East Region Formulary

East Region Formulary Committee
Minutes

Date: 1 February 2023
Time: 2pm – 4pm
Location: MS Teams

Present:

Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Steven Fenton	Project Manager, ERF Project Team
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife – in the Chair
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Kirsty Macfarlane	Regional Formulary Pharmacist, ERF Project Team
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant - Cardiology, NHS Borders
Fraser Notman	Formulary Pharmacist, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Lucy Wall	Consultant – Oncology, 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: Cathryn Park, Lead Pharmacist Acute Care & Medicines Governance / Deputy Director of Pharmacy (NHS Borders)

Apologies: Jane Browning, (Acting) Associate Director of Pharmacy (Specialist Services, Development and Innovation), NHS Lothian
Bryony Drummond, Senior Practice Pharmacist, NHS Fife
Peter Hall, Consultant - Oncology, NHS Lothian
Carol Holmes, Pharmacist - Primary care, NHS Lothian
Lesley Macher, Lead Pharmacist Medicines Governance and Guidance , 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 - Cathryn Park, Lead Pharmacist Acute Care & Medicines Governance / Deputy Director of Pharmacy (NHS Borders)
- Welcome - as above
- Leaving - Euan Reid (NHS Fife)
- 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 progress with the Chapter Expert Working Groups. All adult chapters have now been reviewed (Chapter 8 Malignant Disease and Immunosuppressants discussed under agenda item 2.3). The Wound Care Chapter has been launched and Nutrition and Blood will be launched once outstanding items are completed. A new programme of work for the coming months is being finalised. Work on developing the Paediatric Formulary has commenced.

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 still awaited. The ERFC carried this item forward to the March 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. The Breast Clinical Management Guideline has been received which provides clarification on the place in therapy. Patient criteria/numbers in the FAF1 application have been confirmed. Action completed.

1.3.3 ERFC 30.11.22 item 3.1.1 FAF1 Beclometasone dipropionate /formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2334). Updated FAF1 received - discussed under agenda item 3.1.3.

1.3.4 ERFC 30.11.22 Item 3.1.2 FAF1 Beclometasone dipropionate /formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2335) was reviewed at the ERFC November meeting. The ERFC requested clarification on the place in the pathway. The FAF1 is currently under review and will be brought back to the ERFC once finalised.

1.3.5 ERFC 30.11.22 Item 3.1.3 FAF1 Atezolizumab: Tecentriq (SMC2349) was reviewed at the ERFC November meeting. The ERFC requested clarification regarding availability of a clinical management guideline and that the replacement costs have been taken into consideration. The Clinical Management Guideline has been received along with clarification of the outstanding point regarding replacement costs. Action completed.

1.3.6 ERFC 30.11.22 Item 3.1.7 FAF1 Filgotinib: Jyseleca (SMC2475) was reviewed at the ERFC November meeting. The ERFC requested clarification around the local protocol/rationale for

proposed second line status and confirmation of Fife Clinical Director support. The Protocol received provides extensive information on indication, dose, pre-screening and side effects to ensure appropriate, safe and effective use of filgotinib. The proposed second line status is shown in the treatment pathway which reflects national practice, consultant preference and cost effectiveness.

The ERFC agreed to classify Filgotinib: Jyseleca 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

1.3.7 ERFC 30.11.22 Item 3.1.8 FAF1 Lenvatinib: Kisplyx (SMC 2476) was reviewed at the ERFC November meeting. The ERFC requested clarification on eligibility criteria/rationale for levantinib: Kisplyx compared to other treatment options. Additional information was subsequently received which clarifies eligibility criteria/rationale for use compared to other treatment options.

The ERFC agreed to classify Lenvatinib: Kisplyx 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

1.3.8 ERFC 30.11.22 Item 3.1.10 Upadacitinib: Rinvoq (SMC2480) was reviewed at the ERFC November meeting. The ERFC requested confirmation of Clinical Director support from NHS Fife. Confirmation of NHS Fife Clinical Director support was subsequently received by email. Action completed.

1.3.9 ERFC 30.11.22 Item 3.1.11 Upadacitinib: Rinvoq (SMC2510) was reviewed at the ERFC November meeting. The ERFC requested clarification on the place in the pathway. Updated FAF1 received - discussed under agenda item 3.1.7.

1.3.10 ERFC 30.11.22 Item 3.1.12 FAF1 Belimumab: Benlysta (SMC2530) was reviewed at the ERFC November meeting. The ERFC requested confirmation of NHS Fife Clinical Director support and clarification on the proposed ERF status of SMC2477.

The ERFC noted that belimumab IV (SMC 775/12) is already on the Formulary with associated protocols produced. SMC2477 extends use of Belimumab IV for this indication to patients from 5 years to adulthood. There has been no change in use for adults and any request to use in children should be submitted by Paediatrics specialists. Confirmation of NHS Fife Clinical Director support has been received.

The ERFC discussed the additional information provided and noted a change to the eligibility criteria in SMC2477 compared to the original SMC advice document (SMC 775/12) which potentially widened the patient group. It was also noted that the protocol submitted was in line with the eligibility requirements outlined in SMC 775/12. The ERFC also requested clarification of any potential financial implications.

The ERFC requested clarification on the impact of the change in eligibility criteria as detailed in SMC2477 and clarification of any potential cost implications.

ACTION: NHS Fife Formulary Pharmacist

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.

ACTION: ERF Project Team

1.3.11 ERFC 30.11.22 Item 3.1.14 FAF2 Real-time Continuous Glucose Monitoring (rt-CGM): Dexcom ONE (rt-CGM) sensor only was reviewed at the ERFC November meeting. The ERFC requested further clarification around patient criteria, provision of sensors and implementation plans for teaching/monitoring. Feedback with regard to potential Scottish Health Technology Group (SHTG)/National Procurement guidance was also requested.

Clarification on criteria was received (identical to Freestyle Libre 2 although conversion en masse is not anticipated unless there was a specific indication e.g. adhesive issues, problems with accuracy, problems with alarms). The intention is that sensors would be prescribed by General Practice on recommendation from Secondary Care. Online resources to take forward implementation plans are available on the Edinburghdiabetes.com website.

SHTG has confirmed that it does not currently intend to publish further guidance on CGM and Flash Glucose Monitoring. The SHTG also referred to the NICE type 1 diabetes guideline which is currently being updated.

The ERFC noted the potential benefits of Dexcom ONE compared to Freestyle Libre for certain patient groups but agreed that well defined criteria was required. Clarification of potential financial implications was also requested. To be brought back to the next ERFC.

The ERFC requested well defined criteria for Dexcom ONE compared to Freestyle Libre 2. Further information on the financial implications was also requested.

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.

ACTION: ERF Project Team

3.1.12 ERFC 30.11.22 Item 3.2.1 Morphine sulphate: Actimorph was discussed at the November ERFC meeting. The ERFC requested that criteria and positioning on the ERF be clarified. Depending on the proposed indication, a full FAF1 or FAF3 to be submitted for review by the ERFC.

The ERFC requested clarification on the indication for use and that a FAF1/FAF3 be brought back to the March meeting.

ACTION: NHS Fife Formulary Pharmacist

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 30 November 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 11 January 2023

The minutes of the ERWG meeting on 11 January 2023 were noted for information.

2.3 East Region Formulary (ERF) sections for approval

2.3.1 Immunosuppression

The ERFC discussed the key updates to the ERF chapter Immunosuppression (Adult).

The Chapter Expert Working Group was a specific specialist group with good engagement from all three Boards. The review was done via email. The chapter covers immunosuppression used in organ transplants and includes links to other pages on the website as appropriate as well as links to the Edinburgh Transplant Centre website.

Following feedback from Clinicians several dosage amendments have been made. Ciclosporin had previously been included in the prescribing notes and is now included in the liver transplant pathway. It was noted that there were minor points awaiting clarification, including around the proposed removal of alemtuzumab 12mg/1.2ml solution for infusion vials. Feedback from specialists is that an unlicensed formulation is used on a named patient basis and an information note regarding this has been included. (Confirmation of clarification around outstanding points was received at the end of the ERFC meeting.)

The ERFC noted the key updates to the ERF chapter Immunosuppression (Adult). The ERFC also noted the chapter development notes.

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

ACTION: ERF Project Team

2.3.3 Malignant disease

The ERFC discussed the key updates to the ERF chapter Malignant Disease (Adult).

The Chapter Expert Working Group was split into two meetings – haematology and oncology. It was highlighted that the majority of cancer specialists refer to departmental guidelines but the formulary is useful particularly to inform stock holding and provides clarity on the approved indication, patient group and restrictions for each medicine. The majority of the medicines included in the chapter are from Lothian Formulary decisions which will now be updated as ERF decisions. Most of the medicines flagged as specialist use only will be included in formulary decisions as the place in therapy is defined within Clinical Management Guidelines approved through regional cancer committees/Board haematology committees. The content that remains in the formulary pathways is predominantly medicines flagged as specialist initiation which can be continued in Primary Care. It was noted that fulvestrant has been changed from specialist use only to specialist initiation in line with current practice.

It was noted that work on simplifying the prostate cancer pathway is underway and this has gone out to the specialists for consideration for the next review.

There was a query raised about medicines that are used under a shared care agreement. It was noted that shared care agreements are Board specific and were not looked at as part of the chapter review. The shared care agreements used within NHS Lothian are still available on the website and as the website is rebranded to the ERF consideration to be given to a landing page/link to other Board shared care agreements.

Going forward consideration to be given to inclusion of a landing page/link to other Board shared care agreements.

ACTION: ERWG

The haematology pathways for medicines that are specialist initiation were also revised.

It was highlighted that a new national breast cancer clinical management guideline is expected to be released and links to that will be added when available.

There was a discussion around links to documents used by specialist services and whether access to these was available to all users, e.g. Oncology Online Quality System (OOQS). Individuals experiencing any issues with access to these sites were directed to contact their own IT departments.

The ERFC also noted the chapter development notes.

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

ACTION: ERF Project Team

2.4 ERF amendments for noting

2.4.1 ERF adult acute and chronic diarrhoea - loperamide oral solution 1mg/5ml discontinued
The ERFC noted the amendment to ERF adult acute and chronic diarrhoea.

2.4.2 LJF child acute and chronic diarrhoea - loperamide oral solution 1mg/5ml discontinued
The ERFC noted the amendment to LJF child acute and chronic diarrhoea.

2.4.3 LJF child short bowel syndrome - loperamide oral solution 1mg/5ml discontinued
The ERFC noted the amendment to LJF child short bowel syndrome.

2.4.4 LJF child - sore throat - clarithromycin duration
The ERFC noted the amendment to LJF child - sore throat.

2.4.5 LJF child - sore throat - phenoxymethylpenicillin duration
The ERFC noted the amendment to LJF child - sore throat.

2.4.6 ERF adult - asthma
The ERFC noted the amendment to ERF adult - asthma.

The formulary website will be updated.

ACTION: ERF Project Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Ibrutinib: Imbruvica (SMC2259)

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

Indication: in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia.

SMC restriction: for use in patients who have received at least one prior therapy.

The finance budget template was included with the FAF. Prescriptions charts for CLL were included with the FAF1.

Ibrutinib is an oral treatment. Capacity implications are slightly better for ibrutinib in combination with rituximab, with potentially up to 4 less appointments depending on the number of cycles given. The safety profile in this patient group is similar to what is known for use of ibrutinib in CLL and lymphoma. Trial data shows an improvement in response rate however overall survival data are immature. The patient numbers in the FAF1 are in line with the SMC detailed advice document.

The proposed place in therapy is second line treatment - ibrutinib in combination with rituximab will replace bendamustine in combination with rituximab.

The ERFC noted that the prescription charts included with the FAF1 were for CLL rather than Waldenström's macroglobulinaemia. It was not clear when combination therapy would be used compared to the single agent. It was also noted that there were no patient numbers for NHS Fife detailed on the FAF1.

The ERFC requested condition specific prescription charts, clarification on when combination therapy would be used compared to the single agent and information on anticipated patient numbers for NHS Fife.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Ibrutinib: Imbruvica 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

3.1.2 FAF1 Darolutamide: Nubeqa (SMC2297)

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

Indication: Darolutamide is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

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

Darolutamide: Nubeqa is an oral tablet formulation. Trial evidence showed an increase in overall survival. Proposed place in the ERF is first choice within a treatment pathway. Darolutamide will replace bicalutamide 50mg once daily until progression for patients meeting eligibility criteria.

The ERFC noted that there was no comparator assessment information within the SMC advice document and there was no information to compare efficacy of darolutamide to bicalutamide. Positioning within the ERF prostate cancer pathways was unclear.

The ERFC requested clarification on the positioning of darolutamide within the current Formulary pathways/treatment plans. The ERFC also requested clarification of the criteria for darolutamide replacing bicalutamide. To be brought back to the next ERFC meeting.

ACTION: NHS Lothian Formulary Pharmacist/NHS Fife Formulary Pharmacist

The ERFC agreed to classify Darolutamide: Nubeqa 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

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

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

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 of more asthma exacerbations in the previous year.

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

The FAF1 had been reviewed at the ERFC November meeting and the ERFC requested clarification on the place in the pathway. Updated information to clarify the place in the pathway has been included in the additional information section of the revised FAF1. The proposed place within the ERF is third line within additional add on therapies. The proposed delivery route would be via GP practices; no formulary flags are required.

The ERFC noted that the decision on whether or not to implement any Scriptswitch change would sit with individual Boards.

The ERFC agreed to classify Beclometasone dipropionate/formoterol fumarate dihydrate /glycopyrronium: Trimbow as Routinely available in line with national guidance. The formulary website will be updated.

ACTION: ERF Project Team

3.1.4 FAF1 Ibrutinib: Imbruvica (SMC2387)

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 a single agent for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first-line treatment for patients unsuitable for chemo-immunotherapy.

SMC restriction: for use in patients who have received at least one prior therapy.

The finance budget template was included with the FAF. The prescription charts included with the FAF1 were for CLL.

Ibrutinib is an oral treatment. The safety profile in this patient group is similar to what is known for its use in CLL and lymphoma. Phase II trial data showed improvement in overall response rate however progression free survival and/or overall survival data are immature. The patient numbers outlined in the FAF1 are higher than those in the SMC detailed advice document.

The SMC advice documents that the single agent provides an option for patients who cannot use rituximab. Patients receiving Ibrutinib would not require chair time in the day case unit.

The proposed place in therapy is second line treatment - ibrutinib would replace bendamustine in combination with rituximab. It is not clear when combination therapy would be used compared to the single agent. It was also noted that there were no patient numbers for NHS Fife detailed on the FAF1.

The ERFC requested condition specific prescription charts, clarification on when combination therapy would be used compared to the single agent and information on anticipated patient numbers for NHS Fife.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Ibrutinib: Imbruvica 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 Asciminib: Scemblix (SMC2482)

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 adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and without a known T315I mutation.

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

The proposed indication and local treatment protocol are in line with SMC advice. The proposed place in therapy is 3rd/4th/5th line in patients who have received at least two prior TKI regimens. The ERFC noted that the proposed place in therapy was unclear. The ERFC also noted that the FAF1 states that asciminib: Scemblix would not replace any other ERF choices and sought further clarification on this. Information on replacement medicine costs to be clarified.

The ERFC requested further clarification on the proposed place in therapy and information on any replaced medicines. Replacement medicine costs also require to be clarified.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Asciminib: Scemblix 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

3.1.6 FAF1 Abemaciclib: Verzenios (SMC2494)

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: in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

The local treatment protocol and finance budget template were included with the FAF. The supporting clinical evidence from an open label randomised phase III study showed that the addition of abemaciclib to adjuvant endocrine therapy improved invasive disease-free survival (IDFS) compared with endocrine therapy alone in patients with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence.

The proposed place in the ERF is first choice within a treatment pathway. Abemaciclib: Verzenios would be an additional treatment cost and would not be replacing any current ERF choices. Abemaciclib is an oral treatment option which would be delivered via Home Care service; the aromatase inhibitor endocrine therapy would be prescribed through GP Practices. The ERFC noted that not all Boards would have a Home Care service in place and prescribing/dispensing would require to be undertaken locally. The ERFC noted that this would have a significant impact on the cancer pharmacy team and nurse prescriber workload.

The ERFC noted that the required formulary flags noted on the FAF1 were specialist use and specialist initiation and agreed that specialist use only would be appropriate. Implications of the specialist use flag on the place in the pathway were discussed; abemaciclib would sit in the ERF decisions pending availability of the new national breast cancer pathway.

The ERFC noted a difference between the criteria for patient selection within the protocol compared to the SMC advice. It was noted that the Clinical Directors have signed the FAF1 to confirm their agreement that the resources are in place to deliver the medicine in line with the criteria outlined in the local treatment protocol.

The ERFC noted that there was a significant interaction with clarithromycin and the importance of highlighting this to GPs at the time of initiation was acknowledged. A flag would require to be added to the patient's notes/key information summary so that this information is available to emergency out of hours services.

The ERFC requested that when a patient is initiated on abemaciclib, the specialist service should communicate to the GP practice to request that a flag is added to the patient's notes/key information summary regarding the significant interaction with clarithromycin.

ACTION: ERFC Meeting Admin

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

ACTION: ERF Project Team

3.1.7 FAF1 Upadacitinib: Rinvoq (SMC2510)

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 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.

The local treatment protocol and finance budget template were included with the FAF. The protocol is consistent with SMC advice. The proposed place in the ERF is second choice within a treatment pathway. The proposed delivery route is via Homecare service, specialist use only.

This FAF1 had been deferred from the November 2022 meeting pending clarification on the positioning of the therapies and confirmation of NHS Fife Clinical Director support.

The ERFC noted that the FAF1 included figures for NHS Lothian only. NHS Fife CD support was confirmed however upadacitnib: Rinvoq will not be used for this indication within NHS Fife at present. Upadacitinib would be prescribed in NHS Borders if commenced in a tertiary centre.

The ERFC agreed that the information in the updated FAF1 answered the queries previously raised.

The ERFC noted difficulties with refining the pathway for severe ulcerative colitis at present due to differences between local Board pathways. An interim solution would be to include on the ERF website as an SMC decision but it was noted that this would have implications on its Formulary status within NHS Borders and NHS Fife. It was agreed that upadacitinib should sit in the severe ulcerative colitis pathway pending review of the Gastro-intestinal chapter in due course. It was noted that upadacitinib is cost effective compared to other options within the severe ulcerative colitis pathway.

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

3.1.8 FAF2 Rituximab: Ruxience

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

Indication: Moderate to severe pemphigus vulgaris.

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

The proposed place in therapy is third line for moderate to severe pemphigus vulgaris - to be used after conventional therapies such as potent topical corticosteroids, systemic corticosteroids such as prednisolone and/or steroid sparing treatments such as azathioprine and mycophenolate mofetil have been considered. Initiation would be by a consultant dermatologist; administration would via IV infusion by trained nursing staff in a hospital setting.

The proposed place in therapy is in line with the British Association of Dermatologists Guidelines for management of pemphigus vulgaris (2017).

The ERFC noted that Ruxience is a biosimilar of rituximab and agreed that only the generic name should be included in the ERF. It would up to individual Boards to move forward with switches when other biosimilar medicines become available.

Pathway to be developed in due course in consultation with dermatology specialists.

Post meeting note: The SMC statement on biosimilars indicates that this medicine is considered within SMC remit.
ERFC to write to SMC for clarification prior to formulary classification.

ACTION: NHS Fife Formulary Pharmacist

The ERFC agreed to classify Rituximab: Ruxience 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

3.1.9 FAF3 Abiraterone

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

Indication: High-risk hormone-sensitive non-metastatic prostate cancer: 2 years of abiraterone with radical radiotherapy to the prostate and 3 years of androgen deprivation therapy (ADT).

The local treatment protocol and finance budget template were included with the FAF. The National Cancer Medicines Advisory Group advice document (NCMAG102 abiraterone acetate) supports the use of abiraterone for this indication. The proposed place in therapy is first choice within a treatment pathway.

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

ACTION: ERF Project Team

3.1.10 FAF3 Mycophenolate + Mycophenolic Acid

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

Indication: Uveitis.

It was noted that no local treatment protocol has been developed. It is proposed that the medicine is used via shared care. The supporting evidence is outlined in the Scottish Uveitis National Managed Clinical Network Treatment Guidelines September 2010. The finance budget template was included with the FAF.

The application was discussed by the ERWG who supported ERFC approval subject to clarifications on dosing and position in the formulary pathway.

The ERFC sought clarification on whether the intention is to include this indication in the existing shared care agreement for mycophenolate that is available on the LJF website or whether a new shared care agreement specifically for uveitis is to be produced.

ACTION: ERFC Meeting Admin/NHS Fife Formulary Pharmacist

The ERFC agreed to classify Mycophenolate + Mycophenolic Acid as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: ERF Project 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 N/A.

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Alpelisib: Piqray (SMC2481)
3.4.2 Ferric maltol: Feraccru (SMC2500)
3.4.3 Estetrol / drospirenone: Drovelis (SMC2564)
3.4.4 Setmelanotide: Imcivree (SMC2565)
3.4.5 Tisagenlecleucel: Kymriah (SMC2566)

The formulary website will be updated.

ACTION: ERF Project Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Faricimab: Vabysmo (SMC2512)

The ERFC noted the SMC abbreviated submission Faricimab: Vabysmo (SMC2512).

Indication: for the treatment of adult patients with neovascular (wet) agerelated macular degeneration (nAMD).

The ERFC agreed to classify Faricimab: Vabysmo 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 Micronised progesterone: Utrogestan (SMC2529)

The ERFC noted the SMC abbreviated submission Micronised progesterone: Utrogestan (SMC2529).

Indication for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT).

It was noted that Micronised progesterone: Utrogestan was previously submitted as a FAF4 and approved by the ERFC. The ERFC agreed that the SMC abbreviated advice superseded local advice.

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

ACTION: ERF Project 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 Upadacitinib: Rinvoq (SMC2495)
3.7.2 Mobocertinib: Exkivity (SMC2516)
3.7.3 Tepotinib: Tepmetko (SMC2535)

The ERFC agreed to classify items 3.7.1, 3.7.2, 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: ERF Project Team

4 Central Alerting System COVID-19 Alerts

4.1 COVID-19 Therapeutic Alert CEM/CMO/022/014
4.2 COVID-19 Therapeutic Alert CEM/CMO/022/015
4.3 COVID-19 Therapeutic Alert CEM/CMO/022/016
4.4 COVID-19 Therapeutic Alert CEM/CMO/022/017
4.5 COVID-19 Therapeutic Alert CEM/CMO/022/018

The ERFC noted the COVID-19 Therapeutic Alerts. Local guidance to be reviewed when HTA guidance is available at the end of March 2023.

The ERFC noted the COVID-19 Therapeutic Alerts CEM/CMO/022/014, CEM/CMO/022/015, CEM/CMO/022/014, CEM/CMO/022/017, CEM/CMO/022/018.

5 National Cancer Medicines Advisory Group

5.1 NCMAG102 Abiraterone Acetate advice document
5.2 NCMAG104 Carfilzomib Acetate advice document

5.3 NCMAG105 Trastuzumab Acetate advice document

The ERFC noted the National Cancer Medicines Advisory Group advice documents NCMAG102, NCMAG104 and NCMAG105.

6 Board specific information

6.1 NHS Borders

- **TPN preparations**

A query was raised around TPN preparations and the role of the ERFC in the approval process. It was noted that historically TPN preparations have not been included in the Formulary process.

6.2 NHS Fife

None raised.

6.3 NHS Lothian

- **SBAR - Dapagliflozin for CKD**

The ERFC discussed the SBAR - Dapagliflozin CKD estimated GFR (eGFR) 15-25ml/min/1.73m^2 and noted the background to this.

The ERFC reviewed and approved the FAF1 for dapagliflozin for CKD in May 2022. The application requested use in eGFR 15-25ml/min/1.73m^2 (SMC advice published in May 2022 was restricted to patients with eGFR ≥25 to ≤75 mL/min/1.73m^2 at treatment initiation). Although the request to use in patients with eGFR 15-25ml/min/1.73m^2 was discussed at the ERFC and no objections were put forward, the request to approve for use in this patient group was not recorded in the ERFC minutes. The product is licensed for use in patients with an eGFR > 15 ml/min/1.73m^2 and this use is in line with UK Kidney Association guidance. Initiation in eGFR 15-25ml/min/1.73m^2 would be under specialist supervision only. This is in line with current local prescribing practice. The ERFC agree that eGFR, as a measure for a restriction on use in clinical practice is an arbitrary cut off, though used in the trial design. It was noted that there is a growing body of evidence to support use of SGLT2 inhibitors in patients with eGFR <25 mL/min/1.73m^2 and this group of patients would be expected to benefit from delayed progression of CKD.

The Renal specialists asked for clarification on the ERF decision for use in eGFR 15-25ml/min/1.73m^2. The alternative to ERF approval would be to consider requests on an individual patient basis through the PACS2 approval process which would be prohibitive due to the anticipated patient numbers.

Following discussion, the ERFC was supportive of the request to use dapagliflozin in eGFR 15-25ml/min/1.73m^2 and agreed to write to the three ADTCS to seek their view on ERF approval.

The ERFC to write to the three ADTCs to request approval for the inclusion of use in patients with eGFR 15-25ml/min/1.73m^2 in the ERF.

ACTION: NHS Fife Formulary Pharmacist

The ERFC noted the potential implications for an increase in enquiries for similar requests to approve use of medicines outwith the SMC restriction. It was proposed that a short life working group be set up to consider how to take forward other similar requests in the future

pending review of CEL17 - Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland. It was noted that there is no information on the timeline for review of CEL17 at present.

ACTION: ERWG

- **Pharmacy First**

The ERFC noted the call for suggestions for additions/removals for the forthcoming review of Pharmacy First. Suggestions to be made through the Community Pharmacy Scotland portal by 17 February 2023. A revised list will thereafter be circulated for comment.

7 Any other competent business

None raised.

8 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 29 March 2023.

FAF3s should be submitted by 21 February 2023 (for discussion at the ERWG meeting on 8 March 2023).

FAF1s and FAF2s should be submitted by 14 March 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