	Lead Pharmacist - Regional Formulary Development
Carol Holmes	Lead Pharmacist – West Lothian HSCP, NHS Lothian
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist – Medicines Governance, NHS Lothian
Alice Mathew	Formulary Pharmacist, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant – Cardiology, NHS Borders
Fraser Notman	Lead 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 the Chair
In attendance:	Caitlin Satti, Information Officer, NHS Lothian
Apologies:	Jane Browning, Associate Director of Pharmacy, NHS Lothian Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife Carla Capaldi, Senior Practice Pharmacist, NHS Fife Nicole Cromar, Senior Pharmacist Neurology, NHS Lothian Gillian Donaldson, Specialist 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.
- Welcome – Malcolm Clubb, NHS Borders
- Leaving – Dr Peter Hall, NHS Lothian; the Chair noted Dr Peter Hall's resignation from the ERFC. Dr Hall has been a long-standing member of the Lothian Formulary Committee and part of the ERFC. On behalf of the ERFC, the Chair thanked Dr Hall for his work and contribution to the committee.

1.2 Update on progress with Chapter Expert Working Groups (CEWG)

The ERFC received an update on progress with the Chapter Expert Working Groups.

Since the last meeting, the paediatric Cardiovascular, Gastrointestinal and Respiratory chapters, as well as three out of the four paediatric CNS chapter sections have been completed and launched on the website and app.

The fourth CNS chapter is included in this meeting, item 2.3 for discussion. Additional pathways have been added to CNS chapter B covering abdominal migraine and cyclical vomiting which are included in this meeting, item 2.3 for discussion. The paediatric Infections chapter is also included in this meeting, item 2.3 for discussion. The paediatric Endocrine chapter is currently out for additional comments and will be presented at the next ERWG and come to the next ERFC in early 2024.

Future paediatric chapters for review include Skin, with preliminary meetings schedules for early 2024, as well as Musculoskeletal, and Nutrition and Blood.

The ERFC noted the update on progress with the Paediatric ERF chapters and had no further comments.

1.3 Matters arising

1.3.1 Cemiplimab: Libtayo (SMC2584)

The ERFC noted that Cemiplimab: Libtayo is already on the Formulary with interim acceptance SMC2216, but has recently undergone a reassessment. The NHS Lothian Oncology team have confirmed that there are no changes to the indication or use of the medicine. The SMC number and relevant links will be updated on the ERF.

ACTION: NHS Lothian Admin Team

1.3.2 ERFC 09 August 2023 item 3.1.1 - FAF1 pembrolizumab: Keytruda (SMC2526) was reviewed at the ERFC August meeting. Pembrolizumab: Keytruda (SMC2526) was included on the ERF for Specialist Use Only, for adults > 18 years.

The ERFC requested clarification on potential use in adolescents aged 12 years and older, and input from paediatric oncology specialists if appropriate. Further information has not yet been received from the local paediatric oncology specialists for ages 12-17 years of age. The local decision is for use for adults only, currently. Action complete.

The ERFC also requested confirmation of the finance detail as the finance template included with the FAF1 is based on 3-weekly dosing, total 34 vials, and the proposed dosing schedule is for 6-weekly dosing, total 36 vials.

The ERFC noted that this remains outstanding and agreed that this should be carried forward as ongoing. The applicants are requested to respond with information on the recommended action by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

1.3.3 ERFC 09 August 2023 item 3.1.2 - FAF1 pembrolizumab: Keytruda (SMC2144) was reviewed at the ERFC August meeting. Pembrolizumab: Keytruda (SMC2144) was included on the ERF for Specialist Use only.

The ERFC also requested confirmation of the finance detail as the finance template included with the FAF1 is based on 3-weekly dosing, total 34 vials, and the proposed dosing schedule is for 6-weekly, total 36 vials.

The ERFC noted that this remains outstanding and agreed that this should be carried forward as ongoing. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

1.3.4 ERFC 09 August 2023 item 3.1.11 FAF1 tezepelumab: Tezspire (SMC2541) was reviewed at the ERFC August meeting. The ERFC noted that there was no information/guidance on the criteria for choosing one medicine over the other first line alternatives for this indication. The ERFC requested clarification on the place in the treatment pathway and a review/rationalisation of the first line Formulary choices for this indication.

The ERFC noted the additional information was received regarding the medicine's place in the treatment pathway and the rationalisation of first line Formulary choices. The clinical team advised that Tezepelumab is considered as equal first line to Omalizumab, Mepolizumab, Benralizumab and that health boards are unable to rationalise the formulary choices or order any further. The biologics each have different mechanisms of action and target different inflammatory pathways. As part of the assessment process, respiratory specialists determine the phenotype of asthma and identify which biologic is most likely to be beneficial. The ERFC noted the response and request further details on when one biologic would be used in preference over another and noted that a guideline for the prescribing of respiratory biologics is currently in use in NHS Fife. The ERFC requested that the Fife guideline is shared with respiratory specialists in the other Boards along with any local guidelines currently in use by NHS Lothian and NHS Borders with a view to the consideration of a regional guideline.

The ERFC requested further information from NHS Lothian and NHS Borders regarding their respective respiratory guidelines, with the potential for NHS Fife's guideline to be used regionally. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

1.3.5 ERFC 11 October 2023 Item 3.1.1 FAF1 apalutamide: Erleada (SMC2579) was reviewed at the ERFC October meeting. The ERFC noted that the application stated Enzalutamide as the cost-comparator drug which is not approved for non-metastatic indications. The ERFC requested a review of the finance section to reflect Darolutamide as the cost comparator instead of Enzalutamide.

The ERFC noted that this remains outstanding and agreed that this should be carried forward as ongoing. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

1.3.6 ERFC 11 October 2023 Item 3.1.3 FAF1 pembrolizumab: Keytruda (SMC2538) was reviewed at the ERFC October meeting. The ERFC requested a review of the finance budget template to provide clarity on the cost per annum for all patients.

The ERFC noted that a review of all current outstanding pembrolizumab applications which require updated costings regarding the now more commonly used 6-weekly dosing interval instead of the 3-weekly dosing schedule, is required. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

1.3.7 ERFC 11 October 2023 Item 3.1.4 FAF3 Zoledronic Acid was reviewed at the ERFC October meeting. The ERFC agreed that a new formulary pathway will need to be developed with input from local experts with guidance included on the operational arrangements including recommendations for ongoing doses, monitoring and follow-up of patients.

The ERFC noted that this action remains outstanding with discussion in progress and agreed that this should be carried forward as ongoing.

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 11 October 2023

The minutes of the previous meeting were approved as an accurate record with no changes note.

2.2 East Region Working Group (ERWG) meeting minutes 22 November 2023

The minutes of the ERWG meeting on 22 November 2023 were noted for information.

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

- **CNS Chapter A (Paediatric)**

The ERFC discussed the key points in the ERF CNS Chapter A (Paediatric).

The CEWG was well attended, with a variety of representation from all three Boards. An additional meeting was conducted to further discuss psychosis and related disorders.

A small number of medicines are noted to be used repetitively throughout the chapter, with SSRIs references heavily in the anxiety and depression pathways. It was noted that an additional prescribing note for Sertraline was added; 100mg/5ml concentrated liquid removed due to its high ethanol content, and the increased risk associated with the dilution of a concentrated solution and replaced by 50mg/5ml unlicensed solution. A general information note has been added above SSRIs within the pathway to promote safe prescribing.

It was noted that the CEWG requested a pathway for aggression in autism, with the chapter experts asked to adhere to the governance process and submit formulary application forms for medicines to be added. The ERFC noted the sensitivities around the wording of the pathway, emphasising that there is no treatment for autism, but rather the treatment of conditions in autistic children.

A further pathway for rapid tranquilisation or sedation for acute behavioural disturbance has been requested. It was noted that each Board currently has their own respective guideline, with a decision to be made as to whether the Formulary moves forward with 3 separate guidelines or work to produce a collaborative East Region guideline. The ERFC noted that NHS Lothian has a guideline which covers under eighteens and are the provider of inpatient care for all the region, with the prospect of Lothian's guideline being used across the regions.

The ERFC requested the addition of non-pharmacological measures as first-line treatment within the 'Treatment of bipolar depression' pathway.

ACTION: NHS Fife Formulary Pharmacist

The ERFC discussed the addition of a ''Treatment of bipolar depression' pathway within the Adult CNS chapter, and noted it for the next cycle of Adult chapter reviews as part of business-as-usual within the East Region Formulary.

ACTION: NHS Fife Formulary Pharmacist/Led Pharmacist – Regional Formulary Development

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

ACTION: NHS Fife Formulary Pharmacist/ERF Project Manager

- **CNS Chapter B – Abdominal Migraine and Cyclical Vomiting (Paediatric)**

The ERFC discussed the key updates to the ERF CNS Chapter B – Abdominal Migraine and Cyclical Vomiting (Paediatric).

It was noted that there are no corresponding chapter development notes, but further pathways have been reviewed by Peter Gillett, Lothian Paediatric Gastroenterologist, and Anna Dall, Borders Paediatrician.

In regard to abdominal migraine and cyclical vomiting syndrome, it was established that normal analgesia can be used, with a reference to the BNFC. The ERFC noted previous discussions regarding whether to add actual doses for medicines, however, with monthly updates to the BNFC, it was agreed to advise prescribers to utilise the Formulary alongside the BNF/BNFC or respective prescribing software.

For the 'Treatment of acute abdominal migraine attack (step two)', it was noted that nasal Sumatriptan and buccal Prochlorperazine are licensed for 12 years and above. The tablet formulations instead of orodispersible tablet of Ondansetron have been included for cost-effectiveness.

The ERFC noted that modified release Propranolol 80mg and 160mg preparations were removed from both the 'Prophylaxis of abdominal migraine' and 'Prophylaxis of cyclical vomiting syndrome' pathways due to concerns around prolonged toxicity in overdose. Inclusion of general warnings on Propranolol use – "Prescribers should be aware of the risk of Propranolol in overdose, which can be potentially toxic and lead to seizures and death" were recommended by the committee. For the 'Prophylaxis of cyclical vomiting syndrome' pathway, the ERFC agreed to include guidance that all females of childbearing potential should be advised of potential of foetal malformations with migraine prophylactic medications and to ensure that risks during pregnancy are explained and the importance of using adequate contraception" mirroring the 'Prophylaxis of abdominal migraine' pathway prescribing notes. The tablet formulations of Ondansetron were also included for cost-effectiveness.

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

ACTION: Lead Pharmacist Medicines Governance and Guidance NHS Lothian /ERF Project Manager

- **Infections (Paediatric)**

The ERFC discussed the key updates to the ERF Infections (Paediatric) chapter.

The CEWG was well attended for much of the meeting, with a variety of representation from all three Boards. There was a need to go out for further comments from Dermatology, Ophthalmology, Urology, Renal and Medical Paediatrics specialist groups.

For the treatment of oral candidiasis, it was noted that Lothian previously had Miconazole as first-line treatment, but it was notably more expensive and other Boards had Nystatin as their first-line choice. It was further noted and discussed that there is a specific recommendation in the Adult ERF prescribing notes for simultaneous mother and baby treatment when it is a breastfeeding infant, in which the mother would receive topical Miconazole and the baby would receive oral Miconazole. Concerns were previously raised around the use of Miconazole in infants 4 months and younger, with reference to a previous MHRA warning and subsequent advice regarding oral Miconazole. The ERFC noted that the BNFC does have dosing for oral Miconazole for neonates and up, and there is no current MHRA warning in place for that age group. The Clinical Knowledge Summaries for NICE recommend Miconazole as first-line treatment, citing superior efficacy, however it was noted that some staff groups can only prescribe within the licence and Nystatin is preferred for people with swallowing difficulties. It was further noted that there are current shortages of Miconazole. Consequently, Miconazole and Nystatin have both been listed as first-line treatment options, with

Miconazole listed first, and a link to the BNFC which provides dosing information and further information about cautions and alerts on the licensing status.

The ERFC noted that there had been previous discussions around the inclusion of dosing for all items, however, agreed, for most items, to link to the BNFC for the most up-to-date dosing. Exceptions were made for medicines without a BNFC dose, and deliberately included the dosing information for the first doses of meningitis in primary care settings for those using the Formulary mobile app and potentially using the information offline. This decision was made on the grounds that dosing is subject to change from edition to edition.

Regarding the treatment of fungal nail infections, fungal skin infections and fungal scalp infections, it was noted that systemic treatments are described in detail in the Clinical Knowledge Summaries but lack clarity in what is preferred locally. It was agreed that the Chapter would proceed with the topical management recommendations and defer conversations on systemic management to the future meetings with the Dermatology paediatric group in early 2024.

A new pathway was created for Hepatitis C, with guidance from the Scottish Paediatric and Adolescent Infection and Immunology Network signposted. It was noted that there was the intention for a Hepatitis C pathway within the Adult Infections chapter, but this is still in development, and the Adult Infections team will be contacted for comment. Further information is also required regarding the contact details for specialist advice in relation to Hepatitis C, TB, and HIV for respective prescribing notes, and to confirm the correct signposts for management of blood borne infection post-exposure prophylaxis. The pathways for Hepatitis C, HIV, and TB will be held back from publication subject to confirmation from the local paediatric specialist in infectious diseases.

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

ACTION: NHS Lothian Formulary Pharmacist/ERF Project Manager

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 daratumumab: Darzalex (SMC2536)

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

Indication: To be used in combination with Lenalidomide and Dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).

The local treatment protocol and finance budget template were included with the FAF. Correct patient numbers and consequent financial information were revised and resubmitted for review.

The ERFC discussed the supporting evidence, with information to support the use of Len/Dara/Dex over Len/Dex provided by the MAIA trial. It was noted that Daratumumab is well-established within Haematology in-patient settings, and whilst infusion related reactions can occur with this medicine, most IRS occur after the first dose, and there is guidance in place to support this.

The proposed place in therapy is first-line for the treatment of adult patients with newly diagnosed multiple myeloma.

The ERFC agreed to classify daratumumab: Darzalex (SMC2536) 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 finerenone: Kerendia (SMC2486)

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

Indication: For the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

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

The ERFC discussed the supporting evidence, with the submission drawing on evidence from the FIDELIO-DKD trial. The ERFC noted that the current evidence base did not capture the use of SGLT2 inhibitors as these are relatively new in the treatment landscape. The proposed place in therapy is third-line after maximum treatment with renin-angiotensin-aldosterone system inhibitors and SGLT2 inhibitors (or in individuals who cannot tolerate these medicines) who have serum potassium concentrations < 5mmol/l. Dose depends on initial potassium. Patient numbers are anticipated to be few. The patients may also be eligible for treatment with sodium zirconium to achieve the required serum potassium concentration. The guidelines supporting prescribing and monitoring in primary care following specialist initiation will be hosted on the Edinburgh Renal unit website: edren.org – From Edinburgh Renal Unit

The ERFC agreed to classify finerenone: Kerendia (SMC2486) as routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.3 FAF1 nivolumab: Opdivo (SMC2394)

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

Indication: In combination with Ipilimumab for the treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer after prior Fluoropyrimidine-based combination chemotherapy.

The local treatment protocol and finance budget template were included with the FAF. Small number of current patients with 1 or 2 new patients suitable for treatment each year, and a comprehensive protocol included in the papers.

The ERFC agreed to classify nivolumab: Opdivo (SMC2394) as routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.4 FAF1 olaparib: Lynparza (SMC2518) CMJB HER2

The ERFC noted and discussed the previously circulated FAF1 submission. One personal and one non-personal specific declaration of interest was received. CD support confirmed from all three Boards. This application accompanies item 3.1.5.

Indication: As monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.

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

The ERFC discussed the supporting evidence. It was noted that that this submission is for patients who have hormone receptor positive (HR)+ /human epidermal growth factor receptor 2 (HER2)-negative breast cancer, with the submission based upon evidentiary findings from a previous OlympiA trial.

The ERFC agreed to classify olaparib: Lynparza (SMC2518) 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 olaparib: Lynparza (SMC2518) TNBC

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support confirmed from all three Boards. This application accompanies item 3.1.4.

Indication: As monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.

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

The ERFC discussed the supporting evidence. It was noted that that this submission is for patients who have triple negative breast cancer.

The ERFC agreed to classify olaparib: Lynparza (SMC2518) 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 risankizumab: Skyrizi (SMC2534)

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

Indication: For the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.

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

The ERFC discussed the supporting evidence. The proposed line in therapy is second-line as a treatment option alongside Ustekinumab or Upadacitinib, with Vedolizumab as third-line treatment option.

The ERFC agreed to classify risankizumab: Skyrizi (SMC2534) 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/NHS Fife Formulary Pharmacist

3.1.7 FAF1 tafamidis: Vyndaqel (SMC2585)

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

Indication: For the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The ERFC discussed the extensive patient criteria provided in the application noting the specialised area in which the proposed drug is used, with specialists currently consulting and referring patients to the National Amyloidosis Centre in London for further advice and treatment.

The ERFC agreed for tafamidis: Vyndaqel to sit within Formulary Decisions on ERF. It was agreed that a therapeutic pathway could be developed for the indication as part of the next Adult Cardiovascular chapter review, taking guidance from the National Amyloidosis Centre. Use on the formulary will reflect the SMC advice. For use out with SMC advice, follow local Board non-formulary procedures.

The ERFC agreed to classify tafamidis: Vyndaqel (SMC2585) 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

3.1.8 FAF1 atogepant: Aquipta (SMC2599)

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

Indication: Preventative treatment of chronic and episodic migraine in adults who have at least 4 migraine days per month. SMC restriction: for patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.

The local treatment protocol (for NHS Lothian) and finance budget template were included with the FAF.

The ERFC discussed the supporting evidence. The proposed place in therapy is second-line for prophylaxis of migraine after trial of at least 3 or more migraine preventive treatments (at least 8 weeks at target dose or the highest tolerated dose before assessing efficacy). For chronic migraine patients, Botox may be used, if possible, prior to starting Atogepant. There was discussion regarding the appropriate formulary flagging for the medicine, noting each Board's respective capacity allowances for delivering the necessary care. The application proposal was for GP initiation in NHS Borders and NHS Fife with the option to seek additional specialist advice if required. In NHS Lothian, the proposal was for Specialist Initiation on the advice of a headache specialist with the view that headache specialists are best placed to distinguish between chronic and episodic migraine, and the most appropriate treatment options.

The ERFC agreed for the medicine to be classified as Specialist Initiation, with further review on the formulary flags at the next scheduled Adult chapter review. The ERFC noted the need for appropriate therapeutic pathways in the formulary to provide guidance to prescribers in the region and noted new national headache pathway materials issued from the National Centre for Sustainable Delivery do not yet include this medicine. The ERFC agreed for the Adult migraine CEWG to be consulted on approval of the ERF pathway updates prior to publication.

The ERFC agreed to classify atogepant: Aquipta (SMC2599) as routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.9 FAF1 rimegepant: Vydura (SMC2603)

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

Indication: Preventative treatment of episodic migraine. SMC restrictions: for patients with episodic migraine who have at least 4 migraine attacks per month, but fewer than 15 headache days per month and who have had prior failure on three or more migraine preventive treatments.

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

The ERFC discussed the supporting evidence. The proposed place in therapy is second-line for prophylaxis of migraine after trail of at least 3 or more migraine preventive treatments (at least 8 weeks at target dose or the highest tolerated dose before assessing efficacy) and joint first-line for advanced therapies for the treatment of chronic and episodic migraine. There was discussion regarding the appropriate formulary flagging for the medicine, noting each Board's respective capacity allowances for delivering the necessary care. In the application, the proposal was for GP initiation in NHS Borders and NHS Fife, with the option to seek additional specialist advice if required. In NHS Lothian, the proposal was for Specialist Initiation on the advice of a headache specialist with the view that headache specialists are best placed to distinguish between chronic and episodic migraine, and the most appropriate therapeutic pathways in the formulary to provide guidance to prescribers in the region and noted new national headache pathway materials issued from the National Centre for Sustainable Delivery do not yet include this medicine. The ERFC agreed for the Adult migraine CEWG to be consulted on approval of the ERF pathway updates prior to publication.

The ERFC agreed to classify rimegepant: Vydura (SMC2603) as routinely available in line with national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.10 FAF1 fenfluramine: Fintepla (SMC2569)

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

Indication under review: For the treatment of seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older.

SMC restriction: as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more anti-seizure medicines.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. It was noted that there was a discrepancy between the SMC restrictions for use (patient required to have previously tried two or more seizure medicines) compared with the applicant's proposal for use (patient required to have previously tried only one of more).

There was further discussion regarding the medicine's proposed place in therapy. The ERFC agreed that, for Adults, the medicine would sit within the anti-epileptic list of specialist medicines and the SMC approvals would apply, but would require further clarification from specialists regarding its place in therapy within the Paediatric pathway for Dravet Syndrome.

The ERFC requested further clarification regarding intended prescribing restrictions, and the subsequent place in therapy for Paediatrics. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

Post-meeting note: SMC restriction updated and re-issued to Boards 14 December 2023.

The ERFC agreed to classify fenfluramine: Fintepla (SMC2569) 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/NHs Fife Formulary Pharmacist

3.1.11 FAF2 zuclopenthixol acetate: clopixol acuphase 50mg/1ml solution for injection ampoules

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. CD support confirmed for all three Boards.

Indication: Therapeutic option for the initial treatment of acute psychoses after an acutely psychotic patient has required repeated injections of benzodiazepines or short-acting antipsychotic medications and there would be a potential benefit from Zuclopenthixol Acetate in reducing the need for repeated IM injections.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence, noting that the medicine is currently being used in all three Boards.

The ERFC agreed to classify zuclopenthixol acetate: clopixol acuphase as routinely available in line with local guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

3.1.12 FAF2 methoxyflurane: Penthrox

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. CD support confirmed for NHS Fife and NHS Borders, with support from one NHS Lothian CD and another CD acknowledging the role the medicine has in the pre-hospital environment and supporting its addition to the ERF. In NHS Lothian, implementation is planned in St John's Hospital Emergency Department only currently.

Indication: Emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain (usually involving limb injury, and subsequent procedures including splinting, manipulation, or reduction). Proposal is for use in emergency departments.

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

The ERFC discussed the supporting evidence, noting support from the Scottish Government Head of Pharmaceutical Sustainability and the Royal College of Emergency Medicine. Further supporting evidence is provided by a number of studies, including the STOP! clinical trial – a randomised double blind, multicentre, placebo-controlled study at six sites in the UK.

It was noted that methoxyflurane: Penthrox is currently second-line treatment option (restricted to use in neurosurgery protocols for short-term procedures) in the pathway for analgesia using inhaled

anaesthetics to Entonox, Equanox, or Nitric Oxide through anaesthetic machine with oxygen. The proposed place in therapy is first-line for use in A&E departments for short-term procedures. The applicants note the existing alternatives will be required for procedures where Methoxyflurane is considered unsuitable. The ERFC note that with the proposed addition to the existing pathway, that the update should include prominent signposts to the company-provided risk-minimisation materials.

The ERFC noted the favourable environmental impact of Methoxyflurane compared with Nitrous Oxide.

The ERFC noted within the documents presented from the NHS Fife team the safety measures proposed for the use of Methoxyflurane to ensure safe use of the medicine and reduce the risk of abuse. The local guidance developed for NHS Fife lacks information regarding the safe disposal of used and part-used devices. The ERFC noted that training is planned for prescribers. The ERFC recommended training to also include all those involved in supervision and/ore teaching on administration and that the guidance includes guidance on safeguards to minimise the risk of occupational exposure.

The ERFC noted that there are no details included in the application form with regard to implementation plans for NHS Borders and NHS Lothian (St John's hospital).

The ERFC raised concerns about limiting the volume of medicine consumed in a 3-month period. It was noted that the Scottish Ambulance Service as well as orthopaedic patient pathways within NHS Fife, thus stressing the importance of robust patient monitoring processes, including requirement to take an accurate drug history prior to prescribing, and completion of patient-held records/alert cards.

The ERFC noted NHS Fife's current detailed implementation plan and noted the importance of well-defined guidelines across the region to ensure compliance regarding A&E presentations, and to guarantee that training and education tools are in place for prescribers and staff groups involved in administration. The ERFC noted that replacement costs are difficult to estimate and have, therefore, been omitted. VAT was noted to be missing from the costs. The proposed use of Methoxyflurane is associated with a cost pressure and the ERFC agreed that the overall cost is difficult to predict.

The ERFC request VAT to be included in the costs, details on plans for safe disposal and local Board implementation plans for NHS Lothian and NHS Borders. The applicants are requested to liaise with the contacts for the clinical teams within NHS Lothian and NHS Borders and respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify methoxyflurane: Penthrox as routinely available in line with local or regional guidance. Included on the ERF for Specialist Use only in the Emergency department. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.13 FAF3 testosterone (Testogel & Tostran)

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

Indication: Low sexual desire in menopausal women.

The proposed use is in menopausal patients with secondary and generalized low sexual desire for at least six months not being used for other menopausal symptoms.

The local finance budget template was included with the FAF. It was noted that there are currently no licensed products in the UK for female use, and, thus, would be classified as an Unlicenced Indication. It was further noted that Testogel and Tostran are currently on the ERF for other indications in adults.

For Tostran, the dosing recommendations are for 1 metered pump every alternate day or three times a week, or 1/10th of a sachet of Testogel per day, with each sachet lasting 10 days. Both preparations have been proposed due to frequent supply issues.

The ERFC discussed the supporting evidence provided in the form of NICE guidance on menopause, diagnosis, and management; a clinical tool for the use of testosterone available on the British Menopause Society website giving information on use and monitoring; Global Consensus mission statement on the use of testosterone therapy; as well as an NHS Tayside guideline.

The ERFC noted the application suggests monitoring at baseline and at three months, however, the British Menopause Society guideline stresses the importance of monitoring continually every six to twelve months to ensure that levels remain within the female physiological range to minimize adverse effects. The ERFC further noted that a collaborative regional guideline is currently in development, but not included in the papers. The ERFC discussed formulary tagging; the application requests the prescriber as 'Specialist Use only' and later recommends the formulary tag 'Specialist Initiation' and further states within the proposal is for hospital use initially, continuing in primary care with the medicine being provided via shared care. The ERFC noted that there are recommendations from sexual health in addition to the menopausal services in some of the Boards for the proposed indication and that it would be appropriate for Testogel and Tostran to be included on the ERF with no formulary tagging on the condition that a regional guideline detailing monitoring is established to provide prescribers with clear recommendations on criteria for use, monitoring, and ongoing review. The ERFC agreed that the medicine would be appropriate to be initiated and supervised by a GP with sufficient competence in the management of the condition for the duration of treatment supported by an agreed local or regional guideline with the option to seek additional support from a specialist when required. In the absence of an agreed regional guideline at present, the ERFC agreed on use in line with the recommendations of the British Menopause Society.

The ERFC requested further clarification regarding patient monitoring requirements, in a regional guideline with reference to recommendations in line with the British Menopause Society guideline. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify testosterone (Testogel & Tostran) as routinely available in line with local or regional guidance. Included on the ERF. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.14 FAF3 dexrazoxane

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. CD support confirmed for NHS Lothian and NHS Fife, with oncology services for paediatrics supplied under service level agreements within NHS Lothian on behalf of all three Boards.

Indication: Prevention of cardiotoxicity in children and young people treated with planned cumulative protocol doxorubicin doses of 300mg/m2 or greater (or equivalent Anthraycline dose).

The finance budget template was included with the FAF. The application is for use in the paediatric population, and, thus, will be used as an Unlicensed Indication.

The ERFC discussed the supporting evidence, noting the inclusion of an evidence review commissioned by NHS England. The ERFC discussed the broad patient group noted in the application, noting concerns around the long-term monitoring of paediatric patients into adulthood and the related cardiac toxicities, stressing the importance of limiting exposure to anthracyclines.

The ERFC required CD support from all three Boards, as well as further information regarding the assessment process for the patient to ensure limited anthracycline use, in the first instance, where possible. The applicants are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify dexrazoxane as routinely available in line with local or regional guidance. Included on the ERF for Specialist Use only. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2 Formulary Amendment Forms

3.2.1 Oxycodone 50mg/ml

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

Indication: Treatment of moderate to severe pain in patients with cancer.

The ERFC noted the supporting evidence and SMC advice 648/10. The ERFC noted intermittent supply constraints with Diamorphine and price changes since the original SMC advice and agreed that when Diamorphine is available, Oxycodone may be considered as an alternative option to Diamorphine taking into consideration acquisition cost. The ERFC noted the proposed restricted use in secondary care, hospice, or community setting when requiring the additional syringe pump, with the formulation strength initiated under the supervision of a palliative care consultant. It was further noted that each respective Board has procedures in place for the safe supply and reduction of administration risks, with further guidance available via the Scottish Palliative Care Guidelines.

The ERFC agreed to classify Oxycodone SMC648/10 as routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Accu-chek Instant Testing Strips

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

Indication: Capillary blood glucose monitoring - people requiring district nurse support.

The ERFC noted the supporting evidence and acknowledged that the Accu-chek Instant testing strips are currently on the Formulary for Type 2 diabetes.

The ERFC requested clinical team support from all three Boards.

ACTION: NHS Lothian Admin Team

Subject to the support from clinical teams in all three Boards, the ERFC agreed to classify the Accu-chek Instant Meter as routinely available in line with local or regional guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Apomorphine (Dacepton)

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: Treatment of Parkinson's disease.

The ERFC noted the supporting evidence, acknowledging that the addition is cost neutral compared with current options. The ERFC noted that existing formulations on the formulary are available as pens/pre-filled syringes and requested confirmation on whether the vial formulation is suitable for inclusion on the ERF.

The ERFC requested clinical team support from NHS Fife, and confirmation of the request to add the vial formulation to the ERF.

ACTION: NHS Lothian Admin Team

Subject to clinical team support from NHS Fife and clarification on the formulations, the ERFC agreed to classify Apomorphine (Dacepton) 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/NHS Lothian Formulary Pharmacist

3.2.4 Levomepromazine 5mg/ml oral solution

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support received from NHS Lothian only, with medicine initiated by specialists at the Royal Hospital for Children & Young People.

Indication: Treatment of chemotherapy-induced vomiting in paediatrics.

The ERFC discussed the supporting evidence. It was noted that the proposed oral solution was a more cost-effective option, and clarification has been received to note that the propylene glycol content is within recommended limits when used in the proposed doses. The ERFC noted the guidance in the with NPPG Position Statement on choosing an oral liquid for children.

The ERFC further discussed the more regular use of oral Olanzapine in adult oncology, and growing body of literature on use in paediatrics. The ERFC recommend the applicants review the current literature and consider Olanzapine (off-label) for use for the treatment of chemotherapy-induced nausea in vomiting.

The ERFC agreed to classify Levomepromazine 5mg/ml oral solution as routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicine. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra-Orphan Medicines

3.3.1 None

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 efgartigimod alfa: Vyvgart (SMC2561)
3.4.2 pegunigalsidase alfa: Elfabrio (SMC2591)
3.4.3 progesterone vaginal capsules: Utrogestan (SMC2630)
3.4.4 mercaptamine: Procysbi (SMC2571)

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 Bimekizumab (Bimzelx) (SMC2605)

Post-meeting correction: Clinical teams advised of intention to not submit a formulary application for SMC2605 and should have been noted in the agenda.

Indication: Alone or in combination with methotrexate (MTX), is anticipated to be indicated for the treatment of active psoriatic arthritis (PsA) in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

As per ERFC policy, the formulary classification for Bimekizumab: Bimzelx (SMC2605) is noted 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 Bimekizumab 160mg solution for injection in pre-filled syringe/prefilled pen: Bimzelx (SMC2616)

The ERFC noted the SMC abbreviated submission Bimekizumab 160mg solution for injection in pre-filled syringe/prefilled pen: Bimzelx (SMC2616)

Indication: Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

The ERFC noted that ERF inclusion was not requested at this stage.

The ERFC agreed to classify Bimekizumab: Bimzelx (SMC2616) 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 selpercatinib: Retsevmo (SMC2573)
3.7.2 durvalumab: Imfinzi (SMC2582)
3.7.3 avacopan: Tavneos (SMC2578)

The ERFC agreed to classify items 3.7.1, 3.7.2 and 3.7.3 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

Quarterly Update - *for noting*

The ERFC acknowledged that NCMAG are seeking nominations for council members who are non-oncology ADTC/Formulary representative and encouraged ERFC members to consider this opportunity.

4 Board specific information

4.1 NHS Borders

None.

4.2 NHS Fife

None.

4.3 NHS Lothian

The ERFC noted an enquiry from NHS Lothian regarding Rivaroxaban (SMC2128) which was previously on the Lothian Joint Formulary as 'Routinely available in line with national guidance, Specialist Initiation, further restricted for patients with symptomatic peripheral artery disease at high risk of ischemic events', but was not included in the collaborative East Region Formulary content.

The NHS Lothian team confirmed that they have not changed their practice and request inclusion on the ERF for the proposed use. It was noted that patients from NHS Borders requiring vascular intervention would receive treatment in NHS Lothian (patients in NHS Fife receive their treatment from NHS Tayside). NHS Fife indicated support for the proposal. NHS Borders request more information from the NHS Lothian clinical team including evidence base for patients with symptomatic peripheral artery disease at high risk of ischemic events and a comparison of Rivaroxaban to Apixaban and Edoxaban for the proposed indication. NHS Borders colleagues agreed to present and review the original Lothian formulary application at the NHS Borders Thrombosis Committee with comments returning to ERFC for further consideration on formulary status.

The ERFC requested further data for the proposed indication and patient group, and comparison to Apixaban or Edoxaban. The NHS Lothian clinical teams are requested to respond with information on the recommended actions by 10 Jan 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed for the previously submitted formulary application and additional information to be shared and reviewed by the NHS Borders Thrombosis Committee. The NHS Borders team are requested to respond with information on the recommended actions by 23 Jan 2024.

ACTION: NHS Lothian Admin Team/Dr Paul Neary, Consultant Cardiologist, NHS Borders

5 Any other competent business

Ultra Orphan drugs SMC update: guidance for companies making a submission for ultra-orphan medicines.

The ERFC noted that SMC have updated their guidance for companies making a submission for Ultra-Orphan medicines, and that some medicines currently available within the ultra-orphan pathway undergoing data collection are due to complete their initial data collection period and undergo with full submission to SMC.

6 Date of next meeting

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

FAF3s should be submitted by 8 January 2024 (for discussion at the ERWG meeting on 17 January 2024).

FAF1s and FAF2s should be submitted by 23 January 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