East Region Formulary

East Region Formulary Committee
Minutes

Date: 27 July 2022
Time: 2pm – 4pm
Location: MS Teams

Present:

Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Bryony Drummond	Senior Practice Pharmacist, NHS Fife
Steven Fenton	Project Manager, ERF Project Team
Jane Goddard	Consultant – Renal, NHS Lothian
Fiona Grant	Physiotherapist, NHS Borders
Sarah Hailwood	Consultant – Rheumatology, NHS Fife
Dr Peter Hall	Consultant – Oncology, 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
Fraser Notman	Formulary Pharmacist, NHS Fife
Euan Reid	Lead Pharmacist, NHS Fife
Kate Warner	Meeting Administration, NHS Borders
Alison Wilson	Director of Pharmacy (Co-chair), NHS Borders – in the Chair

Guests/Observing:

Apologies:

Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Gillian Donaldson	Nurse – Cardiology, NHS Borders
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Carol Holmes	Pharmacist – Primary care, NHS Lothian
Dr Paul Neary	Consultant - Cardiology, NHS Borders
Dr Jo Rose	GP, NHS Lothian
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), 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.
- New members, Bryony Drummond, Senior Practice Pharmacist and Alison Casey, Senior Pharmacist Cancer Services both from NHS Fife were welcomed; Alison Casey has sent apologies for this meeting.
- This was the last ERFC meeting for Sarah Hailwood, NHS Fife, and the Chair thanked them for their input.
- Declaration of Interest – there were no additional declarations of interest declared for this meeting. ERFC members reminded to return their Declaration of Interest (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 with some of the CNS section at ERFC for approval today. Due to the complexity of the next set of chapters, they will span the September and November ERFC meetings. Central Nervous System 3 section meetings have commenced and work on the Wound Care chapter is progressing; Nutrition and Blood chapter has also been divided into sections; and Malignant Disease CEWG to meet in the near future. ERFC noted that the Adult CEWG have made good progress and are on target for completion by the end of the year.

1.3 Matters arising

1.3.1 ERFC 25.05.22 item 3.1.8 FAF1 Dapagliflozin: Forxiga (SMC2428) – at May meeting, the prescribing category was set as Specialist Initiation and after the meeting, the renal team requested this be changed to General Use. With guidance on EDREN and as the application was out with SMC approval but had good supporting clinical evidence, the team felt that this should be changed to Specialist Guidance and GP Prescribing – GP can have discussion with Specialist rather than patient having to see Specialist. ERFC heard from renal representation; expectation was for general use; communications ready to be sent which match EDREN information and GPs on committee had agreed to GP prescribing. ERFC agreed that clarification around Specialist Initiation definition as this may mean different things in different Boards. GP representative – GPs would be happy to initiate on Specialist recommendation; Dapagliflozin is prescribed in diabetes and GPs be comfortable with this. Communication between GP and consultants is good. Specialist Initiation or Recommendation. Flag also means – may be initiated in primary care. Comments in Teams chat referred to current definition of Specialist Initiation as "recommended that these medicines must be initiated by a specialist clinician but are appropriate to be continued in a primary care setting. This initiation could be a recommendation or prescribing and supply of the medicine from hospital" and the tooltip on formulary app is "Specialist Initiation: may be continued in a primary care setting". Recommendation could come from specialist or formulary and may not require more detail. Important for GPs not to be contained by flag wording and ensure they are not restricted.

The ERFC requested that the applicant be sent an updated letter to note change in approval.

ACTION: Meeting Admin

The ERFC requested that the SI icon be removed and that the Project Team agree and update the wording for formulary flags.

ACTION: ERF Project Team

1.3.2 ERFC 25.05.22 item 3.1.1 FAF 1 Polatuzumab vedotin: Polivy (SMC2282) – completed.

1.3.3 ERFC 25.05.22 item 3.1.2 FAF 1 Isatuximab: Sarclisa (SMC2303) – completed.

1.3.4 ERFC 25.05.22 item 3.1.3 FAF 1 Brigatinib: Alunbrig (SMC2314) – completed.

1.3.5 ERFC 25.05.22 item 3.1.4 FAF 1 Acalabrutinib: Calquence (SMC2347) – completed.

1.3.6 ERFC 25.05.22 item 3.1.5 FAF 1 Cabozantinib: Cabometyx / Nivolumab: Opdivo (SMC2386) – completed.

1.3.7 ERFC 25.05.22 item 3.1.7 FAF 1 Upadacitinib: Rinvoq (SMC2417) – Dupilumab to remain first line biologic and Upadacitinib first line JAK1 – completed.

1.3.8 ERFC 25.05.22 item 3.1.10 FAF 1 Filgotinib: Jyseleca (SMC2467) – NHS Fife CD approval was received and confirmed 15 patients in Fife and application can now be completed.

1.3.9 ERFC 25.05.22 item 3.4.2 Abbreviated Submission Fedratinib: Inrebic (SMC2462) – Co-Chair's approval was received from all three Boards.
The ERFC agreed to classify Nivolumab: Opidivo 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/Meeting Admin

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 25 May 2022.

The minutes of the previous meeting were approved as an accurate record.

2.2 East Region Working Group (ERWG) meeting minutes 6 July 2022

The minutes of the ERWG meeting were noted for information.

2.3 East Region Formulary (ERF) sections for approval

- **Central Nervous System 1 (Sleep, Anxiety, Depression, Psychoses & Related Disorders)**

It was noted that all points discussed at CEWG meetings have been resolved and these were outlined; dosing regimen, tricyclic anti-depressant warning added, splitting of treatment of acute behavioural disturbance section into three pathways (oral, intramuscular and IV), wording of depression section changed (mild to mild/moderate; mild/moderate to moderate to be more in line with treatment protocols going forward. Follow up expected for "severe" and inclusion of flowcharts to be approved by the CEWG.

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

ACTION: ERF Project Team

- **Central Nervous System 2 (ADHD & Development Disorders)**
  It was noted that this was agreed virtually due to significant overlap between the three Boards. CEWG discussions focused on dosage, wording and prescribing notes. FAF3 for Guanfacine is to be completed and presented for review at a future ERWG meeting. Availability of Xaggatin is being monitored for inclusion before chapter goes live. Parts of the Tourette's and Complex Tic Disorder section requires update with some medicines in current use which will require to be submitted for formulary review as FAFs.

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

  ACTION: ERF Project Team

- **Central Nervous System 4 (Pain)**
  It was noted that after extensive discussion in the CEWG, drugs Pregabalin and Dihydrocodeine were not included in the formulary section due to their association with diversion and misuse; Tramadol included as an opioid for post-op use only with a small supply on discharge from secondary care; Codeine is included as the sole medium potency opioid in the formulary; ceiling of the doses for MR Morphine and MR Oxycodone for the treatment of chronic pain were discussed; minor amendments and final dose check outstanding for this section. Paracetamol soluble tablets not included due to their sodium content. Actions discussed and flagged at the CEWG and ERWG include change to Paracetamol IV for Specialist secondary care use only. Paracetamol soluble is included in a prescribing note and brand vs. generic for Morphine and Oxycodone was discussed. The outstanding issue will be resolved and agreed with the CEWG/ERWG. The ERFC raised questions about brand v generic of Morphine modified release capsules; Ibuprofen oral dosage; communications required for formulary changes to use of Tramadol and Pregabalin to prescribers in general practice as these are currently widely prescribed – it was agreed that communications would be required for this decision. Paracetamol IV preparation and the risks of dose related toxicity raised and the formulary entry will be agreed by CEWG. Updates to chapter will be finished and plan to return to September ERFC meeting for approval.

  The ERFC did not approve the new chapter content, to be updated and back to ERWG and then ERFC.

- **Central Nervous System 5 (Substance Dependence)**
  It was noted that there was good discussion between, and representation from the three Boards with virtual review from smoking cessation representatives. There is the inclusion of NRT inhalator. GBL withdrawal pathway requires specialist prescribing notes before publication. It was agreed that there is a place in therapy for Nalmefene which would be initiated in primary care, not by substance misuse team, for patients who have high drinking risk level without withdrawal symptoms and who do not require immediate detox. Following recent Chlordiazepoxide warning the chapter content will be agreed after receiving updates from specialist review and MHRA. Pabrinex recommendations have been re-worked to

reflect use in practice. Opiate maintenance treatment was clarified and a link added to the relevant SIGN guidance on long acting Buprenorphine. Significant change to wording around Benzodiazepine dependence to reflect harm reduction models and reviewed cost order layout for nicotine products to clarify with information on use of various preparations. Links to be included for guidance - NHS Fife and Borders.

The ERFC requested inclusion of NHS Fife and NHS Borders guidance links.

ACTION: NHS Fife/Borders FP

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

ACTION: ERF Project Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Formoterol fumarate dihydrate / glycopyrronium / budesonide: Trixeo Aerosphere (SMC2321)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest was received – educational initiatives that applicant had been involved with - non-promotional respiratory meetings. CD support received from all three Boards.

Indication: maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. SMC restriction: in patients with severe COPD (forced expiratory volume in one second [FEV1] less than 50% predicted normal). Formoterol fumarate dihydrate / glycopyrronium / budesonide (Trixeo® Aerosphere) offers an additional treatment choice of long-acting beta2-agonist (LABA), long-acting muscarinic antagonist (LAMA) and inhaled corticosteroid (ICS) in a single inhaler.

No local treatment protocol has been developed and finance budget template was included with the FAF.

Application was summarised; proposed use would be in primary care with no formulary flags. The ERFC questioned the requirement for two triple therapy MDIs and what position they would be on formulary. DPI and MDI current choices discussed. Current formulary section content discussed with DPI first for environmental reasons.

The ERFC requested that the applicant give clear reason for inclusion of Trixeo in addition to current formulary triple therapy MDI Trimbow. The ERFC requested clarification as to why two triple therapy MDIs should be included in the formulary and asked if there was any clinical benefit to changing to Trixeo. ERFC preference is to have a single triple therapy MDI unless there is clinical reason for an additional choice.

ACTION: Meeting Admin

The ERFC agreed to classify Formoterol fumarate dihydrate / glycopyrronium / budesonide: Trixeo Aerosphere as Not Routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts.

ACTION: ERF Project Team

3.1.2 FAF1 Nivolumab: Opidivo (SMC2385)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest was received – local investigator on trial with commercial funding received for research trial. CD support received from all three Boards.

Indication: in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM). In a phase III study of patients with previously untreated, unresectable MPM, overall survival was significantly longer in the nivolumab plus ipilimumab group compared with current therapy.

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

The ERFC agreed to classify Nivolumab: Opidivo 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/Meeting Admin

3.1.3 FAF 1 Pemigatinib: Pemazyre (SMC2399)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declarations of interest was received – consultancy for the manufacturer regards to SMC submission; the ERFC agreed that with scrutiny elsewhere, a second signature was not required nor was further information required on SMC submission in this case. CD support received from all three Boards.

Indication: for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. In a phase II, single-arm study, pemigatinib demonstrated anti-tumour activity in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma with a FGFR2 fusion or rearrangement that have progressed on at least one line of prior systemic therapy.

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

The ERFC agreed to classify Pemigatinib: Pemazyre 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/Meeting Admin

3.1.4 FAF 1 Enzalutamide: Xtandi (SMC2400)

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 adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). Enzalutamide improved radiographic progression-free survival compared with placebo and it improved overall survival compared with placebo and an older non-steroidal anti-androgen (NSAA) in adults with mHSPC who were receiving ADT.

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

The ERFC agreed to classify Enzalutamide: Xtandi 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 FAF 1 Pembrolizumab: Keytruda (SMC2420)

The ERFC noted and discussed the previously circulated FAF1 submission. One Non-personal, specific declaration of interest was received – involved in clinical trials and working on further trial in this field; applicant included "we"; to be clarified with applicant. CD support received from all three Boards.

Indication: In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS≥10.

SMC Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase III study, pembrolizumab in combination with chemotherapy was associated with significantly improved progression-free survival and overall survival compared with chemotherapy alone.

The local treatment protocol and finance budget template were included with the FAF. D&G also included in costs as it is SCAN.

The ERFC requested that the non-personal specific declaration is clarified – clarify who is "we". A request Pharmacist applicant completes the declaration of interest as there is a gap at non-personal, non-specific interest.

ACTION: ERF Meeting Admin

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

3.1.6 FAF 1 Sotorasib: Lumykras (SMC2443)

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

Indication: as monotherapy for the treatment of adult patients with KRAS G12C-mutated, locally advanced or metastatic, non-small cell lung cancer (NSCLC), who have progressed on, or are intolerant to platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy. In a single-arm, phase II study, 37% of previously treated patients with advanced or metastatic, KRAS G12C-mutated NSCLC who received sotorasib achieved an objective response.

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

The ERFC agreed that the re-evaluation would be tracked through SMC and that we don't require to have a re-evaluation flag.

The ERFC agreed to classify Sotorasib: Lumykras 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/Meeting Admin

3.1.7 FAF 1 Abrocitinib: Cibinqo (SMC2431)

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

Indication: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. SMC restriction: for use in patients who have not responded to, or have lost response to, at least one systemic immunosuppressant therapy, or in whom these are contraindicated or not tolerated. Four phase III studies demonstrated superiority of abrocitinib in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with medicated topical therapies in patients with moderate to severe atopic dermatitis.

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

Current pathways and options on application discussed along with JAK inhibitor profile and side effects – not proposing to switch patients. The ERFC agreed that approval can be given after clarification on the pathway received.

The ERFC requested clarification on treatment pathway.

ACTION: Meeting Admin

The ERFC agreed to classify Abrocitinib: Cibinqo 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 FAF 1 Relugolix, estradiol, norethisterone acetate tablets: Ryeqo (SMC2442)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from NHS Borders and Lothian. The ERFC agreed to discuss application, pending NHS Fife CD support and numbers.

Indication: treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. SMC restriction: for use in patients who have failed or are unsuitable for conventional therapies (first line treatments), such as tranexamic acid, hormonal contraceptives and intrauterine delivery systems. Relugolix, estradiol, norethisterone acetate tablets (Ryeqo®), compared with placebo, significantly reduced menstrual blood loss volume in patients with uterine fibroids and heavy menstrual bleeding.

No local treatment protocol has been developed and finance budget template was included for Borders and Lothian.

The ERFC requested that CD support and financial figures be provided from NHS Fife.

ACTION: Meeting Admin

The ERFC agreed to classify Relugolix, estradiol, norethisterone acetate tablets: Ryeqo as Routinely available in line with local guidance. Included on the ERF for Specialist Initiation and GP Prescribing. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.1.9 FAF 2 Emtricitabine + tenofovir alafenamide: Descovy

The ERFC noted and discussed the previously circulated FAF2 submission. One non-personal, non-specific declaration of interest was received – sub investigator on trial 2016-22 and department received funding from research nursing during trial; additional clinical evidence was included. CD support received from all three Boards. The formulation is the 200mg/25mg film coated tablets.

Indication: Pre-exposure Prophylaxis for HIV (PrEP), second choice in treatment pathway in Scotland. Restricted to second line use in patients with a history of or at significant risk of developing renal impairment or fragility fractures. Or for patients with GI intolerance to first line PrEP after a trial of alternative preparations of emtricitabine/tenofovir disoproxil.

The local treatment protocol and finance budget template were included with the FAF. National Guidelines and tertiary prescribing in Lothian was discussed.

The ERFC requested that the applicant confirms a link to national guidelines. Also confirm proposed delivery route in Fife and Borders.

ACTION: ERF Meeting Admin

The ERFC agreed to classify Emtricitabine + tenofovir alafenamide: Descovy 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

3.1.10 FAF3 Uromune

The ERFC noted the previously circulated FAF3 submission, reviewed by the ERWG, and ratified the decision of the ERWG to approve.

Indication: Recurrent UTI.

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

The ERFC agreed to classify Uromune as Routinely available in line with local prescribing 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/Meeting Admin

3.1.11 FAF3 Mycophenolate Mofetil

The ERFC noted the previously circulated FAF3 submission, reviewed by the ERWG, and ratified the decision of the ERWG to approve.

Indication: Interstitial Lung Disease.

The finance budget template was included with the FAF. No local treatment protocol was available.

The ERFC agreed to classify Mycophenolate Mofetil as Routinely available in line with local prescribing 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/Meeting Admin

3.1.12 FAF3 Piperacillin with Tazobactam*

The ERFC noted the previously circulated FAF3 submission, reviewed by the ERWG, and ratified the decision of the ERWG to approve.

Indication: The use of extended interval infusions for the treatment of infections requiring piperacillin with tazobactam treatment.

The finance budget template was included with the FAF. No local treatment protocol was available.

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

ACTION: ERF Project Team/Meeting Admin

3.1.13 FAF4 Utrogestan

The ERFC noted the previously circulated FAF4 submission, reviewed by the ERWG, and ratified the decision of the ERWG to approve.

Indication: Adjunctive use with Oestrogen in post-menopausal women with an intact uterus (HRT).

The finance budget template was included with the FAF. No local treatment protocol was has been developed.

The ERFC agreed to classify Utrogestan as Routinely available in line with local prescribing guidance. Included on the ERF with no formulary flags. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.2 Formulary Amendment Forms

3.2.1 Fluticasone + salmeterol: Combisal 50microgram/25 micrograms dose inhaler cfc free

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. No details of support included from other Boards.

Indication: Regular treatment of asthma where use of a combination product (long-acting β_2 agonist and inhaled corticosteroid) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 agonist, or
- Patients already adequately controlled on both inhaled corticosteroid and long-acting β_2 agonist.

The ERFC agreed to classify Fluticasone + salmeterol: Combisal 50microgram/25 micrograms dose inhaler cfc free as Routinely available in line with local prescribing guidance. Combisal 25/50 will replace seretide 25/50 in the Paediatric Respiratory section of the formulary Included on the ERF with no formulary flag. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.2.2 Beclomethasone: Soprobec Inhaler

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support was received from three Boards.

Indication: Regular preventer therapy for children with asthma and additional controller therapy.

Will capture at amendment stage the three strengths are 50microgram, 100microgram and 200microgram, the higher strength is for Specialist initiation - subject to further review when the paediatric reviews take place.

The ERFC agreed to classify Beclomethasone: Soprobec Inhaler as Routinely available in line with local prescribing guidance. Included on the ERF Paediatric Respiratory section with no formulary flags. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.2.3 Fidaxomicin 40mg/ml oral suspension

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. No details of support included from other Boards.

Indication: Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD).

SMC Restriction: Treatment of adults and children in line with product licence with a first CDI recurrence on the advice of local microbiologists or specialists in infectious diseases. Reserved for patients who cannot take film coated tablets.

Would not replace treatment – choice of formulation to crush tablets. Change from the requested No Formulary Flags to Specialist Initiation. AMT input would be required; ERFC agreed that as this was choice of formulation this would not be required.

The ERFC asked that NHS Fife and NHS Borders provide support for the application.

ACTION: ERF Meeting Admin

The ERFC agreed to classify Fidaxomicin 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

3.2.4 Pivmecillinam 200mg tablets

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support was received from three Boards.

Indication: Lower UTI in males.

Changing the duration of treatment from 3 days UTI in males – change to 7 days for treatment of UTIs in males. This reflects expert opinion across the three Boards and other antibiotics treatment is across 7 days. The ERFC agreed to change No Formulary Flags to Specialist Initiation.

The ERFC agreed to amend the duration of treatment - the formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.2.5 Levobupivacaine 50mg/10ml solution for injection ampoules

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. This procedure is only carried out in Lothian currently (Borders and Fife refer patients to Lothian if required).

Indication: Management of pain caused by an inflamed lumbar nerve root.

The ERFC agreed to classify Levobupivacaine 50mg/10ml solution for injection ampoules as Routinely available in line with local prescribing guidance. Included on the ERF for Unlicensed Indication. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

3.2.6 Calcipotriol 0.005% / Betamethasone dipropionate 0.05% cream: Wynzora cream

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. Support was received from dermatology departments in three Boards.

Indication: Mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.

Cream formulation of treatment already on formulary – adds another formulation where cream is better preparation for patient. Costs are similar; to be included as another preparation.

The ERFC agreed to classify Calcipotriol 0.005% / Betamethasone dipropionate 0.05% cream: Wynzora cream as Routinely available in line with local prescribing guidance. Included on the ERF with no formulary flags. The formulary website will be updated.

ACTION: ERF Project Team/Meeting Admin

*Piperacillin with Tazobactam was discussed under FAF3 – this is a Formulary amendment.

3.3 Ultra-Orphan Pathway

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

3.3.1 Odevixibat: Bylvay (SMC2411)

The formulary website will be updated. **ACTION: ERF Project Team**

3.4 SMC not recommended advice

3.4.1 Ixekizumab: Taltz (SMC2440)

3.4.2 Tepotinib: Tepmetko (SMC2457)

3.4.3 Ruxolitinib: Jakavi (SMC2498)

3.4.4 Enfortumab: Padcev (SMC2505)

3.4.5 Vedolizumab: Entyvio (SMC2506)

The ERFC noted the SMC not recommended advice for information.

The formulary website will be updated. **ACTION: ERF Project Team**

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Lenvatinib: Kisplyx (SMC2476)

The ERFC noted the SMC abbreviated submission Lenvatinib: Kisplyx SMC2476.

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. Medicines within this therapeutic class have been accepted under the end of life process for this indication.

The ERFC agreed to classify this medicine as "Not routinely available" as the FC is waiting for advice from local clinical experts. 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 on SMC publishing

The ERFC noted the Non-submissions within 90 days on SMC publishing.

3.7.1 Crizanlizumab: Adakveo (SMC2438)

3.7.2 Solriamfetol: Sunosi (SMC2439)

3.7.3 Pegcetacoplan: Aspaveli (SMC2451)

3.7.4 Delafloxacin: Quofenix SMC2453)

The ERFC agreed to classify each of these medicines 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.

The ERFC asked when Bartcitinib guidance would be updated on webpages.

ACTION: ERF Meeting Admin

5 National Cancer Medicines Advisory Group

5.1 The ERFC noted the NCMAG101 Abiraterone Advice Document.

The ERFC asked for these to be added to ERWG – to be forwarded to ADTCs by meeting admin to Chair of ERWG.

ACTION: ERF Project Team

6 Board specific information

6.1 NHS Borders

FAF2 Gadobutrol: Gadovist

The ERFC noted and discussed the previously circulated FAF2 submission which is here because NHS Fife and Lothian already have this introduced into practice. No declarations of interest were received.

Indication: Referrals for cardiac MRI imaging.

No local treatment protocol has been developed and finance budget template for Borders was included with the FAF. No costs for Lothian and Fife included as the treatment is already in use in these Boards.

The ERFC agreed to include regional formulary decisions until place in Therapeutic chapter.

The ERFC agreed to classify Gadobutrol: Gadovist 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/Meeting Admin

6.2 NHS Fife

None raised.

6.3 NHS Lothian

None raised.

7 Any other competent business

7.1 The ERFC noted that the Brand name prescribing Q&A updated and available as 2 web pages Prescribing by generic or brand name in primary care and Example medicines to prescribe by brand name in primary care. Position statement agreed for ERF; links to updated Q&A with minor updates and Q&A to go into the channel.

7.2 **Galcanezumab Update**

The ERFC noted that this was not added to formulary in February and came back to ERFC to be approved in March and taken to all three ADTCs; NHS Fife declined to approve. Clinical teams are aware they are not able to be added to the formulary at the moment. It may be included with local teams using differently. Migraine section has been reviewed and agreed to include all three in line with SMC advice and communication will go out to Teams; Lothian have developed a protocol. Links to Board protocols required and drug safety review; work is underway to review options. Prescribing was discussed - the pathway following SMC advice; require guidance to back up where no capacity national guidance. Statement or solution required to avoid challenges on decision. Moving forward would be a protocol on intranet site for case by case basis; ensuring prescribers are supported in practice. The ERFC agreed that this is for the CEWG to discuss and that SMC advice is advice for local teams to take forward and ensure patient safety and safe services.

8 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 28 September 2022.

The ERFC agreed that NHS Borders would host September meeting with NHS Fife shadowing the meeting.

FAF3s should be submitted by 23rd August 2022 (for discussion at the ERWG meeting on 7th September 2022).

FAF1s and FAF2s should be submitted by 13th September 2022.

All FAFs need to include information on proposed use and confirmation of clinical director support from all three boards, to be added to the agenda. Except in the case where the

service is only provided by one of the boards, in this case it should be clearly stated in the application.

Apologies for the meeting to be sent to prescribing@nhslothian.scot.nhs.uk