East Region Formulary

East Region Formulary Committee
Minutes

Date: 02 February 2022
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	Lead Pharmacist, ERF Project Team
Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Steven Fenton	Project Manager, ERF Project Team
Anne Gilchrist	Lead Pharmacist, NHS Lothian
Jane Goddard	Consultant – Renal, NHS Lothian
Fiona Grant	Physiotherapist, NHS Borders
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Sarah Hailwood	Consultant – Rheumatologist, NHS Fife
Dr Nicola Henderson	GP, NHS Borders
Carol Holmes	Pharmacist – Primary care, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Kirsty MacFarlane	Regional Formulary Pharmacist, ERF Project Team
Dr Linda McGourty	GP, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Fraser Notman	Formulary Pharmacist, NHS Fife
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian – in the Chair
Alison Wilson	Director of Pharmacy (Co-chair), NHS Borders

Apologies:

Dr Emma Christmas	GP, NHS Fife
Dr Maria Corretge	Consultant Geriatrician, NHS Lothian
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Gillian Donaldson	Nurse – Cardiology, NHS Borders
Dr Peter Hall	Consultant – Oncology, NHS Lothian
Euan Reid	Lead Pharmacist, NHS Fife
Angela Sinclair	Senior Pharmacist, NHS Fife

1 Project update

1.1 Welcome and Apologies

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

- **Declarations of interest**

ERFC members were reminded to return their Declaration of Interest (DOI) forms. DOI forms will be requested yearly. Completed DOIs will be 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)

To date three chapters have been completed and four chapters are pending approval by the ERFC. The first meetings have taken place for a further four chapters which are now in progress by the CEWGs. These are expected to be presented to the ERWG in March 2022. Progress on the adult formulary chapters is progressing well and work is on track. It is anticipated that all adult formulary chapters will be reviewed and completed by late summer 2022.

1.3 Matters arising

1.3.1 Neutralising monoclonal antibodies (nMABs) and antivirals - in the treatment of COVID-19

1.3.1.1 Casirivimab + Imdevimab: Ronapreve

Indication: For hospitalised patients with COVID-19 and patients with hospital onset COVID-19 (adults and children aged 12 and over) in line with local guidance for prescribing and coronavirus (COVID-19) alerts issued by the MHRA Central Alerting System – 24 December 2021 (Neutralising monoclonal antibody and intravenous antiviral treatments for patients in hospital with COVID-19 infection). The ERFC Co-chairs agreed on the 20 January 2022 to classify Casirivimab + Imdevimab: Ronapreve as Routinely available in line with local guidance for prescribing. Classified for use under policy for the use of unlicensed medicines. Included on the ERF for Specialist use only. The formulary website will be updated.

ACTION: ERF Project Team

1.3.1.2 Molnupiravir: Lagevrio

Indication: For non-hospitalised patients with COVID-19 (adults aged 18 and over) in line with local guidance for prescribing and coronovirus (COVID-19) alerts issued by the MHRA Central Alerting System – 16 December 2021 (Neutralising monoclonal antibodies or antivirals for non-hospitalised patients). The ERFC Co-chairs agreed on the 20 January 2022 to classify Molnupiravir: Lagevrio as Routinely available in line with local guidance for prescribing. Included on the ERF for Specialist use only. The formulary website will be updated.

ACTION: ERF Project Team

1.3.1.3 Sotrovimab: Xevudy

Indication: For patients with hospital onset COVID-19 (adults and children aged 12 and over) in line with local guidance for prescribing and coronavirus (COVID-19) alerts issued by the MHRA Central Alerting System – 16 December 2021 (Neutralising

monoclonal antibodies or antivirals in hospitalised patients).' AND For non-hospitalised patients with COVID-19 (adults and children aged 12 and over) in line with local guidance for prescribing and coronavirus (COVID-19) alerts issued by the MHRA Central Alerting System – 16 December 2021 (Neutralising monoclonal antibodies or antivirals for non-hospitalised patients). The ERFC Co-chairs agreed on the 20 January 2022 to classify Sotrovimab: Xevudy as Routinely available in line with local guidance for prescribing. Included on the ERF for Specialist use only. The formulary website will be updated.

ACTION: ERF Project Team

A query was raised from an NHS Lothian representative regarding which specific type of Covid-19 testing was required for patients prior to receiving nMABs. The ERFC will write to the NHS Lothian clinical team to request clarification.

ACTION: ERF Project Team

There was discussion about having a potential East region pathway in place for prescribing of Covid-19 medicines. In NHS Fife and NHS Borders, the medicines management teams are involved in writing local Covid-19 guidelines incorporating updates in national guidance. In NHS Lothian Covid-19 guidelines incorporating updates in national guidance are written by specialists in infectious diseases and approved by NHS Lothian University Hospitals Division Drug and Therapeutics Committee. The ERFC recognised the duplication of effort, however, also noted that individual board guidelines incorporate service delivery and local implementation arrangements. The ERFC agreed to write to the Scottish Antimicrobial Prescribing Group (SAPG) seeking information on whether national prescribing pathways for Covid-19 medicines are planned.

ACTION: ERF Project Team

1.3.2 ERFC 24 November 2021, Item 3.1.8 FAF3 Metformin

The ERFC noted the new pathway for antipsychotic associated weight gain, approved by the ERWG with changes recommended by specialists from the East region, the formulary decision has been changed to reflect the proposed supply routes. The recommendations will be incorporated in the future scheduled East region review of the CNS chapter.

ACTION: ERF Project Team

The ERFC agreed to classify Metformin as Routinely available in line with local guidance. Included on the ERF for Specialist initiation. The formulary website will be updated.

ACTION: ERF Project Team

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 24 November 2021

An amendment will be made to the ERFC minute to clarify the wording around the section for Pharmacy First which did not have a CEWG. The amended minute will be re-published and the formulary website will be updated.

ACTION: ERF Project Team

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

2.2 East Region Working Group (ERWG) meeting minutes 12 January 2022

The minutes of the ERWG meeting were noted for information.

2.3 East Region Formulary (ERF) amendments

- **ERFC Formulary Application Forms**

  Minor revisions were made to the FAF 1, 2 and 3 templates and the formulary amendment form. These changes were approved by the ERFC. The revised templates and forms will be introduced in early February 2022.

  ACTION: ERF Project Team

- **Cardiovascular chapter (Adult)**

  It was noted that meetings had taken place to discuss the Cardiovascular chapter and that there was good consensus from all three boards participants. The finalised draft of the Cardiovascular chapter was sent to the ERWG. The ERFC approved the new chapter content. The formulary website will be updated.

  ACTION: ERF Project Team

- **Diabetes chapter (Adult)**

  It was noted that meetings had taken place to discuss the Diabetes chapter. There was a full team of multi-disciplinary representatives and good participation across all three boards. Some earlier work had been done on glucose meters by Diabetes Specialist Nurses. There were some comments raised by the ERWG on the prescribing notes - these points were addressed and shared with the CEWG. There was a request for having links to Toxbase incorporated for hyperglycemia management – this was not possible at present but a link to Toxbase will be looked at for whole website. The ERWG agreed to include pen needles and lancets- this has not yet been incorporated but will be looked by representatives of NHS Borders, NHS Lothian and NHS Fife Diabetes MCNs with a view to make joint recommendations for the East region. The joint MCN recommendations are requested to go to the ERWG and then to the ERFC. The ERFC approved the new chapter content. The formulary website will be updated.

  ACTION: ERF Project Team

- **Endocrine chapter (Adult)**

  It was noted that the review for the Endocrine chapter was undertaken virtually through use of email rather than scheduled meetings. This was due to the high degree of overlap in the medicines choices across the 3 boards for the pathways for this chapter. Diabetes was covered separately (as above). The ERFC noted in the prescribing note for growth hormones which is appropriate for shared care agreement to facilitate care from secondary care to general practice and to primary care, that there is no specialist initiation noted under the product. The ERFC agreed that this should be corrected, and specialist initiation should be noted under this product.

  ACTION: ERF Project Team

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

ACTION: ERF Project Team

- **Respiratory chapter (Adult)**
  It was noted that meetings had taken place to discuss the Respiratory chapter. It was highlighted that the Asthma and COPD pathways both needed more work and were taken away and looked at again by the CEWG. The pathway for COPD is reflective of the Global Initiative for Chronic Obstructive Lung Disease 'GOLD' COPD guidelines. The ERFC noted that antibiotic treatment for infective exacerbations does not feature in the chapter. A suggestion was made to consider a link for acute exacerbations in the Infections chapter. The ERFC agreed to look into this further.

  ACTION: ERF Project Team

  The ERFC noted that the prescribing choices were in perspective of environmental impact issues. Clinical pharmacists will be looking into this work as evidence emerges. 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 Caplacizumab: Cablivi (SMC2266).

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received.

Indication: For the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression. The proposed use of this medicine is as per SMC approved indication for Caplacizumab: Cabliv.

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

The ERFC agreed to classify Caplacizumab: Cabliv 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 Lenalidomide: Revlimid (SMC2281)

The ERFC noted and discussed the previously circulated FAF1 submission. Personal, Non-Specific declarations of interest were received.

Indication: In combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated Follicular Lymphoma (Grade 1 - 3a). The proposed use of this medicine is as per SMC approved indication for Lenalidomide: Revlimid.

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

The ERFC agreed to classify Lenalidomide: Revlimid 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

3.1.3 FAF 1 Brentuximab vedotin: Adcetris (SMC2310)

The ERFC noted and discussed the previously circulated FAF1 submission. One Personal, Non Specific declaration of interest was received.

Indication: In combination with cyclophosphamide, doxorubicin and prednisone (CHP) is indicated for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL). The proposed use of this medicine is as per SMC approved indication for Brentuximab vedotin: Adcetris.

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

The ERFC agreed to classify Brentuximab vedotin: Adcetris 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 FAF 1 Galcanezumab: Emgality (SMC2313)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received.

Galcanezumab: Emgality. Indication: prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: For the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.

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

The proposed place in therapy for galcenezumab in the application is after a trial of four oral prophylactic migraine treatments and botulinum toxin A where available (only for chronic migraine patients). Galcanezumab will be used for chronic migraine patients who have 15 or more headache days each month, of which at least 8 are migraine days. For episodic migraine patients galcenezumab will be used for high frequency episodic migraine (presence of migraine headache 10-14 days each month). Patients will receive a 3-month trial with review of effectiveness and consideration to stopping. Stopping criteria: episodic migraine (failure to achieve a 50% reduction in migraine frequency); chronic migraine (failure to achieve a 30% reduction in migraine frequency). Additionally, treatment would be stopped if worse after initial response

or pregnancy/breast-feeding. The ERFC noted that there is a lack of safety data in patients with cardiovascular risks noted in the SMC advice. The protocol did not stipulate place in therapy compared with other agents such as erenumab or fremanezumab, the ERFC noted that this will form part of the discussions in the East region chapter reviews for CNS. The proposal is for specialist use only with supplies delivered via homecare.

There was concern around the additional restrictions for use noted on the FAF which differ from the SMC recommendations. The ERFC requested the clinical team to explain why additional restrictions for indication for use were placed and for the clinical team to confirm if patients with cardiovascular risks are excluded from treatment.

ACTION: ERF Project Team

The ERFC noted a calculation error in the net costs and observed that the patient numbers for each health board are out of proportion to the population estimates in the region. During discussions it was noted that patient numbers by board may be disproportionate due to different levels of maturity of some services across the boards.

The ERFC requested the clinical team to revise the total net cost and confirm the estimated patient numbers for each health board.

ACTION: ERF Project Team

The ERFC requested that the clinical team provide clarification on these points raised before a formulary decision could be made. The ERFC requested the clinical team to respond via email to justify and answer the queries noted above. This will then allow the ERFC to make a formulary decision for the FAF submitted.

ACTION: ERF Project Team

The ERFC agreed to classify Galcanezumab: Emgality as Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 30 March 2022.

ACTION: ERF Project Team

3.1.5 FAF 1 Daratumumab: Darzalex (SMC2326)

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

Indication: In combination with bortezomib, thalidomide and dexamethasone is indicated for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. The proposed use of this medicine is as per SMC approved indication for Daratumumab: Darzalex.

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

The ERFC agreed to classify Daratumumab: Darzalex 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 Trifluridine + Tipiracil: Lonsurf (SMC2329)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received.

Indication: As monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease. SMC restriction: For use as third line treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction. The proposed use of this medicine is as per SMC approved indication and restriction for Trifluridine + Tipiracil: Lonsurf.

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

The ERFC agreed to classify Trifluridine + Tipiracil: Lonsurf 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

3.1.7 FAF 1 Osimertinib: Tagrisso (SMC2382)

The ERFC noted and discussed the previously circulated FAF1 submission. One Personal Specific and one Non Personal Specific declarations of interest were received.

Indication: As monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations. The proposed use of this medicine is as per SMC approved indication for Osimertinib: Tagrisso.

The local treatment protocol is being updated to include the new indication, a finance budget template was included with the FAF.

The ERFC agreed to classify Osimertinib: Tagrisso 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 Bimekizumab: Bimzelx (SMC2410)

The ERFC noted and discussed the previously circulated FAF1 submission. One Personal Non Specific, one Personal Specific and one Non personal, non specific declarations of interest were received.

Indication: Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: For patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments. The proposed use of this medicine is as per SMC approved indication and restriction for Bimekizumab: Bimzelx.

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

It was noted that NHS Lothian do not wish to use this medicine at present but support the FAF. The ERFC requested NHS Lothian's clinical team to clarify their position and reason for not wishing to use this medicine at present.

The ERFC agreed to make a formulary decision on Bimekizumab: Bimzelx after NHS Lothian's clinical team have provided clarification. The formulary decision will be made via Co-Chair approval out with the ERFC meeting.

The ERFC agreed to classify Bimekizumab: Bimzelx as Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 30 March 2022.

ACTION: ERF Project Team

3.1.9 FAF 1 Bempedoic acid: Nilemdo (SMC2363)/ Bempedoic acid + Ezetimibe: Nusteni (SMC2406)

The ERFC noted and discussed the previously circulated FAF1 submission. One Personal Non Specific and one Non personal, non specific declarations of interest were received.

Bempedoic acid: Nilemdo
Indication: - For treatment in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin
  or
- alone or in combination with other lipid-lowering therapies in patients who

Restriction: for use in combination with ezetimibe in patients who are:

- statin intolerant or for whom a statin is contra-indicated

  and

- where ezetimibe alone does not appropriately control LDL-C

and

- where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate

Bempedoic acid + Ezetimibe: Nustendi
Indication: - Adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe

- alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone

- in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

Restriction: for use in patients who are:

- statin intolerant or for whom a statin is contra-indicated
- where ezetimibe alone does not appropriately control LDL-C
- where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate

The proposed use of these medicines is as per SMC approved indication and restriction for Bempedoic acid: Nilemdo and Bempedoic acid + Ezetimibe: Nustendi.

The local treatment protocols and finance budget templates were included with the FAF.

The ERFC agreed to classify Bempedoic acid: Nilemdo and Bempedoic acid + Ezetimibe: Nustendi as Routinely available in line with national guidance. Included on the ERF for Specialist initiation. The formulary website will be updated.

ACTION: ERF Project Team

3.1.10 FAF2 Hydroxypropylmethylcellulose: Ocucoat

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received.

Indication: HPMC 2%: Ocucoat is indicated for use as an ophthalmic surgical aid in retinal surgery.

A finance budget template was included with the FAF. Numbers are for NHS Lothian only, retinal surgery is delivered for the region by NHS Lothian as the specialist centre. The evidence presented was for use in cataract surgery, not retinal surgery. The evidence presented was for a different product. The comparative data was

against a balanced salt solution not the product currently in use in NHS Lothian, sodium hyaluronate.

The ERFC requested the clinical team to provide further evidence supporting the use of the Ocucoat product for the proposed use. Or if there are no direct studies of Ocucoat use in retinal surgery further information on why the clinical evidence presented supports the proposed use of the Ococoat formulation.

The ERFC agreed to classify Hydroxypropylmethylcellulose: Ocucoat as Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 30 March 2022.

ACTION: ERF Project Team

3.1.11 FAF3 Temozolamide + Capecitabine

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. The application has been approved by Cancer Therapeutics Advisory Committee (CTAC) and the ERWG.

Indication: Inoperable pancreatic neuroendocrine tumours.

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

The ERFC agreed to classify Temozolamide + Capecitabine 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

3.1.12 FAF3 Oxaliplatin + Capecitabine + Trastuzumab

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. The application has been approved by Cancer Therapeutics Advisory Committee (CTAC) and the ERWG.

Indication: Palliative treatment of gastro-oesophageal adenocarcinoma with Her-2 over-expression.

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

The ERFC agreed to classify Oxaliplatin + Capecitabine + Trastuzumab as Routinely available in line with local prescribing guidance. Included on the ERF for Specialist use only.

ACTION: ERF Project Team

3.2 Formulary Amendment Forms

3.2.1 Insulin Lispro: Lyumjev

The ERFC noted and discussed the previously circulated formulary amendment form. One Personal Non Specific declaration of interest was received.

Indication: For the treatment of adults > 18 years with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis. Restriction: To where the prescriber believes a faster onset of action would be beneficial to the patient.

The ERFC requested the clinical team to clarify the different formulations to be added to the formulary. The application requests the inclusion of Lyumjev Junior KwikPen (but the Humalog Junior KwikPen is not on formulary) and the 200unit/ml strength KwikPen has not been requested (but this strength is available for Humalog). Additionally the place in therapy on the formulary clinical team to confirm position as joint choice of options in 2nd choice position or as 3rd choice insulin lispro formulation.

ACTION: ERF Project Team

The ERFC expressed that insulin lispro formulations included on the formulary should be reviewed in one year's time to see which products are preferred for use. With a view to rationalising the number of options. This should be noted for the next scheduled review.

ACTION: ERF Project Team

The ERFC agreed to classify Insulin Lispro: Lyumjev 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

3.2.2 Rivaroxaban: Xarelto

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

The proposal is to add rivaroxaban: Xarelto formulations (granules for oral suspension, 2.5mg, 10mg, 15mg and 20mg tablets) for the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.

The ERFC noted there are differences in the individual product licences by age groups or weight depending on the formulations for the indication of the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence. The ERFC agreed that provided the supply problems with the granules for oral suspension have resolved to include the granules for oral suspension and the 15mg and 20mg tablets in line with the product licence for the patient groups in question. The ERFC agreed that off-label use of the 2.5mg and 10mg tablet strengths for smaller doses is clinically appropriate but agreed not to include on the formulary for routine use if supplies are uninterrupted.

Rivaroxaban: Xarelto 1mg/ml granules for oral suspension
Indication: Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.

Rivaroxaban: Xarelto tablets 15mg
Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment

Rivaroxaban: Xarelto tablets 20mg
Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment

Rivaroxaban: Xarelto tablets 2.5mg and 10mg – not licensed for use in children. The ERFC agreed not to include these formulations for the indication and patient group in question if the supply problem of the licensed formulation is resolved. The ERFC request that the clinical team confirm the supply status of the 2.5mg and 10mg tablets.

ACTION: ERF Project Team

The ERFC agreed to classify Rivaroxaban: Xarelto granules for oral suspension, 15mg and 20mg tablets 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

3.3 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information. The formulary website will be updated.

ACTION: ERF Project Team

3.3.1 Nivolumab: Opdivo SMC2397
3.3.2 Tafamidis: Vyndaqel SMC2426
3.3.3 Anakinra: Kineret SMC2449
3.3.4 Nitisinone: Orfadin SMC2450
3.3.5 Eculizumab: Soliris SMC2456

3.4 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions. The formulary website will be updated for each medicine.

ACTION: ERF Project Team

3.4.1 Olopatadine hydrochloride/ mometasone furoate monohydrate: Ryaltris SMC2418

The ERFC agreed to classify Olopatadine hydrochloride/ mometasone furoate monohydrate: Ryaltris 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.

3.4.2 Opicapone: Ongentys SMC2430

The ERFC discussed the request from local clinical teams for the formulary inclusion of Opicapone: Ongentys in line with the SMC abbreviated submission SMC2430.

Indication: Adjunctive therapy to preparations of levodopa / DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

The ERFC agreed to classify Opicapone: Ongentys as Routinely available in line with national guidance. Included on the ERF.

3.4.3 Budesonide: Cortiment SMC2448

The ERFC agreed to classify Budesonide: Cortiment 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.

3.5 Paediatric licence extensions

3.5.1 No paediatric licence extensions were noted for this meeting. An update was given noting that the Medicines Governance and Guidance (MGG) team compile a database of paediatric licence extensions noted by SMC and the information is shared with NHS Lothian Paediatric and Neonatal Drug and Therapeutics Committee (PNDTC). The Professional Secretary for NHS Lothian PNDTC is seeking information from local clinical teams on proposals for formulary inclusion and will report back to MGG. As part of the paediatric reviews for the East region it is proposed that items not yet classified will be discussed as part of the planned chapter reviews.

3.6 Non-submissions within 90 days on SMC publishing

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

3.6.1 Olaparib: Lynparza SMC2368
3.6.2 Buprenorphine: Sixmo SMC2372
3.6.3 Ibrutinib: Imbruvica SMC2387
3.6.4 Trastuzumab deruxtecan: Enhertu SMC2388
3.6.5 Nivolumab: Opdivo SMC2394
3.6.6 Tirbanibulin: Klisyri SMC2395
3.6.7 Tucatinib: Tukysa SMC2398
3.6.8 Tralokinumab: Adtralza SMC2403
3.6.9 Amikacin liposomal nebuliser dispersion: Arikayce SMC2432

4 Board specific information

4.1 NHS Borders

A query was raised by the Dental service in NHS Borders about the Infections chapter regarding use of antibiotics for penicillin allergic patients with dental abscess. Previously the board had used doxycycline or metronidazole for penicillin allergic patients. The board sought clarification on how best to request this amendment for use of these medicines. The ERFC agreed that an email can be sent to the Infections CEWG to highlight this specific amendment request.

4.2 NHS Fife

None raised.

4.3 NHS Lothian

A guide has been developed to help ERFC members for preparing and presenting FAF reviews at ERFC meetings. This will be made available on Teams after the meeting. ERFC members are reminded to check the agenda when circulated ahead of ERFC meetings for allocated review of applications.

ACTION: ERF Project Team

The NHS Lothian Cancer services clinical team asked if FAF3s from cancer services could bypass the ERWG as they go through various clinical working groups for approval such as the local East Region CTAC and in future the national Cancer Medicines Advisory Group (NCMAG). With meeting timescales, submitting FAF3s to the ERWG for consideration could potentially hold up treatment. The ERFC accepted this request and noted that the FAF3s from the cancer services with prior review and approval by CTAC and/or NCMAG will come direct to the ERFC for approval.

ACTION: ERF Project Team

5 Any other competent business

None raised.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 30 March 2022.

FAF3s should be submitted by 22 February 2022 (for discussion at the ERWG meeting on 09 March 2022).

FAF1s and FAF2s should be submitted by 15 March 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