East Region Formulary

East Region Formulary Committee
Minutes

Date: 07 February 2024
Time: 2.00pm – 4.00pm
Location: MS Teams

Present:

Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife – in the Chair
Nikki Gilluley	Lead Pharmacist - Regional Formulary Development
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist, NHS Lothian
Alice Mathew	Senior Clinical Pharmacist Medicines Utilisation and Therapeutics, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Cathryn Park	Deputy Director of Pharmacy, NHS Borders
Dr Jo Rose	GP, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian
In attendance:	Caitlin Satti, Information Officer, NHS Lothian
Apologies:	Jane Browning, (Acting) Associate Director of Pharmacy, NHS Lothian Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife Malcolm Clubb, Director of Pharmacy (Co-chair), NHS Borders Gillian Donaldson, Nurse – Cardiology, NHS Borders Steven Fenton, Project Manager, NHS Lothian Carol Holmes, Pharmacist - Primary Care, NHS Lothian Dr Paul Neary, Consultant – Cardiology, NHS Borders Fraser Notman, Senior Pharmacist – Medicines Management, NHS Fife Dr Lucy Wall, Consultant – Oncology, 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.

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

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

It was noted that five Paediatric chapters have now been completed and launched on the website and app, including Gastrointestinal, Respiratory, Cardiovascular, Infections, and CNS.

The Paediatric Endocrine chapter is included in this meeting, item 2.3 for discussion. The Paediatric

Skin chapter is in development, with the first draft currently with chapter experts for comment. This chapter will be presented at the next ERWG, and come to the next ERFC meeting in March. Following the completion of the Paediatric Skin chapter, planning for the Paediatric Nutrition and Blood chapter review will commence.

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

1.3 Matters arising

1.3.1 ERFC 09 August 2023 Item 3.1.1 FAF1 Pembrolizumab: Keytruda (SMC2526) was reviewed at the ERFC August meeting. The ERFC 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 12 March 2024.

ACTION: NHS Lothian Admin Team/ NHS Lothian Formulary Pharmacist

1.3.2 ERFC 09 August 2023 Item 3.1.2 FAF1 Pembrolizumab: Keytruda (SMC2144) was reviewed at the ERFC August meeting. The ERFC 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 12 March 2024.

ACTION: NHS Lothian Admin Team/ NHS Lothian Formulary Pharmacist

1.3.3 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 the requested information had been received. Action completed.

1.3.4 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 the requested information had been received. Action completed.

1.3.5 ERFC 12 December 2023 Item 3.1.10 FAF1 Fenfluramine: Fintepla (SMC2569) was reviewed at the ERFC December meeting. The ERFC requested further clarification regarding intended prescribing restrictions, and the subsequent place in therapy for Paediatrics.

The ERFC noted that requested information regarding prescribing restrictions for Adults had been received. Fenfluramine will be included in the specialist list of epilepsy treatments on the ERF, noting the associated SMC restriction. Action complete.

The ERFC noted that information regarding intended prescribing restrictions, and the subsequent place in therapy for Paediatrics is still outstanding. The ERFC agreed that this should be carried

forward as ongoing. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Admin Team

1.3.5 ERFC 12 December 2023 Item 3.1.12 FAF3 Methoxyflurane: Penthrox was reviewed at the ERFC December meeting. 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 ERFC noted that the requested information had been received. Action completed.

1.3.6 ERFC 12 December 2023 Item 3.1.13 FAF3 Testosterone (Testogel & Tostran) was reviewed at the ERFC December meeting. The ERFC requested further clarification regarding patient monitoring requirements in a local guideline with reference to recommendations in line with the British Menopause Society guideline.

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 12 March 2024.

ACTION: NHS Lothian Admin Team

1.3.7 ERFC 12 December 2023 Item 3.1.14 FAF3 Dexrazoxane was reviewed at the ERFC December meeting. 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 ERFC noted that the requested information had been received. Action completed.

1.3.8 ERFC 12 December 2023 Item 4.3 Rivaroxaban was discussed at the ERFC December meeting. NHS Borders requested further data for the proposed indication and patient group, and comparison to Apixaban or Edoxaban. The ERFC noted that this information was received. This additional information and the previously submitted formulary application have been shared with NHS Borders with the intention to review at the NHS Borders Thrombosis Committee in due course.

The NHS Borders team are requested to respond with information on the recommended actions 12 March 2024.

ACTION: NHS Lothian Admin Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 12 December 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 17 January 2024

The minutes of the ERWG meeting on 17 January 2024 were noted for information. ERFC members provided discourse on the previously discussed proposal to have applicants present their own formulary applications at committee meetings.

The ERFC noted the benefit of having applicant representation when reviewing certain specialist formulary applications or an advanced therapy, but agreed not to implement as a standardised process moving forward, noting the wide range of specialities represented on the ERFC committee, as well as the already full meeting agendas, and the current meeting time-restrictions for both the ERWG and ERFC.

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

- **Endocrine (Paediatric)**

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

It was noted that the Prednisolone soluble tablets have been removed from the relevant pathway choices, with an information note added to advise that standard Prednisolone 5mg tablets can be dispersed in water. The Prednisolone 10mg/ml oral solution sugar free remains, with a note to specify that this is restricted to patients unable to swallow, and an additional note included to advise that Prednisolone enteric coated tablets are non-formulary. The ERFC requested the inclusion of additional information within the prescribing notes to highlight that the dispersal of Prednisolone tablets in water is an off-label use of the medicine, thus providing prescribers with the required dispensing information and mirroring the Prednisolone prescribing notes within the Respiratory pathways on the ERF.

For the Treatment of persistent hyperinsulinaemic hypoglycaemia of infancy, Diazoxide 50mg tablets and 250mg/5ml oral solution have been included under the Specialist Initiation flag, and 'dose as per specialist' dosing instructions.

In regard to the Oral glucose tolerance test pathway, the dosing instructions were updated to remove the instruction for it to be given with 200-300ml fluid, with direction now for Rapilose "To be used as per manufacturer's directions."

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

ACTION: NHS Fife Senior Pharmacist – Medicines Management/ERF Project Manager

2.3.1 ERF Adult Amendment – Chronic Obstructive Pulmonary Disease (COPD) GOLD Guideline

The ERFC discussed the updated ERF adult pathways for Chronic Obstructive Pulmonary Disease (COPD).

The ERFC noted that the amendment is the result of an update to the GOLD guideline which includes new definitions of COPD and COPD exacerbation, emphasises combined bronchodilator therapy, and minimises use of inhaled corticosteroids. The ERFC further noted that there will be a COPD poster, compiled by the Respiratory Managed Clinical Network, and an Asthma poster available to provide further information which will be used across the region. Hyperlinks to the posters will be included on the ERF.

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

ACTION: NHS Lothian Admin Team/NHS Fife Senior Clinical Pharmacist Medicines Utilisation and Therapeutics

2.3.2 ERF Adult Pathway – Bone metabolism, Osteoporosis - Zoledronic Acid

The ERFC discussed the updated ERF adult new pathway – 'Treatment of osteoporosis in men and women post low-trauma hip fracture'.

The ERFC noted that Zoledronic Acid was originally discussed at the October ERFC meeting, with further information requested regarding the operational arrangements for Zoledronic Acid in the post-op period from each Board to ensure effective continuation of treatment and patient safety. The ERFC noted that NHS Fife have guidelines for both in-patient and post-op patients, and NHS Lothian have an in-patient guideline. It was further noted that all Boards will be required to have a post-op guideline as part of their governance, with the potential to adapt NHS Fife's current guideline into a regional guideline for use across all three Boards.

***Post-meeting note**:* Further input from the NHS Lothian clinical team is awaited, and thus, the pathway remains unfinalised.

ACTION: NHS Fife Senior Clinical Pharmacist Medicines Utilisation and Therapeutics

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Deucravacitinib: Sotyktu (SMC2581)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support was received from NHS Lothian and NHS Fife.

Indication: For the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including Ciclosporin, Methotrexate and Phototherapy), are intolerant to, or have a contra-indication to these treatments.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence, noting the comprehensive list of medicines for the treatment of psoriasis on the ERF. The ERFC discussed the proposed position of Deucravacitinib: Sotyktu within the relevant pathways, with NHS Fife intending to use the medicine after systemic treatment but before biologics, whereas NHS Lothian intend to use the medicine after all biologics.

The ERFC requested further clarification from the clinical team regarding the intended positioning of Deucravacitinib: Sotyktu within the relevant pathways on the ERF. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Formulary Pharmacist

The ERFC agreed to classify Deucravacitinib: Sotyktu (SMC2581) 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 Dostarlimab: Jemperli (SMC2404)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific and one personal non-specific declaration of interest was received. CD support was received from NHS Lothian.

Indication: As monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

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

The ERFC discussed the supporting evidence. The ERFC noted the SMC approval of the medicine on an interim basis, subject to ongoing evaluation and future assessment, with evidence provided by the GARNET study.

The ERFC noted the potential cost-saving of the medicine in comparison to the current treatment options of Paclitaxel and Caelyx, with a reduction in aseptic capacity, chair time, nursing etc. However, the ERFC further noted the possible further costings associated with the medicine due to

increased levels of testing to determine whether patients have the mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) endometrial cancer.

The ERFC noted whilst other regimes have set cycles, there is a lack of concise information regarding the duration of treatment for this medicine, with the potential for the medicine to be continued until toxicity or disease progression. It was further noted that the finance budget template was not reflective of a full-year of treatment, but rather a reflection of the median duration for reported patients to date, with variable durations of treatment per patient.

The ERFC requested further clarification from the clinical team regarding patient testing and the associated potential additional costings as well as the total treatment costs per patient per annum to ensure robust financial forecasting. The ERFC further requested named CD support from all three Boards to ensure awareness of budgetary implications. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Dostarlimab: Jemperli (SMC2404) 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 Durvalumab: Imfinzi (SMC2582)

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

Indication: In combination with Gemcitabine and Cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.

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

The ERFC discussed the supporting evidence. The ERFC noted that the medicine will be delivered as a day-case treatment, resulting in decreased chair time with the pre- and post-hydration regime reduced from three hours to thirty minutes.

The ERFC requested the names of the Clinical Directors who is support of the medicine to ensure awareness of budgetary implications. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Durvalumab: Imfinzi (SMC2582) 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 Vutrisiran: Amvuttra (SMC2596)

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.

Indication: For the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.

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

The ERFC discussed the supporting evidence, with Vutrisiran: Amvuttra proposed to replace Patisiran, a previously SMC-approved medicine on the Ultra-Orphan pathway in 2019.

The ERFC agreed for Vutrisiran: Amvuttra to sit within the Formulary Decisions section of the ERF.

The ERFC agreed to classify Vutrisiran: Amvuttra (SMC2596) 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 Avacopan: Tavneos (SMC2578)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support confirmed from NHS Lothian and NHS Fife.

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

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The ERFC noted the intended use of Acacopan as a replacement for Prednisolone, with evidence provided by the ADVOCATE study.

It was noted that no local treatment protocol has been developed/provided, nor a local clinical management guideline or implementation plan for the use of the medicine across the region. The ERFC agreed that a local treatment protocol which is aligned with SMC recommendations is required.

Discrepancies within the finance budget template were also noted.

The ERFC requested NHS Fife CD support, as well as further information from the clinical team regarding associated protocols and guidelines, and a revised formulary application with clarification on costings. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Avacopan: Tavneos (SMC2578) 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

3.1.6 FAF2 Actimorph

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

Indication: Severe pain which can be managed adequately only by opioids. SMC Restriction: Used as an alternative for patients unable to swallow morphine sulphate 'Sevredol' tablets, or where a lower dose is required and unable to measure morphine sulphate oral solution due to dexterity issues or visual impairment.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence, noting the variety of strengths available and the substantial evidence provided in support of the medicine.

The ERFC agreed to classify Actimorph as Routinely available in line with local guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.7 FAF2 FreeStyle Libre 3

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

Indication: For people using insulin pumps which are interoperable with FreeStyle Libre 3 (creating a hybrid closed loop system).

The finance budget template was included with the FAF.

The ERFC noted the supporting evidence. The ERFC agreed for the FreeStyle Libre 3 to sit within the Formulary Decisions section of the ERF.

The ERFC discussed the safety concerns and subsequent complexities of ensuring patients receive the correct FreeStyle Libre pump with different types available. The ERFC noted the detailed information available to prescribers on different GP prescribing systems across the region regarding all variations of the FreeStyle Libre pump, with an additional information note to be included in the FreeStyle Libre 3 formulary decision to minimise the risk of mis-prescribing.

The ERFC agreed to classify FreeStyle Libre 3 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

3.1.8 FAF3 Carfilzomib (NCMAG104)

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

Indication: Once-weekly regimen in combination with Dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

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

The ERFC discussed the supporting evidence. The ERFC noted the associated NCMAG approval, and the intended off-label use of the medicine, with supportive evidence provided by the A.R.R.O.W study. Further evidence was provided in the form of the CHAMPION-1 study and ENDEAVOR study.

It was noted that the medicine is currently being used in all three Boards, and the Haematology teams are familiar with the side effects.

The ERFC agreed to classify Carfilzomib as Routinely available in line with national 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

3.1.9 FAF3 Lenalidomide (NCMAG103)

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

Indication: Lenalidomide in combination with Dexamethasone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant and are suitable for thalidomide-containing regimens.

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

The ERFC discussed the supporting evidence. The ERFC noted the associated NCMAG approval, with evidence provided by the phase III FIRST study.

The ERFC requested the names of the Clinical Directors who is support of the medicine to ensure awareness of budgetary implications. The applicants are requested to respond with information on the recommended actions by 12 March 2024.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify Lenalidomide 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

3.1.10 FAF3 Fampridine

The ERFC noted and discussed the previously circulated FAF3 submission. One non-personal non-specific declaration of interest was received. CD support confirmed for all three Boards.

Indication under review: For the treatment of Downbeat nystagmus. This is the most frequent form of nystagmus which impairs visual acuity and is associated with postural instability.

The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The ERFC noted that the proposed medicine will treat a static number of three patients per year; prescribing will always be by the Princess Alexandra Eye Pavilion within NHS Lothian and carried out through Homecare, with NHS Fife and Borders incurring cross-charging costs.

Key evidence in support of the medicine was provided in the form of randomised double-blind crossover trial which looked at the effects of Fampridine compared against a placebo, with subjects analysed to assess slow-phase velocity, their stance, locomotion, visual acuity, patient satisfaction, and side effects. It was noted that side effects were consistent with those reported in the SPC and generally well-tolerate.

The ERFC noted that there are no trials currently being undertaken or pursual of a licence, and agreed for the proposed medicine to sit within the Formulary Decisions section of the ERF.

The ERFC agreed to classify Fampridine 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

3.1.11 FAF3 Dexamethasone

The ERFC noted the FAF3 for Dexamethasone. No declarations of interest were received. CD support confirmed for all three Boards.

Indication for use: For CT guided perineural injection for radicular pain.

Post-meeting decision: The Chair reviewed the FAF3 for Dexamethasone Sodium Phosphate, with the procedure currently carried out within NHS Lothian only, but with the intention to increase current capacity by way of a PGD to allow radiographers to administer.

Further information was provided by the clinical team, with confirmation received that the PGD will have the required information addressing safety concerns when using steroids and maximum dosing, as well as the specific brand of Dexamethasone to provide additional support to the new staff group who'll be administering the injection to ensure they have a working knowledge of which medicine to choose when encountering drug shortages.

The clinical team further clarified that there is no requirement for more frequent injections of Dexamethasone compared to Triamcinolone due to a shorter duration of action.

The Chair approved Dexamethasone for the proposed indication and noted that the medicine should be used in line the NHS Lothian PGD. The Chair agreed for the proposed medicine to sit within the Formulary Decisions section of the ERF.

The ERFC agreed to classify Dexamethasone 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 Ezetimibe

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 Primary Hypercholesterolaemia.

Application to remove the requirement for the specialist initiation of the medicine.

The ERFC noted the supporting evidence, and agreed with the proposed recommendation to include an additional prescribing note in the 'Secondary prevention – statin' pathway, and inclusion of the SMC restriction.

The ERFC agreed to classify Ezetimibe (SMC61/03) as Routinely available in line with local or regional guidance. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Dimethyl Fumarate

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: For the treatment of Multiple Sclerosis.

Application to remove the remove the brand of Tecfidera in the 'Treatment of active relapsing remitting MS' pathway, and keep the generic medicine.

The ERFC noted the supporting evidence, with the MHRA confirming that the generic Dimethyl Fumarate 120mg and 240mg capsules are both licenced for treatment of adult and paediatric patients aged 13 years and older with relapsing remitting MS (SMC have previously approved for adults).

The ERFC agreed to classify Dimethyl Fumarate (SMC886/13) 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

3.2.3 Fingolimod

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: For the treatment of Multiple Sclerosis.

Application to remove the remove the brand of Gilenya and keep the generic medicine.

The ERFC noted the supporting evidence, and agreed to update the Formulary Decisions entry for Fingolimod: Gilenya to state the preferred use of the generic medicine.

The ERFC agreed to classify Fingolimod: Gilenya (SMC763/12) 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

3.2.4 Teriflunomide

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: For the treatment of Multiple Sclerosis.

Application to remove the remove the brand of Aubagio in the 'Treatment of active relapsing remitting MS' pathway, and keep the generic medicine.

The ERFC discussed the supporting evidence, and agreed to update the relevant pathway and Formulary Decisions entry for Terifluonamide: Aubagio to state the preferred use of the generic medicine.

The ERFC agreed to classify Teriflunomide: Aubagio (SMC940/14) 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

3.3 Ultra-Orphan Medicines

3.3.1 Burosumab: Crysvita (SMC2588) - *for information.*

The clinical team has been contacted to advise.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Amivantamab: Rybrevant (SMC2638)
3.4.2 Lumasiran: Oxlumo (SMC2639)
3.4.3 Osilodrostat: Isturisa (SMC2640)
3.4.4 Belantamab mafodotin: Blenrep (SMC2597)
3.4.5 Axicabtagene ciloleucel: Yescarta (SMC2646)
3.4.6 Setmelanotide: Imcivree (SMC2647)

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 Degarelix injection: Firmagon (SMC2625)

The ERFC noted the SMC abbreviated submission for Degarelix injection: Firmagon (SMC2625).

Indication:

- for treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy.
- as neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.

Degarelix offers an additional treatment choice in the therapeutic class of gonadotrophin releasing hormone (GnRH) antagonist/agonist in this setting.

The ERFC agreed to classify Degarelix injection: Firmagon (SMC2625) 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 Cipaglucosidase alfa powder for concentrate for solution for infusion: Pombiliti (SMC2606)

The ERFC noted the SMC abbreviated submission for Cipaglucosidase alfa powder for concentrate for solution for infusion: Pombiliti (SMC2606).

Indication: as a long-term enzyme replacement therapy used in combination with the enzyme stabiliser miglustat for the treatment of adults with late-onset Pompe disease (acid α-glucosidase [GAA] deficiency).

Cipaglucosidase alfa plus miglustat offers an additional treatment choice of enzyme replacement therapy for GAA deficiency.

The ERFC agreed to classify Cipaglucosidase alfa powder for concentrate for solution for infusion: Pombiliti (SMC2606) 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 Trastuzumab deruxtecan: Enhertu (SMC2608)
3.7.2 Nivolumab concentrate for solution for infusion: Opdivo (SMC2619)
3.7.3 Pembrolizumab: Keytruda (SMC2589)

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 noted that the National Cancer Medicines Advisory Group will be sharing the first annual horizon scanning report for off-label and off-patent cancer medicines to support financial and service planning at health board level, and the report will provide early intelligence on off-label uses and new off-patent uses that may be proposed to NCMAG in 2024-2025.

The ERFC further 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 raised.

4.2 NHS Fife
None raised.

4.3 NHS Lothian
None raised.

5 Any other competent business
None noted.

6 Date of next meeting
The next ERFC meeting is scheduled for Wednesday 27 March 2024 at 1400 - 1630 hours via MS Teams. NHS Fife will be hosting the meeting.

FAF3s should be submitted by 20 February 2024 (for discussion at the ERWG meeting on 06 March 2024).

FAF1s and FAF2s should be submitted by 12 March 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