East Region Formulary

East Region Formulary Committee
Minutes

Date: 9 August 2023
Time: 2.00pm – 4.30pm
Location: MS Teams

Present:

Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Steven Fenton	Project Manager, NHS Lothian
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Peter Hall	Consultant - Oncology, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist, NHS Lothian
Alice Mathew	Senior Pharmacist Medicines Utilisation &Therapeutics, NHS Fife
Fraser Notman	Formulary Pharmacist, NHS Fife
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian – in the Chair
Sandra MacDonald	Meeting Administration, NHS Fife

Guests/Observing: Tricia Mieduniecki, NHS Borders

Apologies:
Jane Browning, (Acting) Associate Director of Pharmacy, NHS Lothian
Gillian Donaldson, Nurse – Cardiology, NHS Borders
Diane Murray, Formulary Pharmacist, NHS Lothian
Carol Holmes, Pharmacist - Primary care, NHS Lothian
Dr Paul Neary, Consultant - Cardiology, NHS Borders
Dr Jo Rose, GP, NHS Lothian
Alison Wilson, Director of Pharmacy, NHS Borders

---

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.
- Observing - Tricia Mieduniecki, NHS Borders
- Welcome - Carla Capaldi, NHS Fife; Alice Mathew, NHS Fife

- Leaving - none
- Declaration of Interest (DOI) – there were no additional declarations of interest declared for this meeting. ERFC members were reminded to return their DOI forms if appropriate. DOI forms will be requested yearly with completed DOIs retained by the project team and shared with the individual's board. ERFC members were advised that annual DOI forms had recently been circulated for completion and return.

ACTION: ALL

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

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

The Paediatric Cardiovascular ERF chapter has been launched and is on the ERF website. The next stage for Paediatric chapter development is the Central Nervous System (CNS). In line with the Adult CNS chapter, the Paediatric CNS chapter will be broken down into sections. The first group has met and the other two groups are scheduled to meet in the coming weeks.

The ERFC noted the update on progress with the Paediatric ERF chapters.

1.3 Matters arising

1.3.1 ERFC 07 June 2023 item 3.1.6 FAF1 upadacitinib: Rinvoq (SMC2575) was reviewed at the ERFC June meeting. The ERFC requested clarification on the positioning of ustekinumab and vedolizumab in all three Boards. Discussed under item 2.3.3. Action completed.

1.3.2 ERFC 07 June 2023 item 3.1.7 - FAF1 ozanimod: Zeposia (SMC2478) was reviewed at the ERFC June meeting. The ERFC requested that comparative treatment costs of second line options be reviewed to confirm that they sit equally within the pathway. Discussed under item 2.3.4. Action completed.

1.3.3 ERFC 07 June 2023 item 3.1.1 FAF1 daratumumab: Darzalex (SMC2447) was reviewed at the ERFC June meeting. A typographical error within the finance budget template was noted and it was also unclear whether the updated PAS for daratumumab was reflected in the financial section. The ERFC requested that the financial budget template be reviewed and updated as required. The ERFC noted that this remains outstanding and agreed that this should be carried forward as ongoing.

ACTION: NHS Lothian Admin Team

1.3.4 ERFC 07 June 2023 item 3.1.4 FAF1 pembrolizumab: Keytruda (SMC2501) was reviewed at the ERFC June meeting. The ERFC noted a typographical error/discrepancy in the patient numbers and finance template and requested that the financial budget template be reviewed and updated as required.

The ERFC noted that the requested information had been received. Action completed.

1.3.5 ERFC 07 June 2023 item 3.1.5 FAF1 empagliflozin: Jardiance (SMC2523) was reviewed at the ERFC June meeting. The ERFC requested confirmation of NHS Fife CD support.

The ERFC noted that confirmation of NHS Fife CD support was still awaited.

ACTION: NHS Fife Formulary Pharmacist

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 7 June 2023

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

2.2 East Region Working Group (ERWG) meeting minutes 19 July 2023

The minutes of the ERWG meeting on 19 July 2023 were noted for information.

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

- **Gastrointestinal Chapter (Paediatric)**

The ERFC discussed the key points in the ERF chapter gastrointestinal (paediatric).

It was noted that the review was undertaken over two meetings. A number of new pathways have been included in the paediatric chapter that are not included in the adult chapter (bowel evacuation for colonoscopy, infant colic, initial management of IBS and functional abdominal pain, treatment of gastric statis and cholestasis). The pathways listed in the adult chapter that are not currently included in paediatric chapter were also noted.

The ERFC discussed the chapter content and the rationale for any variations between the adult and paediatric chapter content/pathways.

The ERFC noted that metronidazole 200mg and 400mg tablets were included in the H. pylori-associated dyspepsia pathway and it was proposed that the 500mg tablet formulation should also be included.

The ERFC agreed that metronidazole 500mg tablets should also be included in the H. pylori-associated dyspepsia pathway.

ACTION: NHS Lothian Formulary Pharmacist

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

ACTION: ERF Admin Team/NHS Lothian Formulary Pharmacist

- **Respiratory Chapter (Paediatric)**

The ERFC discussed the key information the ERF chapter respiratory (paediatric).

It was noted that the review was undertaken by a well-attended group with Consultant, GP, Respiratory Specialist Nurse and Pharmacist representation.

The ERFC noted the pathways included in the adult chapter that are not currently in the paediatric chapter as well as the additional pathways included in the paediatric chapter.

The ERFC discussed the chapter content and the rationale for any variations between the adult and paediatric chapter content/pathways.

It was highlighted that there is no information in the paediatric chapter on the use of prednisolone tablets dispersed in water as an alternative to soluble or liquid preparations and the ERFC agreed that an appropriate prescribing note should be included. It was also

agreed that prednisolone dosage information should be included in the management of croup pathway (currently prescribers are referred to the BNF for Children). It was also recommended that the statement about use with pressurised inhalers be removed from pathway 13 – peak flow meters.

ACTION: NHS Fife Formulary Pharmacist

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

ACTION: ERF Admin Team/NHS Fife Formulary Pharmacist

- **Pharmacy First**

The ERFC discussed the key updates to Pharmacy First including the addition of three hay fever preparations. It was noted that the preparations are all in line with the ERFC adult allergy pathway.

The three Formulary Pharmacists to confirm that the appropriate PGDs are in place. The formulary website will be updated.

ACTION: ERF Admin Team /NHS Borders, NHS Fife and NHS Lothian Formulary Pharmacists

2.3.1 ERF Adult - New Condition Pathway - Gender Dysphoria or Incongruence

The ERFC discussed the adult ERF new condition pathway, gender dysphoria or incongruence.

The new condition pathway was developed in conjunction with a specialist team and includes treatment pathways for masculinising endocrine treatment and feminising endocrine treatment. The pathway is in line with the Scottish Government Gender Reassignment Protocol 2012.

The ERFC noted that the products within the pathway are all classified as Specialist Initiation. It was agreed that development of a Shared Care Protocol is a decision for individual Boards. Feedback from NHS Fife is that national guidance would be accepted and a Shared Care Protocol would not be required.

The ERFC recommended to check availability of Sustanon and update if required.

ACTION: NHS Lothian Formulary Pharmacist

The ERFC requested that reference to GPPC NHS Lothian be removed from the pathway documentation and replaced with ”Further information is available via NHS Lothian RefHelp resources”.

ACTION: NHS Lothian Formulary Pharmacist

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

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

2.3.2 ERF Adult - New Condition Pathway - Motor Neurone Disease

The ERFC discussed the adult ERF new condition pathway - motor neurone disease – riluzole for the treatment of amyotrophic lateral sclerosis.

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

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

2.3.3 ERF Adult - Severe Active or Active Fistulising Crohn's Disease

The ERFC discussed the updated ERF adult pathway for severe active or active fistulising Crohn's Disease.

The pathway has been updated to clarify the positioning of ustekinumab and vedolizumab. GI teams in all three Boards have agreed that upadacitinib should be placed 2nd line alongside ustekinumab and vedolizumab; 1st line treatment remains anti-TNF alpha inhibitors, infliximab and adalimumab.

The ERFC noted a concern around the wording in the pathway documentation regarding the use of JAK inhibitors, including upadacitinib, in younger patients due to increased incidence of malignancy with longer-term use and requested that this be fed back to the CEWG. The ERFC noted that choice of treatment would be based on GI Consultant review and patient preferences. The ERFC recommended that patient information leaflets be developed to assist patients with the decision making process.

ACTION: NHS Lothian Formulary Pharmacist

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

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

2.3.4 ERF Adult - Treatment of Ulcerative Colitis with Biologic and Targeted Synthetic DMARDs

The ERFC discussed the updated ERF adult pathway treatment of ulcerative colitis with biologic and targeted synthetic DMARDs.

The ERFC noted that the boards differed on proposed place in therapy of medicines in the pathway, following further discussion with the three Boards it has been proposed that infliximab, adalimumab should remain first line treatment and other preparations in the pathway (vedolizumab, filgotinib, ustekinumab, upadacitinib, tofacitinib, ozanimod and golimumab) should be placed 2nd line. The ERFC agree that the proposed order is appropriate for the ERF pathway with consideration to safety, efficacy and cost-effectiveness.

The ERFC noted the importance of appropriate prescribing notes around JAK inhibitors and the increased risk of malignancy. The ERFC noted that there is robust local guidance/checklists available covering the safety, efficacy and cost effectiveness of these medicines. The ERFC recommended that consideration be given to adding information in the prescribing notes regarding the availability of up-to-date guidance including links to the MHRA guidance on JAK inhibitors.

ACTION: Adult GI CEWG/NHS Lothian Formulary Pharmacist

It was noted that golimumab was not generally used within the three Boards for this indication and the ERFC requested clarification from the specialists on its removal from the pathway.

ACTION: Adult GI CEWG/NHS Lothian Formulary Pharmacist

The ERFC approved the pathway amendments with requested revisions to be agreed by the CEWG. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 pembrolizumab: Keytruda (SMC2526)

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

Indication: As monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB or IIC melanoma and who have undergone complete resection.

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

The ERFC discussed the supporting evidence.

The ERFC noted that the SMC approval for use includes treatment in adolescents aged 12 years and older however there was no supporting local protocol presented regarding use in this age-group.

The ERFC requested clarification on potential use in adolescents aged 12 years and older and input from paediatric oncology specialists if appropriate.

The ERFC discussed the supporting evidence. It was noted that the proposed 6-weekly dosing interval was not in line with SMC advice (3-weekly) and no clinical evidence was presented to support this variation.

The ERFC requested clarification/further information on the proposed 6-weekly dosing interval as this is not in line with the clinical trial evidence in the SMC advice (3-weekly). The ERFC also requested confirmation of the finance detail as the finance template included with the FAF1 is based on 3-weekly dosing.

The applicants are requested to respond with information on the recommended actions by 26 Sept 2023.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify pembrolizumab: Keytruda as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.2 FAF1 pembrolizumab: Keytruda (SMC2144)

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

Indication: As monotherapy for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.

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

The ERFC discussed the supporting evidence. It was noted that the proposed 6-weekly dosing interval was not in line with SMC advice (3-weekly) and no clinical evidence was presented to support this variation.

The ERFC requested clarification/further information on the proposed 6-weekly dosing interval as this is not in line with the clinical trial evidence in the SMC advice (3-weekly). The ERFC also requested confirmation that the finance detail in the FAF1 is correct.

The applicants are requested to respond with information on the recommended action by 26 Sept 2023.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify pembrolizumab: Keytruda 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 mobocertinib: Exkitivity (SMC2516)

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: as monotherapy for the treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received prior platinum-based chemotherapy.

The local treatment protocol and finance budget template were included with the FAF. The treatment protocol is line with SMC advice.

The ERFC discussed the supporting evidence. The proposed place in therapy is second line within a treatment pathway. Mobocertinib: Exkitivity would replace docetaxel for this indication.

The ERFC noted that both specialist initiation and specialist use only formulary flags had been highlighted in the FAF and agreed that specialist use only would be appropriate. For more information on formulary flags refer to additional information on the ERF website https://formulary.nhs.scot/east/help-and-support/formulary-governance/new-medicine-decisions/

The ERFC agreed to classify mobocertinib: Exkitivity 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 atezolizumab: Tecentriq (SMC2492)

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

Indication: as monotherapy as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC staging system) non-small cell lung

cancer (NSCLC) whose tumours have PD-L1 expression on ≥50% of tumour cells and whose disease has not progressed following platinum-based adjuvant chemotherapy.

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 first line adjuvant treatment of resected stage II-IIIa lung cancer, following platinum based chemotherapy. The ERFC discussed its positioning within the treatment pathway and whether this would be in 1st or 2nd line position and requested the applicants to clarify the positioning in the clinical management guideline.

The applicants are requested to respond on the recommended actions by 26 Sept 2023.

ACTION: NHS Lothian Admin Team

The ERFC noted that both specialist initiation and specialist use only formulary flags had been highlighted in the FAF and agreed that specialist use only would be appropriate.

The ERFC to contact Oncology/Haematology representatives to clarify the definition of specialist initiation and specialist use only formulary flags. More information on formulary flags is available on the ERF website https://formulary.nhs.scot/east/help-and-support/formulary-governance/new-medicine-decisions/

ACTION: NHS Lead Pharmacist Medicines Governance and Guidance NHS Lothian

The ERFC agreed to classify atezolizumab: Tecentriq 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 nivoluzumab: Opdivo (SMC2519)

The ERFC noted and discussed the previously circulated FAF1 submission. One non-personal specific declaration of interest was declared. CD support was received from all three Boards. Indication: in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell programmed death ligand 1 (PD-L1) expression ≥1%.

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 first choice within a treatment pathway. The criteria for patient selection is in line with SMC advice.

The ERFC agreed to classify nivoluzumab: Opdivo 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 venetoclax: Venclyxto (SMC2293 + SMC2427)

The ERFC noted and discussed the previously circulated FAF1 submission. Personal specific, personal non-specific and non-personal specific interests were declared. CD support was received from all three Boards.

Indication: In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

SMC2293 restriction: for use in (1) patients without del (17p)/TP53 mutation who are not fit to receive FCR (fludarabine, cyclophosphamide and rituximab) chemo-immunotherapy and (2) patients with del (17p)/TP53 mutation.

SMC2427 restriction: in patients without del (17p)/TP53 mutation who are fit to receive fludarabine, cyclophosphamide and rituximab (FCR) chemo-immunotherapy.

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

The ERFC discussed the supporting evidence. It was noted that the comparator treatment in the FAF1 (acalabrutinib) was different to the comparator treatment in the SMC advice (chlorambucil). The ERFC noted that there was no clear clinical evidence provided to support the use of venetoclax: Venclyxto compared to acalabrutinib. The ERFC also noted that as acalabrutinib would be given until disease progression this would potentially have an impact on the accuracy of the modelling used in the financial section.

The ERFC requested clarification on the evidence base and rationale for the comparator treatment (acalabrutinib) and a review of the modelling/finance section to reflect the potential implications of longer term treatment with acalabrutinib compared to venetoclax: Venclyxto.

The applicants are requested to revise the application form with information on the recommended action and to resubmit by 26 Sept 2023.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify venetoclax: Venclyxto as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.7 FAF1 bulevirtide: Hepcludex (SMC2520)

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 hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease. **SMC restriction:** to use in patients with evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based therapy or who are ineligible to receive interferon-based therapy due to intolerance or contra-indication.

A local treatment protocol has not been developed. The finance budget template was included with the FAF.

The proposed place in therapy is second choice within a treatment pathway. The ERFC noted that there is no alternative second choice treatment option. The criteria for patient selection is in line with SMC advice.

The ERFC agreed to classify bulevirtide: Hepcludex 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 trifarotene: Aklief (SMC2441)

The ERFC noted and discussed the previously circulated FAF1 submission. No declaration of interests were received. CD support was received from all three Boards however individual details were not provided.

Indication: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.

A local treatment protocol has not been developed. The finance budget template was included with the FAF.

The criteria for patient selection is in line with SMC advice. Trifarotene: Aklief should not be used in pregnancy or in women who are planning a pregnancy. The proposed place in therapy is equal third line alongside adapalene for mild to moderate acne. Trifarotene: Aklief would be a partial replacement for adapalene. The ERFC also noted a proposed change to the wording in the treatment pathway/prescribing notes.

The ERFC noted that trifarotene: Aklief was presented as cost effective compared to adapalene. Though when compared with cost for weight the ERFC considered trifarotene:Aklief to be similar in cost to adapalene. The ERFC also noted that predicted patient numbers were potentially lower than expected given the prevalence of acne. Clarification on the rationale for use of trifarotene: Aklief compared to adapalene was requested to inform the updates to the pathway.

The ERFC requested clarification on patient numbers, corrected costs and additional guidance on the criteria for when to use trifarotene: Aklief or adapalene.

The applicants are requested to revise the application form with information on the recommended actions and to resubmit by 1 Sept 2023.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify trifarotene: Aklief as Routinely available in line with national guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.9 FAF1 rimegepant: Vydura (SMC2521)

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 acute treatment of migraine with or without aura in adults. **SMC restriction:** for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.

A local treatment protocol has not been developed. The finance budget template was included with the FAF.

The proposed place in therapy is joint 3rd line for treatment of an acute attack – moderate to severe migraine. The criteria for patient selection is in line with SMC advice. No additional monitoring is required and no formulary flags are proposed.

The ERFC noted that the budget impact information is based on prescribing in Primary Care. It was also noted that patient numbers could potentially be significantly higher than estimated in the FAF.

The ERFC agreed to classify rimegepant: Vydura as Routinely available in line with national guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

3.1.10 FAF1 dapagliflozin: Forxiga (SMC2577)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support was received from all three Boards however details of individual CDs were not provided.

Indication: In adults for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) >40%. Dapagliflozin offers an additional treatment choice in the therapeutic class of sodium-glucose cotransporter 2 Inhibitors (SGLT2i).

A local treatment protocol has not been developed. The finance budget template was included with the FAF.

The ERFC discussed the supporting evidence. The proposed place in therapy is equal first choice alongside empagliflozin for this indication. The criteria for patient selection is in line with SMC advice.

The ERFC agreed to classify dapagliflozin: Forxiga as Routinely available in line national guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Borders Pharmacist

3.1.11 FAF1 tezepelumab: Tezspire (SMC2541)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific interest was declared. CD support was received from all three Boards.

Indication: Add on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment and either i) experience at least three exacerbations in the previous year and not receiving maintenance treatment with oral

corticosteroids or ii) have a blood eosinophils ≥150 cells/microlitre and are receiving maintenance treatment with oral corticosteroids.

The finance budget template was included with the FAF. The ERFC noted that a local treatment protocol has not been developed.

The ERFC discussed the supporting evidence. The criteria for patient selection is in line with SMC advice. The proposed place in therapy is equal first line alternative to mepolizumab, benralizumab or omalizumab. No information was provided on the criteria for selecting each of the first line options. It is proposed that a Homecare service would be implemented locally however this would be a matter for individual Boards. Prescribing would be by specialist use only within a specialist outpatient clinic.

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 also queried whether there was any plan to rationalise the current Formulary choices. The ERFC noted that feedback from the applicant prior to the meeting was that Formulary choices would be reviewed in the future however there was no information on the potential timeframe for this. It was noted that the next Respiratory chapter review is scheduled for 18-24 months.

The ERFC requested clarification on the place in the treatment pathway and a review/rationalisation of the first line Formulary choices for this indication.

ACTION: Adult Respiratory CEWG/ NHS Fife Formulary Pharmacist

The ERFC agreed to classify tezepelumab: Tezspire 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

3.1.12 FAF1 nintedanib: Ofev (SMC2513)

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 adults for the treatment of idiopathic pulmonary fibrosis (IPF). **SMC restriction**: For use in patients with a predicted forced vital capacity (FVC) >80%.

A local treatment protocol has not been developed. The finance budget template was included with the FAF. The proposed place in therapy is joint first line alongside pirfenidone. Criteria for patient selection is in line with SMC advice. The ERFC noted that the treatment criteria for nintedanib is slightly different to the criteria for pirfenidone. Prescribing would be on a trial basis and regular respiratory reviews to ensure efficacy and tolerability would be undertaken. A Homecare service is in place for delivery of the medicine.

The ERFC agreed to classify nintedanib: Ofev 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

3.1.13 FAF3 droperidol - treatment of acute behavioural disturbance in adult critical care environments

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. CD support was received from NHS Lothian.

Indication: Rapid tranquillisation in acute behavioural disturbance in critical care environments.

The finance budget template was included with the FAF. A Rapid Tranquillisation Guideline for use in Adult Critical Care Units in NHS Lothian has been produced and approved by the ITU Quality Improvement Team but this was not included with the FAF3. The ERFC noted that the Lothian Guideline is broadly in line with the NHS Fife Guidance for Droperidol for Rapid Tranquillisation in the Emergency Department.

The application is for off-label use of a licensed medication. Droperidol is licensed as an antiemetic but not licensed for the proposed indication. The proposed place in the ERF is second line after ketamine. There is currently no treatment pathway for this indication.

Following discussion there was consensus that a wider regional piece of work was required to take this forward. A group with representation from all three Boards Adult Critical Care and Emergency Department representatives to be set up with the aim of bringing an update back to the next ERFC meeting in October.

ACTION: ERWG Chair/NHS Fife Formulary Pharmacist

The ERFC agreed to classify droperidol as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.2 Formulary Amendment Forms

3.2.1 There were no Formulary Amendment Forms for review.

3.3 Ultra-Orphan Pathway

3.3.1 Belumosudil: Rezurock (SMC2583)

The ERFC noted the SMC Ultra-orphan advice for information.

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 Selumetinib: Koselugo (SMC2540)
3.4.2 Ropeginterferon alfa-2b: Besremi (SMC2563)
3.4.3 Baricitinib: Olumiant (SMC2572)
3.4.4 Tixagevimab and cilgavimab: Evusheld (SMC2580)
3.4.5 Aflibercept: Eylea (SMC2612)

3.4.6 Dermatophagoides pteronyssinus and dermatophagoides farinae: Acarizax (SMC2613)

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 Avalglucosidase alfa: Nexviadyme (SMC2546)

The ERFC noted the SMC abbreviated submission avalglucosidase alfa: Nexviadyme (SMC2546).

Indication: long-term enzyme replacement therapy for the treatment of patients with Pompe disease (acid α-glucosidase deficiency).

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

The ERFC agreed to classify Avalglucosidase alfa: Nexviadyme 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 Apalutamide: Erleada (SMC2579)

The ERFC noted the SMC abbreviated submission apalutamide: Erleada (SMC2579).

Indication: in adults for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

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

The ERFC agreed to classify Apalutamide: Erleada 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 N/A.

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 Polatuzumab vedotin: Polivy (SMC2524)
3.7.2 Azacytidine: Onureg (SMC2533)
3.7.3 Icosapent ethyl: Vazkepa (SMC2602)

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 Central Alerting System COVID-19 Alerts

No Central Alerting System COVID-19 alerts were available for noting at the time of the ERFC meeting.

3.9 National Cancer Medicines Advisory Group

The ERFC noted the NCMAG advice documents published July 2023 (NCMAG advice documents (healthcareimprovementscotland.org).

The ERFC noted the NCMAG Quarterly update (NCMAG Quarterly Update_June v1.0).

4 Board specific information

4.1 NHS Borders

FAF 2 - zuclopenthixol acetate: Clopixol Acuphase. The ERFC noted that the FAF2 received was incomplete. The application is supported by NHS Borders and NHS Lothian; support from NHS Fife is awaited.

NHS Lothian ERFC Co-Chair to discuss with colleagues in NHS Fife.

ACTION: NHS Lothian ERFC Co-Chair

4.2 NHS Fife

None.

4.3 NHS Lothian

The ERFC ratified the following Formulary decisions discussed at the ERWG in June 2023: glycerine trinitrate + verapamil and bleomycin - Routinely available in line with local guidance. Included on the ERF Specialist Use only. Classified for use under policy for the use of unlicensed medicines.

5 Any other competent business

The ERFC noted an amendment to the Gluten Free Formulary section to include a loaf suitable for vegans.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 11 October 2023 at 1400 - 1630 hours via MS Team. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 5 September 2023 (for discussion at the ERWG meeting on 20 September 2023).

FAF1s and FAF2s should be submitted by 26 September 2023.

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