East Region Formulary

East Region Formulary Committee
Minutes

Date: 30 November 2022
Time: 2pm – 4pm
Location: MS Teams

Present:

Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Bryony Drummond	Senior Practice Pharmacist, NHS Fife
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife – in the Chair
Dr Peter Hall	Consultant – Oncology, NHS Lothian
Carol Holmes	Pharmacist – Primary care, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Kirsty Macfarlane	Regional Formulary Pharmacist, ERF Project Team
Lesley Macher	Lead Pharmacist, NHS Lothian
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant - Cardiology, NHS Borders
Fraser Notman	Formulary Pharmacist, NHS Fife
Euan Reid	Lead Pharmacist, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian
Alison Wilson	Director of Pharmacy (Co-chair), NHS Borders
Sandra MacDonald	Meeting Administration, NHS Fife

Guests/Observing: Emily Dodd, NHS Lothian
Niamh Doyle, NHS Lothian
Genna Johnston, NHS Lothian

Apologies: Ruth Cameron, Advanced Clinical Nurse Specialist – Urology, NHS Fife
Gillian Donaldson, Nurse – Cardiology, NHS Borders
Steven Fenton, Project Manager, ERF Project Team
Dr Jane Goddard, Consultant – Renal, NHS Lothian
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.
- Observing - Emily Dodd, NHS Lothian; Niamh Doyle, NHS Lothian; Genna Johnston, NHS Lothian
- Welcome - as above.
- 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.

ACTION: ALL

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

The ERFC received an update on the chapters which have been reviewed to date. The vast majority of adult chapters have now been reviewed. The remaining adult chapter still to be completed is Chapter 8 Malignant Disease and Immunosuppressants which is on track to be presented at the ERWG and ERFC meetings in January 2023. The next steps include taking forward a piece of work on the formulary decisions as well as development of the Paediatric formulary. The Chair thanked everyone involved for their contribution.

1.3 Matters arising

1.3.1 ERFC 28.09.22 item 3.1.3 FAF1 Atezolizumab: Tecentriq (SMC2267) was reviewed at the ERFC September meeting. Clarification on the SMC decision is awaited. The ERFC carried this item forward to the February meeting pending this information.

The ERFC requested clarification on SMC approval.

ACTION: NHS Fife Formulary Pharmacist

1.3.2 ERFC 28.09.22 item 3.1.5 FAF1 Sacituzumab Govitecan: Trodelvy (SMC2446) was reviewed at the ERFC September meeting. The ERFC requested clarification that the place in therapy of the medicine will be updated in clinical management guidelines and confirmation of place in therapy, patient criteria wording and patient numbers. No information has been received and it was agreed to carry this item forward to the February 2023 ERFC meeting.

ACTION: Meeting Admin Team

1.3.3 ERFC 28.09.22 item 3.1.7 FAF3 Loperamide 2mg orodispersible tablets sugar free: Imodium Instant Melts and Loperamide 2mg capsules. The ERFC requested confirmation from NHS Borders whether both orodispersible and capsule formulations were required. The ERFC noted that the orodispersible tablet formulation has been included on the pathway. Action completed.

ACTION: ERF Project Team

1.3.4 ERFC 28.09.22 Item 3.2.2 FAF Alendronic acid 70mg effervescent tablets. The ERFC reviewed the paper ERF - adult osteoporosis. It was highlighted that when editing the eLJF it had been identified that the administration instructions for alendronic acid effervescent tablets were incorrect. There were a number of pathways within the osteoporosis section that contained effervescent tablets (Pathway 3 Treatment of postmenopausal osteoporosis, Pathway 4

Corticosteroid-induced osteoporosis - treatment and prevention, and Pathway 5 Male osteoporosis) and they have all been amended with the correct administration instructions.

Final version of the amended pathways approved and to be taken to the East Region Working Group (ERWG) for noting.

ACTION: ERWG

1.3.5 ERFC 28.09.22 item 3.2.5 Metolazone: Xaqua. The ERFC requested that the formulary amendment be brought back to the November ERFC following further discussion at the CEWG. The MHRA warning regarding the licensed preparation for metolazone has been added to the ERFC chapter and the three Boards are in discussion with specialists around implementation plans to move patients from unlicensed medication.

The ERFC agreed to classify Metolazone: Xaqua as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts.

ACTION: ERF Project Team

1.3.6 ERFC 28.09.22 item 6.1 NHS Borders - FAF1 Delta-9 tetrahydrocannabinol: Sativex (SMC2473). The ERFC reviewed the paper ERF adult - treatment of chronic severe muscle spasticity.

Following further discussion between meetings it was deemed that the positioning of delta-9 tetrahydrocannabinol: Sativex should be fourth line for spasticity due to MS only.

It was noted that the original FAF1 submission requested a formulary flag of specialist use only and a query was raised around the rationale for the decision to classify as specialist initiation rather than specialist use only. It was noted that differing views were put forward by representatives at the ERWG. The ERFC agreed that a formulary flag of specialist initiation should be applied as this would allow specialists to maintain delta-9 tetrahydrocannabinol: Sativex as specialist use only where this was deemed appropriate.

Final version of the pathway approved and to be taken to the ERWG for noting.

ACTION: ERWG

The ERFC agreed to classify Delta-9 tetrahydrocannabinod: Sativex as Routinely available in line with national prescribing guidance. Included on the ERF for Specialist Initiation.

ACTION: ERF Project Team

Matters arising actions - the formulary website will be updated accordingly.

ACTION: ERF Project Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 28 September 2022

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 9 November 2022

The minutes of the ERWG meeting were noted for information.

2.3 East Region Formulary (ERF) sections for approval

2.3.1 Nutrition and Blood

The Nutrition and Blood ERF section was split into four different CEWGs as outlined below. Detailed development notes are included under item 2.3.2.

- **Blood**
  The ERFC noted the following:
  - Oral treatment of iron deficiency anaemia. Dosage for both treatment and prophylaxis is once daily which is in line with the BNF. Feedback from ERWG awaited regarding proposal to highlight in a prescribing note.
  - Parenteral treatment of iron deficiency anaemia. CosmoFer is no longer used within any of the East Region Boards and it is proposed that the prescribing notes be removed from the pathway and a link to MHRA Drug Safety Update guidance added instead.
  - Anaemia in pregnancy. A link to each of the Board's guidelines has been added.
  - Oral cyanocobalamin was used during the COVID pandemic. A formulary application will be required for continued use for vitamin B12 deficiency.
  - The pathway for the treatment of thalassaemia is incomplete. At present there is only one treatment within the pathway and clarification around other treatments is awaited.

  The ERFC highlighted the clinical indications for IV iron treatments/the SMC restriction for Ferinject and agreed that this should be consistent.

  ACTION: ERF Project Team/NHS Fife Formulary Pharmacist

- **Fluid and electrolytes**
  The ERFC noted the following:
  - The fluid and electrolytes section meetings were conducted virtually. Links to NHS Borders/NHS Lothian guidelines and the Society for Endocrinology guidelines have been added. The link to NHS Fife guidelines is awaited and will be added when available.
  - Treatment of hyperkalaemia. The abbreviated submission for sodium zirconium cyclosilicate: Lokelma (SMC2515) will be discussed by the ERFC under item 3.5.1.
  - Treatment of hypocalcaemia. Clarification on calcium chloride formulation and dose is awaited.
  - Treatment of hyponatraemia. A considerable prescribing note was added around the cause/treatment of hyponatraemia in hospital patients.
  - Plasma and plasma substitutes. The pathway has been removed pending further discussions between Boards around links to IV fluid guidance.

- **Nutrition**
  The ERFC noted the following:
  - Due to variations between Board contracts a decision was made to include links to individual Board lists. A regional approach to contract negotiations in the future to be explored.
  - A link to vitamin B deficiency guidelines was removed and a link to be added to this pathway in the Substance Dependence section.
  - Refeeding syndrome. It was decided that creation of a pathway would be too complex. Links to Borders, Lothian and Fife guidelines to be included instead.

- The calcium and vitamin D pathway has been amended in line with the osteoporosis section.

The ERFC queried the feasibility of progressing an agreement on enteral nutrition across the three Boards. There was support in principle but agreed that this would be challenging due to the different supply models across the Boards.

- **Renal**

  The ERFC noted the following:

  - Treatment of slow progression of chronic kidney disease. It was agreed that standard treatments should be first line and that has been reflected throughout the chapter.
  - Treatment of hyperphosphataemia in chronic renal impairment. Calcium acetate and calcium carbonate were included as first line treatments and the ERWG sought clarification on this/the inclusion of branded products. Feedback from the Fife Renal team was that calcium carbonate can be used if a calcium binder is required however a switch to sevelmar or lanthanum is likely.

  The ERFC highlighted the information around calcium carbonate and sought clarification on whether Adcal or Calcichew should be included.

ACTION: NHS Fife Formulary Pharmacist

The ERFC approved the new chapter content with changes as noted, finalised content not required to come back to ERFC. The formulary website will be updated.

ACTION: ERF Project Team

2.3.2 Chapter development notes document for Nutrition and Blood

The ERFC noted the development notes.

2.3.3 Wound Care

The Wound Care Chapter review was undertaken based on products within the national list and the reduced lists for the three East Region Boards. Representation on the CEWG was mainly from tissue viability nurses, a podiatrist, other specialist nurses, a care home manager and a consultant plastic surgeon. There were two meetings of the group, the first one to narrow down the individual products and the second one to agree pathways. Both meetings were well attended with good engagement by individuals across all three Boards. A final draft was produced, subject to clarification of outstanding queries:

- Feedback from Plastic Surgeons around the preferred product for scar management.
- An outstanding query relating to silver antimicrobials. There was uncertainty around inclusion of a formulary flag. Feedback was that there should be no restriction due to staff capacity and different practices between the Boards.
- Additional points were added in relation to Cavilon advance to clarify the circumstances for use.
- Absorbants. There was some discussion around zetufit which is not currently on the national list. The view from the CEWG was that this is a cost effective product which should be included on the ERF.

A query was raised about inclusion of quantities and noted that it would be difficult to include this information in a general formulary as different quantities are appropriate for different situations and due to the variations in ordering practices across the Boards. A discussion on the PECOS model ensued.

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

ACTION: ERF Project Team

2.3.8 Chapter development notes document for Wound Care

The ERFC noted the development notes.

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2334)

3.1.2 FAF1 Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2335)

The ERFC noted and discussed the previously circulated FAF1 submissions. As items 3.1.1 and 3.1.2 related to different strengths of Trimbow a decision was taken to review the submissions simultaneously.

Two personal specific interests were declared. Clinical Director (CD) support received from all three Boards.

FAF1 Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2334)

Indication: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.

Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium: Trimbow offers an additional treatment choice of high dose inhaled corticosteroid (ICS), long-acting beta2-agonist (LABA) and long-acting muscarinic antagonist (LAMA) in a single inhaler. SMC has previously accepted an alternative LAMA as an add-on treatment to ICS and LABA in asthma.

FAF1 Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2335)

Indication: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.

Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium: Trimbow offers an additional treatment choice of medium dose inhaled corticosteroid (ICS), long-acting beta2-agonist (LABA) and long-acting muscarinic antagonist (LAMA) in a single inhaler. SMC has previously accepted an alternative LAMA as an add-on treatment to ICS and LABA in asthma.

It was noted that no local treatment protocols have been developed. The finance budget template was included with the FAFs.

Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow is already on the ERF for COPD.

The place in therapy is unclear. The request is for SMC2335 to be added into the prescribing notes and for SMC2334 to be added in as first choice within the treatment pathway.

The ERFC queried whether this treatment should be third line treatment, with first line being beta2 agonist and ICS. It was agreed that clarification on the place in the pathway should be sought.

The ERFC also noted the potential conflict of interest.

The ERF agreed that clarification on the place in the pathway should be sought. The Clinical Directors should also be asked to approve the pathway/protocol to give assurance that they concur with the proposed place in therapy. To be brought back to the ERFC in February 2023 under matters arising.

ACTION: NHS Fife Formulary Pharmacist

The ERFC agreed to classify Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow 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: ERF Project Team

3.1.2 FAF1 Beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2335)

Discussed above under item 3.1.1.

3.1.3 FAF1 Atezolizumab: Tecentriq (SMC2349)

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

Indication: in combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

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

Evidence from phase 3 clinical trials was noted. The potential patient numbers and costs were discussed.

The proposed place of therapy is first choice within a treatment pathway. The ERFC noted that this treatment would displace rather than replace the first line treatment (Sorafenib). The ERFC also queried whether it would displace the current second line treatment (Regorafenib) rather than the current first line treatment (Sorafenib).

As this is an additional therapy there would be implications for SACT capacity. There would also be costs associated with the replaced therapy rather than costs avoided.

No clinical management guideline was submitted. The criteria for patient selection is in line with the SMC recommendation.

The ERFC requested clarity around availability of a clinical management guideline and that the replacement costs have been taken into consideration.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Atezolizumab: Tecentriq (SMC2349) as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.4 FAF1 Venetoclax: Venclyxto (SMC2412)

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

Indication: in combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.

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

The proposed place in therapy is first choice in a treatment pathway. The criteria for patient selection is in line with the SMC recommendation. The patient numbers and cost implications were discussed.

The ERFC agreed to classify Venetoclax: Venclyxto (SMC2412) as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.5 FAF1 Nivolumab: Opdivo (SMC2458)

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: In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.

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

The proposed place in therapy is first line in a treatment pathway and nivolumab: Opdivo will replace pembrolizumab for some patients with adenocarcinoma. It is an intravenous formulation and will only be used in secondary care.

It was noted that that there are no additional training implications as nivolumab: Opdivo is already in use for other indications. Patient numbers and cost implications were discussed.

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

ACTION: ERF Project Team

3.1.6 FAF1 Roxadustat: Evrenzo (SMC2461)

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

Indication: treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).

SMC restriction: for use in patients who are non-dialysis dependent (NDD) at the time of treatment initiation.

Roxadustat was non-inferior to an erythropoiesis stimulating agent (ESA) and superior to placebo for improving haemoglobin (Hb) levels in adults with anaemia in CKD who were NDD.

A local treatment protocol has been developed. The finance budget template was included with the FAF. Patient numbers and costs implications were discussed.

Proposed use is via shared care. The proposed delivery route would be via hospital initially with supply continuing via primary care. The proposed place in therapy is first choice within the treatment pathway. Criteria for patient selection - non-dialysis dependent patients with symptomatic anaemia associated with chronic kidney disease especially those who may be needle phobic or who otherwise would require district nurses to visit the patient to administer by subcutaneous injection.

Roxadustat is an alternative oral preparation for symptomatic anaemia associated with chronic kidney disease which may be useful in patients who are needle phobic or those who require a district nurse to attend to administer injections. The current formulary choices – darbepoetin: Aranesp (Fife) or methoxy polyethylene glycol-epoetin beta: Mircera (Lothian/Borders) are only available via injection that is administered subcutaneously to pre-dialysis patients. The addition of roxadustat will increase the options available for patients.

Variations in practice for prescribing between NHS Fife and NHS Borders/Lothian were noted due to differences in patient numbers.

Roxadustat: Evrenzo (SMC2461) to be added in the pathway as joint first line to allow for variation between the Boards. SMC restriction to be included as an information note.

ACTION: ERF Project Team

The ERFC agreed to classify Roxadustat: Evrenzo as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist Initiation. The formulary website will be updated.

ACTION: ERF Project Team

3.1.7 FAF1 Filgotinib: Jyseleca (SMC2475)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. It was noted that the FAF states that CD support has been received from all three Boards, however NHS Fife is currently between CDs and Associate Medical Director support has been requested.

Indication: for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate.

SMC restriction: in adults with moderate disease (a disease activity score [DAS28] of 3.2 to 5.1) when intensive therapy with 2 or more conventional DMARDs has not controlled the disease well enough, in combination with methotrexate or as monotherapy when methotrexate is contraindicated.

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

The additional information estimating prevalence of moderate RA/potential eligibility for filgotinib along with supporting data was noted. The proposed assessment timeframes specified in the Protocol are in line with the clinical trials. Filgotinib would be prescribed by the Specialist Service only and proposed delivery route is via Homecare. Service impact would be minimal as filgotinib is already on the ERFC.

Proposed use is second line within a treatment pathway, however there is lack of clarity around the rationale for second line use as opposed to first line use after patients have failed on two conventional DMARDs. There is no comparison or information on current second line treatment options.

The ERFC requested clarification around the local protocol/rationale for proposed second line status.

The ERFC requested confirmation of AMD support from NHS Fife.

ACTION: ERFC Meeting Admin/NHS Fife Formulary Pharmacist

The ERFC agreed to classify Filgotinib: Jyseleca 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: ERF Project Team

3.1.8 FAF1 Lenvatinib: Kisplyx (SMC 2476)

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

received from all three Boards. Lead Cancer Pharmacists for other SCAN Health Boards have been sent the FAF1 to share information with CDs and seek support and no objections were received.

Indication: treatment of adults with advanced renal cell carcinoma (RCC), in combination with pembrolizumab, as first-line treatment.

SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.

Lenvatinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors given in combination with a PD-1/PD-L1 inhibitor for this indication.

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

Patient numbers and cost implications were discussed.

The ERFC requested clarification on eligibility criteria/rationale for levantinib: Kisplyx compared to other treatment options.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Lenvatinib: Kisplyx 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: ERF Project Team

3.1.9 FAF1 Pembrolizumab: Keytruda (SMC2479)

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

Indication: As monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

In a phase III study, pembrolizumab significantly improved investigator-assessed disease-free survival (DFS) when compared with placebo.

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

The ERFC discussed patient numbers and potential financial implications. Pembrolizumab: Keytruda does not replace any existing therapies. No replacement treatment costs or additional staff training needs have been identified. The proposed place in therapy is as a new adjuvant treatment option for patients at increased risk of recurrence following nephrectomy. Proposed use is Specialist use only.

The ERFC agreed to classify Pembrolizumab: Keytruda as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.10 Upadacitinib: Rinvoq (SMC2480)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interests were received. The FAF states that CD support received from all three Boards, however NHS Fife are currently between CDs and Associate Medical Director support has been requested.

Indication: for the treatment of active ankylosing spondylitis (AS) in adult patients who have responded inadequately to conventional therapy.

In a phase III and a phase II/III study, upadacitinib when compared with placebo, significantly improved symptoms of AS in adults with active disease that was inadequately controlled with non-steroidal anti-inflammatory drugs (NSAIDs).

Upadacitinib: Rinvoq is an oral tablet. Upadacitinib is already on the ERF as a second choice option for the treatment of psoriatic arthritis and as a third line option for rheumatoid arthritis. The proposed delivery route is via Homecare.

The proposed position on the ERF is second choice within a treatment pathway. It was noted that the proposed formulary flags are Specialist Initiation and Specialist Use. The ERFC agreed that Specialist Use only would be appropriate.

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

AMD/CD support from NHS Fife to be clarified.

ACTION: ERFC Meeting Admin/NHS Fife Formulary Pharmacist

The ERFC agreed to classify Upadacitinib: Rinvoq as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.11 Upadacitinib: Rinvoq (SMC2510)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interests were received. CD support received from NHS Borders and NHS Lothian. CD support from NHS Fife to be clarified. Differences between the medical management structure job titles within Lothian/Borders and Fife were highlighted.

Indication: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

Upadacitinib offers an additional treatment choice in the therapeutic class of janus kinase inhibitors.

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

The proposed place in therapy is second choice within a treatment pathway (alongside tofacitinib, upadacitinib, ustekinumab and vedolizumab) for patients with ulcerative colitis who meet the criteria for therapy. First line options are infliximab +/- azathioprine and

filgotinib. There is lack of clarity around the positioning in relation to some of the other second line options. The pathway will require to be reviewed and updated accordingly.

Patient numbers and financial implications were discussed. Figures for NHS Lothian were included only.

Pathway to be updated to reflect the moderate indication and positioning of the therapies.

ACTION: ERF Project Team

AMD/CD support from NHS Fife to be clarified.

ACTION: ERFC Meeting Admin/NHS Fife Formulary Pharmacist

The ERFC agreed to classify Upadacitinib: Rinvoq 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: ERF Project Team

3.1.12 FAF1 Belimumab: Benlysta (SMC2530)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interests were received. CD support received from NHS Borders and NHS Lothian. AMD support from NHS Fife to be clarified.

Indication: add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.

SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.

SMC has previously accepted belimumab powder for concentrate for infusion for restricted use (SMC2477).

The local treatment protocol and finance budget template were included with the FAF. The criteria for patient selection is in line with SMC advice. Proposed use would be Specialist Use only and proposed delivery route is via Homecare. Proposed place in therapy is second choice within a treatment pathway. It does not replace a current ERF therapy. The criteria for patient selection is in line with SMC advice. It is administered via subcutaneous injection and will replace IV infusion of belimumab for many patients. It offers patients more freedom and avoids the need for patients to attend the hospital day unit infusion suite for administration.

It was noted that agenda item 3.7.3 Belimumab: Benlysta (SMC2477) relates to an IV infusion formulation which is also included within the protocol. The ERFC sought clarification on whether SMC2477 advice should be captured within the current FAF1 submission.

The ERFC requested clarification on the proposed ERF status of SMC2477.

ACTION: NHS Fife Formulary Pharmacist

AMD/CD support from NHS Fife to be clarified.

ACTION: ERFC Meeting Admin/NHS Fife Formulary Pharmacist

The ERFC requested that going forward the names of Clinical Directors confirming support should be stated on FAFs.

ACTION: ERF Project Team/ERWG

The ERFC agreed to classify Belimumab: Benlysta 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: ERF Project Team

3.1.13 FAF2 Gadoteric Acid: Clariscan

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interests were received. CD support received from NHS Borders.

Indication: MRI Imaging examinations.

A local treatment protocol has not been developed. The finance budget template was included with the FAF. Clariscan is already in use within NHS Lothian and NHS Fife.

There was a discussion around the proposed place of Clariscan within the ERF. It was noted that this is the second contrast medium that has been brought to the ERF for review and the place on the ERF requires clarification. It was agreed that the way forward would be development of a section for diagnostic medium.

The ERFC agreed that a section for diagnostic medium should be developed.

ACTION: ERWG

The ERFC agreed to classify Gadoteric Acid: Clariscan as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.14 FAF2 Real-time Continuous Glucose Monitoring (rt-CGM): Dexcom ONE (rt-CGM) sensor only

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

Indication:

- Newly diagnosed patients with Type 1 or Type 2 diabetes on multiple daily insulin injections and including pregnant women
- Patients with Type 1 Diabetes 2years+
- Current patients using self-monitoring blood glucose (SMBG)
- Current patients not meeting targets when using other technology such as intermittent scanning-CGM/Flash Glucose Monitoring.

The application was discussed by the ERWG who supported ERFC approval.

A local treatment protocol has not been developed. The proposed position in the ERF is first choice within a treatment pathway. Dexcom ONE will be a direct replacement for Libre 2 for some patients. Proposed use is Specialist initiation, with continuation in primary care.

The ERFC discussed the supporting evidence, potential patient numbers and cost implications. The finance budget template was included with the FAF.

In the case of freestyle libre 2 the criteria for patient selection differs, patients are required to attend training sessions, are assessed on their ability to use the device, and must agree to ongoing monitoring of outcomes. The ERFC requested clarification around implementation plans for CGM teaching and required ongoing monitoring. Clarification around the number of sensors provided/provision of additional sensors is also required.

The ERFC requested clarity around the proposed patient criteria for CGM. Potential differences in patient criteria compared to freestyle libre 2 which could change patient numbers were highlighted. Information from the Scottish Health Technologies Group has been requested and feedback is awaited. The ERFC noted that a SIGN review is anticipated for publication in Autumn 2024.

Potential financial implications were discussed. It was proposed that a National Procurement contract for Continuous Glucose Monitoring devices should be explored.

The ERFC agreed that prior to consideration for ERF inclusion, further clarification is required around patient criteria, provision of sensors, implementation plans for teaching/monitoring. Feedback with regard to potential Scottish Health Technology Group/National Procurement guidance is also required.

ACTION: ERFC Meeting Admin /NHS Fife Formulary Pharmacist

The ERFC agreed to classify Real-time Continuous Glucose Monitoring(rt-CGM): Dexcom ONE (rt-CGM) sensor only 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: ERF Project Team

3.1.15 FAF3 Flucloxacillin (sodium) 2g powder for solution for injection vials

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

Indication: Treatment of invasive Staphylococcus aureus infections.

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

The application has been discussed by the ERWG who supported ERFC approval.

Estimated prevalence and patient numbers across the region were discussed. It is off-label use through a continuous infusion using a Vygon device. The aim is to avoid admission to hospital/reduction in length of stay. Potential cost savings resulting from reduced admission to hospital were noted. It was noted that this treatment is currently provided within NHS Lothian and NHS Borders. NHS Fife is supportive of the application but not currently in a position to implement the service.

Applicants to be reminded of the requirement to adhere to their local governance process for unlicensed use of the solution.

ACTION: ERFC meeting Admin

The ERFC agreed to classify Flucloxacillin (sodium) 2g powder for solution for injection vials as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.16 FAF3 Octreotide

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

Indication: In high output stoma and enterocutaneous fistula, to reduce output when other means have failed (loperamide, codeine, proton pump inhibitor and fluid restriction).

The local NHS Lothian treatment protocol and finance budget template were included with the FAF. There is no implementation plan at present.

The application was discussed by the ERWG who supported ERFC approval.

This is an off-label indication for a licensed drug. Proposed use is Specialist use only, however prescribing in primary care could be continued under Specialist supervision.

The ERFC discussed patient numbers and cost implications. There is no information on costs of replaced therapy as this would be additional treatment if other treatment options have been unsuccessful. Potential District Nursing costs in the event that the patient is unable to self-administer at home were noted. The proposed place within the ERF is unclear within the FAF3. It was noted that the ERWG has subsequently developed a pathway for short bowel syndrome.

There is no safety information around this specific indication however safety information on potential side effects based on other licensed indications/dosages is available.

The ERFC agreed to classify Octreotide as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist Initiation. Unlicensed indication formulary flag to be added. The formulary website will be updated.

ACTION: ERF Project Team

3.1.17 FAF3 Piperacillin/Tazobactam

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interests were received. CD support received from all three Boards. NHS Fife is supportive of the application but does not foresee the use of this medicine in this way.

Indication: Treatment of invasive Pseudomonas or Enterobacteriaceae infections with borderline resistance (high minimum inhibitory concentrations (MICs)) e.g., necrotising otitis externa (NOE).

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

The ERFC discussed the supporting evidence. The proposed use is outpatient in OPAT departments. This would avoid a 6 week hospital admission for this treatment. Evidence suggests a good safety profile using nurse filled pumps as continuous infusions in outpatient settings.

The application was discussed by the ERWG who supported ERFC approval.

There was a discussion around the place in therapy in the ERF as it is unclear where hospital antimicrobials fit into the pathway. The issue of IV antibiotics not appearing on the ERF was raised. It was agreed that when next reviewing the Infections chapter consideration should be given to including a section on IV antibiotics. The proposed status is routinely available in line with local prescribing guidance.

A query was raised around unlicensed sodium chloride solution and the ERFC agreed that the governance process for unlicensed medicines within each of the Boards should be adhered to.

Applicants to be reminded of the requirement to follow their local governance process for unlicensed use of the solution.

ACTION: ERFC meeting Admin

The ERFC agreed to classify Piperacillin/Tazobactam as Routinely available in line with local prescribing guidelines. Included on the ERFC for Specialist Use only. Unlicensed indication formulary flag to be added. The formulary website will be updated.

ACTION: ERF Project Team

3.1.18 FAF3 Triamcinolone acetonide: Kenalog

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

Indication: Inflammation of the lumbar nerve root - CT Guided nerve root injection

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

The application has been discussed by the ERWG who supported ERFC approval.

The proposed use is image guided perineural injection only. This is a licensed medication but being given via an unlicensed route. The NERVES Trial evidence was discussed.

Triamcinolone acetonide: Kenalog is a cost effective treatment that has the potential to expand capacity of service across the region.

The ERFC agreed to classify Triamcinolone acetonide: Kenalog as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist Use only. Unlicensed indication formulary flag to be added. The formulary website will be updated.

ACTION: ERF Project Team

3.2 Formulary Amendment Forms

3.2.1 Morphine sulphate: Actimorph

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received.

Indication: For the titration of opioids in moderate to severe pain or for breakthrough analgesia in those already established on modified release morphine.

Can be used as an alternative to Oramorph (e.g. dexterity issues) or Sevredol tablets.

Morphine sulphate: Actimorph is an orodispersible tablet that can be used as an alternative to Oramorph, particularly in patients with dexterity issues and as an alternative to Sevredol tablets.

The ERFC noted that there are potential cost and controlled drug implications. The proposed position on the ERF is unclear. It was noted that Actimorph is only licensed for severe pain and the proposed indication for use would be unlicensed. It was also noted that the application is from the Palliative Care team only. Oramorph and severedol are included in the ERF CNS section for acute or chronic pain.

The ERFC requested that criteria and positioning on the formulary be clarified. A full FAF1 to be submitted for review by the ERFC.

ACTION: ERFC meeting Admin

The ERFC agreed to classify Morphine sulphate: Actimorph 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: ERF Project Team

3.3 Ultra-Orphan Pathway

3.3.1 N/A.

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Defatted powder of Arachis hypogaea L, semen: Palforzia (SMC2487)
3.4.2 Venetoclax: Venclyxto (SMC2509)
3.4.3 Esketamine: Spravato (SMC2539)

The formulary website will be updated.

ACTION: ERF Project Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Buprenorphine/naloxone: Zubsolv (SMC2123)

The ERFC noted the SMC abbreviated submission Buprenorphine/naloxone: Zubsolv (SMC2123).

Indication: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. SMC restriction: for use in patients for whom methadone is not suitable.

The ERFC agreed to classify Buprenorphine/naloxone: Zubsolv 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: ERF Project Team

3.5.2 Brolucizumab: Beovu (SMC2508)

The ERFC noted the SMC abbreviated submission Brolucizumab: Beovu (SMC2508).

Indication: In adults for the treatment of visual impairment due to diabetic macular oedema. SMC restriction: treatment of visual impairment due to diabetic macular oedema in adults with best corrected visual acuity 75 Early Treatment Diabetic Retinopathy Study letters or less at baseline. Brolucizumab offers an additional treatment choice in the class of vascular endothelial growth factor inhibitors in this indication.

The ERFC agreed to classify Brolucizumab: Beovu (SMC2508) 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: ERF Project Team

3.5.3 Upadacitinib: Rinvoq (SMC2510)

FAF1 reviewed under agenda item 3.1.11.

The ERFC agreed to classify Upadacitinib: Rinvoq 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: ERF Project Team

3.5.4 Levofloxacin plus dexamethasone: Ducressa (SMC2511)

The ERFC noted the SMC abbreviated submission Levofloxacin plus dexamethasone: Ducressa (SMC2511).

Indication: Prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The ERFC agreed to classify Levofloxacin plus dexamethasone: Ducressa (SMC2511) 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: ERF Project Team

3.5.5 Sodium zirconium cyclosilicate: Lokelma (SMC2515)

The ERFC noted the SMC abbreviated submission Sodium zirconium cyclosilicate: Lokelma (SMC2515).

Indication: for the treatment of hyperkalaemia in adult patients.
SMC restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care. Sodium zirconium cyclosilicate offers an additional treatment choice in the therapeutic class of non-absorbed cation-exchange compounds that act as selective potassium binders.

The ERFC noted the proposed status is Routinely available in line with national guidance for use in secondary care only.

The ERFC agreed to classify Sodium zirconium cyclosilicate: Lokelma as Routinely available in line with national guidance. Included on the ERF for Specialist Use only. The formulary website will be updated.

ACTION: ERF Project Team

3.5.6 Belimumab: Benlysta (SMC2530)

FAF1 reviewed under agenda item 3.1.12.

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 Pembrolizumab: Keytruda (SMC2460)
3.7.2 Pembrolizumab: Keytruda (SMC2474)
3.7.3 Belimumab: Benlysta (SMC2477)
Clarification to be sought in relation to FAF1 reviewed under agenda item 3.1.12.
The ERFC agreed to classify Belimumab: Benlysta 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: ERF Project Team

3.7.4 Ozanimod: Zeposia (SMC2478)
3.7.5 Asciminib: Scemblix (SMC2482)
3.7.6 Finerenone: Kerendia (SMC2486)
3.7.7 Faricimab:Vabysmo (SMC2499)
3.7.8 Zanubrutinib: Brukinsa (SMC2528)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.4, 3.7.5, 3.7.6, 3.7.7, 3.7.8 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: ERF Project Team

4 Central Alerting System COVID-19 Alerts

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

5 National Cancer Medicines Advisory Group

5.1 No National Cancer Medicines Advisory Group alerts were available for noting at the time of the ERFC meeting.

6 Board specific information

6.1 NHS Borders
None raised.

6.2 NHS Fife
None raised.

6.3 NHS Lothian
None raised.

7 Any other competent business
None raised.

8 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 1 February 2023.

FAF3s should be submitted by 20 December 2022 (for discussion at the ERWG meeting on 11 January 2023).

FAF1s and FAF2s should be submitted by 17 January 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