East Region Formulary

East Region Formulary Committee
Minutes

Date: 02 April 2025
Time: 2.00pm – 3:30pm
Location: MS Teams

Present:

Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Malcolm Clubb	Director of Pharmacy (Co-Chair), NHS Borders – in the Chair
Dr Konstantinos Dabos	Consultant, GI, NHS Lothian
Dr Joan Egerton	GP, NHS Fife
Dr David Griffith	Consultant – Microbiologist, NHS Fife
Ryan Headspeath	Senior Clinical Pharmacist, Dermatology and Shared Care, NHS Fife
Carol Holmes	Pharmacist - Primary Care, NHS Lothian
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist - Medicines Governance and Guidance, NHS Lothian
Iain Macintyre	Consultant – Renal (Co-Chair), NHS Lothian
Diane Murray	Formulary Pharmacist, NHS Lothian
Fraser Notman	Senior Pharmacist – Medicines Management, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Monica Szabo	Consultant Oncologist, NHS Lothian

In attendance: Caitlin Satti, Information Officer, NHS Lothian (minutes)

Apologies:
Jane Browning, Associate Director of Pharmacy, NHS Lothian
Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife
Dr Grace Ding, Consultant Oncologist, NHS Lothian
Dr Tariq Farrah, Consultant - Renal, NHS Lothian
Alice Mathew, Senior Clinical Pharmacist - Medicines Utilisation and Therapeutics, NHS Fife
Dr Paul Neary, Consultant – Cardiology, NHS Borders
Cathryn Park, Deputy Director of Pharmacy, NHS Borders
Sarah Tait, Lead Advanced Practitioner, NHS Borders

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1 Welcome and Apologies

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

- ERFC noted that the meeting is being recorded
- Joining – The Chair and ERFC committee members welcomed new member and NHS Lothian co-Chair, Dr Iain Macintyre. Dr Macintyre will Chair the next cycle of ERFC meetings.

1.2 Matters arising

None noted.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 05 February 2025

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 12 March 2025

The ERFC noted that FAF3 applications for Zivafert and Human Chorionic Gonadotrophin for the treatment of hypogonadotropic hypogonadism were reviewed at the East Region Working Group meeting. The ERWG requested further information from the applicants, and it is expected that both applications will be reviewed at the next East Region Formulary Committee meeting in May.

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

None noted.

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Elexacaftor, ivacaftor, tezacaftor: Kaftrio (SMC2713)

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

The ERFC discussed the submission in conjunction with 3.1.2 FAF1 Lumacafator-Ivacaftor: Orkambi (SMC2712) and 3.1.3 FAF1 Tezacaftor-Ivacaftor: Symkevi (SMC2711).

Indication: in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 2 years to less than 6 years (granules in sachet) and 6 years and older (film-coated tablets) who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene.

The finance budget template was included with the FAF.

The ERFC reviewed the submission, acknowledging the intended use of the medicine in the treatment of Cystic Fibrosis, specifically for patients with a qualifying genotype, is consistent with the evidence outline in the NICE TA988 Technology Appraisal Guidance.

The ERFC noted information provided on selection criteria for the treatments in relation to comparative efficacy of combination treatments, age and individual patient safety considerations.

The ERFC agreed to classify FAF1 Elexacaftor, ivacaftor, tezacaftor: Kaftrio (SMC2713) 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 Lumacafator-Ivacaftor: Orkambi (SMC2712)

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

The ERFC discussed the submission in conjunction with 3.1.1 FAF1 Elexacaftor, ivacaftor, tezacaftor: Kaftrio (SMC2713) and 3.1.3 FAF1 Tezacaftor-Ivacaftor: Symkevi (SMC2711).

Indication: Treatment of cystic fibrosis (CF) in patients aged 1 year and older (granules in sachet) or 6 years and older (film-coated tablets) who are homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR)* gene.

The finance budget template was included with the FAF.

The finance section detailing estimated patient numbers per annum is incomplete.

The ERFC requested the submission of a revised application with completed finance section. The applicants are requested to respond with information on the recommended action by 13 May 2025.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify FAF1 Lumacafator-Ivacaftor: Orkambi (SMC2712) 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

3.1.3 FAF1 Tezacaftor-Ivacaftor: Symkevi (SMC2711)

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

The ERFC discussed the submission in conjunction with 3.1.1 FAF1 Elexacaftor, ivacaftor, tezacaftor: Kaftrio (SMC2713) and 3.1.2 FAF1 Lumacafator-Ivacaftor: Orkambi (SMC2712).

Indication: In a combination regimen with ivacaftor tablets for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the *F508del* mutation or who are heterozygous for the *F508del* mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene: *P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G,* and *3849+10kbC→T*.

The finance budget template was included with the FAF.

The ERFC agreed to classify FAF1 Tezacaftor-Ivacaftor: Symkevi (SMC2711) 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 Trifluridine/Tipiracil: Lonsurf (SMC2654)

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

Indication: In combination with Bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received two prior anticancer treatment regimens including

fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents.

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

The ERFC reviewed the submission, with evidence to support the efficacy of Trifluridine/Tipiracil: Lonsurf provided by the SUNLIGHT study which demonstrated that there was a statistically significant difference between Trifluridine/Tipiracil in combination with Bevacizumab compared with Trifluridine/Tipiracil monotherapy in regard to overall survival and progression-free survival. It was further noted that safety profile is consistent with what has previously been reported for Trifluridine/Tipiracil and Bevacizumab, respectively.

Patients receiving Trifluridine/Tipiracil + Bevacizumab will require day care admission for Bevacizumab infusion thereby incurring additional costs for nursing and chair time, as well as aseptic dispensing time. Additional monitoring requirements will be required with blood pressure monitoring and urine dipstick testing at day 1 and day 15 of each cycle, however, this is not deemed to have significant financial impact.

The ERFC agreed that Trifluridine/Tipiracil: Lonsurf (SMC2654) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Trifluridine/Tipiracil: Lonsurf (SMC2654) 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 Momelotinib: Omijara (SMC2636)

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

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

The ERFC reviewed the submission, with supporting evidence provided by the SIMPLIFY-1 and SIMPLIFY-2 studies, respectively.

The committee acknowledged that Momelotinib can be used as a first-line or subsequent line of treatment as per SMC approval depending on patient haemoglobin levels. It was noted that due to lack of alternative medicine options, anaemic patients have been receiving Ruxolitnib as first-line treatment option; with the inclusion of Momelotinib: Omijara, the same group of patients with myelofibrosis and anaemia may receive Momelotinib instead of Ruxolitinib as a cost-saving alternative treatment.

The ERFC agreed that Momelotinib: Omijara (SMC2636) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Momelotinib: Omijara (SMC2636) 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 Ivosidenib (with azacitidine): Tibsovo (SMC2615)

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: In combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.

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

The ERFC reviewed the submission, noting that the addition of Ivosidenib to Azacitidine will replace Azacitidine alone as first-line treatment for patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation. For elderly, but fitter patients who would not be eligible for intensive Systemic Anti-Cancer Therapy (SACT), the local haematology consultant team have indicated that some patients will continue to receive Venetoclax with Azacitidine alternatively.

It was noted that the relevant implementation plan has not been provided with the application, however, the committee acknowledged that there are robust cancer care management plans in place across Scotland, and the applicants have provided assurance that a clinical management plan will be in place in due course.

The ERFC agreed that Ivosidenib (with azacitidine): Tibsovo (SMC2615) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Ivosidenib (with azacitidine): Tibsovo (SMC2615) 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

3.1.7 FAF1 Epcoritamab: Tepkinly (SMC2632)

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

Indication: As monotherapy for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

The ERFC reviewed the submission, noting that whilst both applicants have declarations of interest, the application is in line with approved SMC advice which takes account of the views from a Patient and Clinician Engagement (PACE) meeting, and has support from the Cancer Medicines Management Committee. Support for proposed use was provided by a local consultant haematologist without declarations of interest.

The EPCORE NHL-1 study, a phase I/II open-label trial, provides evidence supporting the efficacy and safety of Epcoritamab for this indication. In the study, 62% of patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) who had undergone two or more lines of systemic therapy achieved an objective response, with 39% of patients reaching complete response. It was further noted that a *Nature* peer-reviewed study, published in 2024, provides additional two-year follow up data in which treatment response trends remained the same - 61.9% overall response rate and complete response in 40% of patients, with a median progression free survival of 4.4 months and a median overall survival of 19.4 months.

The committee acknowledged that there is now also a three-year update with trial data cut-off in May 2024. Evidence from this trial indicates similar treatment response trends, with finalised trial data expected by the end of 2026.

The ERFC noted that Epcoritamab will be available as a third-line onwards treatment option for DLBCL. CAR-T treatment is also available in the third-line setting, however, not all patients are eligible. It was noted that there is no other Systemic Anti-Cancer Therapy (SACT) on the formulary for third-line treatment of DLBCL, therefore, if unsuitable for Epcoritamab, the patient will receive end-of-life care. CAR-T cell therapy will be considered and Epcoritamab may be used prior (rarely) or post CAR-T cell therapy, or as an alternative in patients unsuitable for CAR-T cell therapy. The applicants have stressed that Epcoritamab is not a replacement for other SACT, but rather an alternative to end-of-life care. The ERFC noted that comparators used in the economic assessment in the SMC appraisal would be used in earlier treatment lines in current local practice. There is no cost-effectiveness assessment of Epcoritamab compared to end-of-life care available, therefore, cost effectiveness in this position is unknown. The costings noted in the application account for this proposed use of Epcoritamab: Tepkinly.

In regard to safety, the most common treatment-emergent adverse events were cytokine release syndrome, pyrexia, fatigue, and neutropenia. However, it was noted that the safety profile is in line with what the clinical team expect from this class of medicine. The local treatment protocol also provides additional information regarding monitoring and management guidelines.

The ERFC agreed that Epcoritamab: Tepkinly (SMC2632) is appropriate for inclusion in the Formulary Decision section of the ERF, with Specialist Use Only formulary flagging.

The ERFC agreed to classify FAF1 Epcoritamab: Tepkinly (SMC2632) 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 Cabotegravir: Apretude (SMC2718)

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: Cabotegravir prolonged-release injection: in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg.

Cabotegravir tablets: in combination with safer sex practices for short term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. Cabotegravir tablets may be used as:

- Oral lead-in to assess tolerability of cabotegravir prior to administration of long acting cabotegravir injection
- Oral PrEP for individuals who will miss planned dosing with cabotegravir injection

SMC restriction: Adults and adolescents (weighing at least 35kg) at high risk of sexually acquired HIV who are eligible for PrEP, including oral PrEP, but for whom oral PrEP is not appropriate to meet their HIV prevention needs.

The finance budget template was included with the FAF.

The ERFC reviewed the submission, noting that the proposed inclusion of Cabotegravir: Apretude is as third-line treatment option after Emtricitabine + Tenofovir: Descovy for patients whose HIV prevention needs cannot be met by first- or second-line PrEP options.

The applicants have indicated that estimating costs per annum is challenging as it is difficult to predict how many patients will qualify for treatment as these patients are not eligible for standard PrEP and, therefore, are not part of the current patient cohorts. As a result, the applicants have reasoned that actual patient numbers and the associated costings will be less than the number noted on the submission.

It was noted that there is not a local clinical management guideline, however, there is robust criteria for patient selection - patient is identified by self or clinician as having a need for Cabotegravir PrEP as HIV prevention needs are not being met by first- or second-line therapy. The patient is then discussed at National Complex PrEP MDT to decide if eligible.

The ERFC agreed to classify FAF1 Cabotegravir: Apretude (SMC2718) 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

3.1.9 FAF1 Latanoprost + Netarsudil: Roclanda (SMC2720)

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 reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.

SMC restriction: for use in patients for whom treatment with a prostaglandin analogue alone provides insufficient IOP reduction, only if:

- the patient had then tried a fixed-dose combination treatment, and it has not sufficiently reduced IOP, or
- a fixed-dose combination treatment containing beta-blockers is unsuitable

The ERFC reviewed the submission, with supporting evidence provided by the MERCURY 3 trial – a randomised, double-blind, non-inferiority phase III study. The MERCURY 3 trial found Netarsudil + Latanoprost to be non-inferior to Bimatoprost + Timolol at week two, week three, and month three. The committee further noted that previous MERCURY 1 and MERCURY 2 studies both highlighted a significantly better outcome for Latanoprost + Netarsudil compared with Latanoprost alone. Therefore, it was noted that the proposed inclusion of Latanoprost + Netarsudil will provide a suitable treatment option for patients who are unable to take beta-blockers, or there has not been a sufficiently reduced IOP with first-line treatments. The applicants have advised that the intended use of Latanoprost + Netarsudil: Roclanda across the East Region is in line with SMC restrictions.

In regard to positioning within the 'Treatment with combination products' pathway, the ERFC agreed to include Latanoprost + Netarsudil: Roclanda as second-line treatment option with an information note to advise prescribing in line with the approved restricted use.

It was noted that the safety profile of Latanoprost + Netarsudil appears to be less favourable than that of Bimatoprost + Timolol, however, adverse events were generally mild or moderate in severity and often resolved spontaneously.

The ERFC agreed to classify FAF1 Latanoprost + Netarsudil: Roclanda (SMC2720) 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

3.2 Formulary Amendment Form

3.2.1 Latanoprost + Timolol

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 Glaucoma

Application for amendment to include additional formulation of preservative-free multidose bottle to enable the supply of both single dose units and multidose to meet patient compliance needs. Latanoprost + Timolol to be included on the ERF for Specialist Initiation.

The ERFC reviewed the supporting evidence.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.2 Natalizumab biosimilar: Tyruko

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

Indication: Treatment of highly active relapsing-remitting multiple sclerosis (RRMS)

Application for amendment to include new biosimilar product in the list of Natalizumab products on the formulary. Natalizumab: Tyruko to be included on the ERF for Specialist Use Only.

The ERFC discussed the supporting evidence, noting that Tyruko is not proposed to replace originator medicine, Tysabri, but to be added as the preferred vial formulation for new patients. The ERFC noted plans for a biosimilar switch programme for existing patients on Tysabri vials. The ERFC agreed for preferred formulations to be reviewed at the next scheduled chapter review.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.3 Clarithromycin

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

Indication: Lactation mastitis

Application for amendment to update various aspects in the 'Treatment of mastitis/ breast abscess associated with lactation' pathway.

The ERFC reviewed the supporting evidence, noting the updated prescribing guidance for Flucloxacillin from 500mg every 6 hours for 10 days to 1g every 6 hours for 7 days. For penicillin allergy, Erythromycin

has been removed, with updated prescribing guidance for Clarithromycin. Prescribing notes will also be updated.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.4 Faricimab: Vabysmo

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

Indication: Treatment of age-related macular degeneration and diabetic macular oedema

Application for amendment due to include pre-filled syringe formulation to allow for simplified administration. Faricimab: Vabysmo to be included on the ERF for Specialist Use Only in addition to existing formulations.

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2.5 Colestyramine

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

Indication: Biliary cirrhosis – Treatment of bile acid malabsorption

Application for amendment to include Colestyramine 4g oral powder sachets alongside Colestyramine 4g oral powder sachets sugar free as first-line treatment option in the 'Treatment of bile acid malabsorption' pathway. Colestyramine 4g oral powder sachets to be included on the ERF for Specialist Initiation.

Colestyramine is also included on ERF for children for treatment of bile acid malabsorption, therefore, the paediatric clinical teams will be contacted to confirm support for inclusion in the recommendations for children.

The ERFC noted the supporting evidence.

The paediatric clinical teams will be contact to review, and the formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3 Ultra Orphan Medicines Initial Assessment – *none noted.*

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Lecanemab: Leqembi (SMC2700)
3.4.2 Ripretinib: Quinlock (SMC2722)
3.4.3 Spesolimab: Spevigo (SMC2729)
3.4.4 Amivantamab: Rybrevant (SMC2768)
3.4.5 Atezolizumab: Tecentriq (SMC2769)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

3.5.1 Durvalumab: Imfinzi (SMC2743)

The ERFC noted the SMC abbreviated submission for Durvalumab: Imfinzi (SMC2743).

Indication: As monotherapy for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥50% TPS and progressing on or after platinum-containing chemotherapy.

The ERFC agreed to classify Durvalumab: Imfinzi (SMC2743) 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 Olaparib: Lynparza (SMC2737)

The ERFC noted the SMC abbreviated submission for Olaparib: Lynparza (SMC2737).

Indication: Monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

The ERFC agreed to classify Olaparib: Lynparza (SMC2737) 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

3.5.3 Talazoparib: Talzenna (SMC2753)

The ERFC noted the SMC abbreviated submission for Talazoparib: Talzenna (SMC2753).

Indication: In combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

The ERFC acknowledged that information was provided by the clinical team in support of Talazoparib: Talzenna's inclusion on the formulary, however, it was noted that the inclusion of Talazoparib: Talzenna will incur additional costs. As a result, the clinical team have been advised to submit a FAF1 application for review at an upcoming pre-ERFC panel/ERFC meeting.

The ERFC agreed to classify Talazoparib: Talzenna (SMC2753) 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

3.5.4 Cabozantinib: Cabozantinib Ipsen (SMC2754)

The ERFC noted the SMC abbreviated submission for Cabozantinib: Cabozantinib Ipsen (SMC2754).

Indication: As monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.

The ERFC agreed to classify Cabozantinib: Cabozantinib Ipsen (SMC2754) 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 noted.

3.7 Non-submissions within 90 days of SMC publishing

The ERFC noted the non-submissions within 90 days of SMC publishing.

3.7.1 Cemiplimab: Libtayo (SMC2719)
3.7.2 Fenfluramine: Fintepla (SMC2723)

The ERFC agreed to classify items 3.7.1 and 3.7.2 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

The ERFC acknowledged that conversations are ongoing across the East Region regarding COVID antiviral medicines and the NICE Technology Appraisals. Further advice from the SMC has been sought, with each Board continuing to evaluate both cost- and clinical-effectiveness of the medicines. Applications to update ERF formulary status will be submitted to ERFC where required.

5 Any other competent business

The ERFC noted the newly published MHRA Drug Safety Update (DSU) regarding prolonged-release opioids, and the removal of indication for relief of post-operative pain (Prolonged-release opioids: Removal of indication for relief of post-operative pain - GOV.UK). The MHRA have advised that the indication for the treatment of post-operative pain has been removed from the licences of all prolonged release opioids due to the increased risk of persistent post-operative opioid use (PPOU) and opioid-induced ventilatory impairment (OIVI).

It was noted that information regarding opioids is present on the formulary in both the Anaesthesia and CNS chapter; there are also mentions of modified-release opioids throughout the Pain section of the ERF. The committee recognised that each Board is at a different stage in revising current practices and updating the relevant guidelines.

A Chapter Expert Working Group recently met to discuss revisions to the formulary in regard to Lidocaine plasters and topical Capsaicin. The group additionally discussed the recent MHRA DSU, and the potential updates to the formulary. Further comments are currently being sought from pain specialists across the East Region, and revised formulary pathways are expected to come to the next East Region Working Group meeting in May for discussion.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 28 May 2025 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 16 April 2025 (for discussion at the pre-ERFC panel meeting on 23 April 2025).

FAF1s for consideration by the pre-ERFC panel should be submitted by 16 April 2025 (for discussion at the pre-ERFC panel meeting on 23 April 2025).

All other FAF1s, FAF2s, and Formulary Amendments should be submitted by 13 May 2025.

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 eos.prescribing@nhs.scot.