East Region Formulary

East Region Formulary Committee
Minutes

Date: 29 March 2023
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	(Acting) Associate Director of Pharmacy (Specialist Services, Development and Innovation), NHS Lothian
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Gillian Donaldson	Nurse – Cardiology, NHS Borders
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
Peter Hall	Consultant - Oncology, NHS Lothian
Carol Holmes	Pharmacist - Primary care, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Kirsty Macfarlane	Regional Formulary Pharmacist, ERF Project Team
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 Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian (joined meeting late)
Sandra MacDonald	Meeting Administration, NHS Fife

Guests/Observing: Cathryn Park, Lead Pharmacist Acute Care & Medicines Governance / Deputy Director of Pharmacy (NHS Borders)

Apologies:
Ruth Cameron, Advanced Clinical Nurse Specialist – Urology, NHS Fife
Alison Casey, Senior Pharmacist Cancer Services, NHS Fife
Bryony Drummond, Senior Practice Pharmacist, NHS Fife
Lesley Macher, Lead Pharmacist Medicines Governance and Guidance , NHS Lothian
Dr Lucy Wall, Consultant – Oncology, NHS Lothian
Alison Wilson, Director of Pharmacy, NHS Borders

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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 (NHS Borders)
- Welcome - as above
- Leaving - Bryony Drummond (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 and the transition to the business-as-usual phase.

ERF Chapter 8 Malignant Disease and Immunosuppressants has now been launched. Outstanding actions relating to the Nutrition & Blood Chapter have now been completed and the updated Chapter is being prepared for uploading to the website.

Work on developing the Paediatric Formulary is progressing; the first meetings for Gastroenterology, Cardiovascular and Respiratory have been scheduled for late April.

Historic Formulary decisions are being reviewed and these will be updated when all three Boards transition to the website.

An update on the risk register was also given. The ERFC noted the two ongoing risks (potential loss of local engagement and impact on prescribing costs across the Boards). It was agreed that the risk around potential contradictions due to existence of three different websites be removed following transition to the ERF website.

The ERFC also noted that the ERF Pharmacy First chapter content has been updated in line with amendments to the national list.

The ERFC thanked Kirsty Macfarlane and other members of the project team for the work involved in implementation of the ERF.

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 requested clarification on SMC approval.

ACTION: NHS Fife Formulary Pharmacist

1.3.2 ERFC 30.11.22 Item 3.1.2 FAF1 Beclometasone dipropionate /formoterol fumarate dihydrate/glycopyrronium: Trimbow (SMC2335). Updated FAF1 received - discussed under agenda item 3.1.3.

1.3.3 ERFC 30.11.22 Item 3.1.12 FAF1 Belimumab: Benlysta (SMC2530) and (SMC2477) were reviewed at the ERFC November meeting. The ERFC requested clarification on the impact of the change in eligibility criteria as detailed in SMC2477 and clarification of any potential cost implications.

The ERFC discussed the additional information received. It was noted that the change in SMC eligibility criteria is not expected to impact on anticipated patient numbers/costs. Belimumab subcutaneous (SC) is currently dispensed in NHS Lothian via hospital dispensary however launch of a Homecare service in the near future is anticipated.

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

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

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

The ERFC discussed the additional information received. It was noted that there are differences in anticipated usage within the Boards. In NHS Lothian it is envisaged that Dexcom ONE would be used in a niche group of individuals where there are issues with Freestyle Libre 2 (e.g. skin reactions, patients who cannot tolerate adhesives) and there are no plans for a large-scale switch. No significant cost implications are anticipated. Discussions around proposed usage within NHS Fife are ongoing.

The ERFC agreed to classify Real-time Continuous Glucose Monitoring (rt-CGM): Dexcom ONE (rt-CGM) sensor only as Routinely available in line with local or regional guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Lothian Formulary Pharmacist

1.3.5 ERFC 30.11.22 Item 3.2.1 Morphine sulphate: Actimorph was reviewed at the ERFC November meeting. The ERFC requested clarification on the indication for use and that a FAF1/FAF3 be submitted. It was noted that no additional information has been received and the ERFC agreed that this item should be recorded as completed.

The ERFC agreed to classify Morphine sulphate: Actimorph 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.

ACTION: NHS Lothian Admin Team

1.3.6 ERFC 01.02.23 Item 3.1.1 FAF1 Ibrutinib: Imbruvica (SMC2259) was reviewed at the ERFC February meeting. 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.

Clarification on anticipated patient numbers for NHS Fife and use of combination therapy/single agent was received. SACT protocols and prescriptions are in the process of being written. In the meantime, the use of either Ibrutinib or R-Ibrutinib would be at the clinician's discretion. Action completed.

1.3.7 ERFC 01.02.23 Item 3.1.2 FAF1 Darolutamide: Nubeqa (SMC2297) was reviewed at the ERFC February meeting. 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.

The SCAN treatment protocol for men with high-risk non-metastatic castration resistant prostate (nm-CRPCa) was submitted which clarifies the positioning of darolutamide within the current Formulary pathways/treatment plans. Clarification of the criteria for darolutamide replacing bicalutamide was also noted.

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

ACTION: NHS Lothian Admin Team

1.3.8 ERFC 01.02.23 Item 3.1.4 FAF1 Ibrutinib: Imbruvica (SMC2387) was reviewed at the ERFC February meeting. 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.

Clarification of anticipated patient numbers for NHS Fife and use of combination therapy/single agent received. SACT protocols and prescriptions are in the process of being written. In the meantime, the use of either Ibrutinib or R-Ibrutinib would be at the clinician's discretion. Action completed.

1.3.9 ERFC 01.02.23 Item 3.1.5 FAF1 Asciminib: Scemblix (SMC2482) was reviewed at the ERFC February meeting. The ERFC requested further clarification on the proposed place in therapy and information on any replaced medicines. Replacement medicine costs also required to be clarified.

The ERFC discussed the additional information received. It was noted that asciminib would be used in line with the SMC recommendation, following at least 2 previous therapies/ tyrosine kinase inhibitors. Asciminib would not replace existing therapies but would give an additional option to patients that are refractory or intolerant to existing treatments. For patients with cardiovascular events asciminib may be the preferred option compared to ponatinib. Asciminib is cost effective compared to ponatinib.

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

ACTION: NHS Lothian Admin Team

1.3.10 ERFC 01.02.23 Item 3.1.8 FAF2 Rituximab: Ruxience was reviewed at the ERFC February meeting. Post meeting the ERFC noted that the SMC statement on biosimilars indicates that this medicine is considered within SMC remit. The ERFC agreed to write to the SMC for clarification prior to formulary classification.

It was noted that a response from the SMC is awaited.

To be brought back to ERFC under matters arising.

ACTION: ERF Meeting Admin

1.3.11 ERFC 01.02.23 Item 3.1.10 FAF3 Mycophenolate + Mycophenolic Acid was reviewed at the ERFC February meeting. The ERFC requested clarification on whether the intention was to include this indication in the existing shared care agreement for mycophenolate that is available on the Lothian Joint Formulary (LJF) website or whether a new shared care agreement specifically for uveitis was to be produced.

The ERFC noted that the existing shared care agreement is to be updated to include uveitis. Action completed.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 1 February 2023

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

2.2 East Region Working Group (ERWG) meeting minutes 8 March 2023

The minutes of the ERWG meeting on 8 March 2023 were noted for information.

The ERFC noted the proposed CNS chapter amendment ERF Adult - treatment of trigeminal neuralgia. It was noted that this formed part of the original CNS chapter review and has been supported by the ERWG.

The ERFC approved the proposed amendment ERF Adult - treatment of trigeminal neuralgia and agreed that a Formulary Amendment Form was not required.

2.3 East Region Formulary (ERF) sections for approval

2.3.1 Wound Care

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

The ERF chapter Wound Care (Adult) was discussed and the chapter content approved at the ERFC in November 2022. Following feedback from the wider teams within the Boards, various amendments have been made. The majority of the changes relate to clarification of the content rather than fundamental changes to products. Changes include the addition/amendment of information notes, changes to section titles, clarification of Specialist Initiation flags and the addition of links to the Wound Care Handbook and Scottish Drug Tariff. The proposed amendments have been agreed by all three Boards.

The ERFC noted the good collaboration across all three Boards and the proposals for further education associated work around wound care.

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

ACTION: NHS Lothian Admin Team

2.4 Website transition from LJF to ERF - for noting

The ERFC discussed the SBAR outlining the proposals for the transition of the LJF website to ERF.

The ERFC noted the aim is for adoption of the website platform by all three Boards by the end of April 2023. Formulary decisions on the platform are currently being reviewed and amended where appropriate to ensure that they reflect the new ERF content rather than historical LJF content. The interim solution pending availability of the ERF Paediatric Chapters was also noted.

The ERFC noted the SBAR - website transition from LJF to ERF and agreed with the proposed approach.

3 New Medicines

3.1 Formulary Application Forms (FAF)

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

The ERFC noted and discussed the previously circulated 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 medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.

It was noted that no local treatment protocol has 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 and confirmation of Clinical Director approval of the pathway/protocol to give assurance that they concur with the proposed place in therapy.

The ERFC noted the updated information to clarify the place in the pathway which was included in the additional information section of the revised FAF1. The proposed place within the ERF is 1st line within additional add on therapies for MDI (alternative to high ICS/LABA). Trimbow would provide an alternative to increasing Fostair from 100/6 to 200/6. An additional prescribing note relating to its potential benefit for patients on moderate dose ICS/LABA who are unlikely to benefit from high dose ICS is also proposed. The proposed place within the ERFC has been discussed with colleagues in all three boards and relevant Clinical Director approval confirmed.

The ERFC noted that proposed use would be in a small group of patients who do not show evidence of T2-high driven asthma where increase in ICS would be recommended. Due to the relatively small numbers of patients who would be considered eligible for treatment with Trimbow for this indication and complexities of identifying T2 patients, details of the ERF positioning would require to be clarified with the CEWG prior to amendment to the pathway.

ACTION: ERWG/NHS Fife Formulary Pharmacist

The ERFC discussed whether a Specialist Initiation Formulary flag would be appropriate due to potential difficulties with identifying T2 patients. A Specialist Initiation Formulary flag would also encompass initiation by Specialist health professionals in Primary Care settings. An ERF information note to be agreed with the CEWG.

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

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

3.1.2 FAF1 Imlifidase: Idefirix (SMC2445)

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

Indication: for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.

The draft local treatment protocol, British Transplantation Society guideline and finance budget template were included with the FAF. Imlifidase: Idefirix would be used for a very select group of patients as assessed by a national expert MDT. Imlifidase: Idefirix would be funded under a financial risk sharing scheme, with all Scottish Health Boards paying a proportion of the cost depending on the size of the Board.

Due to the small numbers of patients who would potentially be eligible for treatment with imlifidase within individual Boards and in order to minimise medicines waste, the ERFC was supportive of consideration being given to retention of stock centrally.

The ERFC requested that comments raised around potential central retention of stock be fed into national discussions.

ACTION: Dr Jane Goddard, Consultant – Renal, NHS Lothian

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

ACTION: NHS Lothian Admin Team

3.1.3 FAF1 Faricimab: Vabysmo (SMC2499)

The ERFC noted and discussed the previously circulated updated FAF1 submission. One personal specific and two personal non-specific interests were declared. CD support was received from all three Boards however individual names were not provided.

Indication: For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO). SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.

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

The proposed place in therapy is first line for DMO (aflibercept to move to second choice and ranibizumab to third choice for this indication). The ERFC noted that at present the pathway lists all options as equal first choice.

The ERFC discussed the supporting evidence provided and noted that evidence beyond two years is limited. The ERFC noted that there was no strong evidence presented to support the proposed order of use for faricimab compared to aflibercept and ranibizumab. The ERFC also noted that information presented in the financial details section was unclear, and could be

clarified by including additional details of unit costs and treatment regimen used. The application states that faricimab would not be replacing a current ERF choice medicine. The replaced therapy section has been completed however there is no information with regard to the comparator medicine, unit cost or treatment regimen used to calculate the cost of replaced therapy. It was noted that there are associated monitoring and administration costs, it is not clear if they are included in the costs shown. The application also states that no discount is available however there is an approved Patient Access Scheme for faricimab and confidential contract prices may apply for the comparator product(s).

The ERFC requested clarification on patient numbers/costs and information from all three Boards on the proposed order/positioning of faricimab compared to other therapies in the pathway. The ERFC also requested details of CD support.

ACTION: ERFC Meeting Admin

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

ACTION: NHS Lothian Admin Team

3.1.4 FAF1 Faricimab: Vabysmo (SMC2512)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific interest was declared. CD support was received from all three Boards however individual names were not provided.

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

The ERFC noted that the same individual has completed the form as applicant and supporting pharmacist. It was noted that the application is supported by a consultant in PAEP and SJH.

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

The proposed place in therapy is second choice within a treatment pathway. Faricimab offers an additional treatment choice in the therapeutic class of antineovascularisation agents for this indication. Patient selection will be by Consultant dependant on response to Eylea. Ranibizumab is the current first choice in the treatment pathway, Eylea second and brolocizumab third. The ERFC noted that there was no strong evidence presented to support the proposed order of use for faricimab compared to aflibercept and ranibizumab.

The ERFC noted that details of service/staffing implications at board level were not included with the submission. Clarification of the cost of faricimab and replaced therapy is also required.

The ERFC requested details of service/staffing implications and clarification of the cost of faricimab and replaced therapy. The ERFC also requested details of CD support and confirmation of separate applicant/supporting pharmacist support.

ACTION: ERFC Meeting Admin

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

ACTION: NHS Lothian Admin Team

3.1.5 FAF1 Nivolumab: Opdivo (SMC2503)

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

Indication: as monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥1%, who are at high risk of recurrence after undergoing radical resection of MIUC.

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

The proposed place in therapy is first choice within a treatment pathway. There are no therapeutic treatment options currently approved in the adjuvant setting MIUC post-surgery however use of immunotherapy in the adjuvant setting is likely to reduce use in the metastatic setting.

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

ACTION: NHS Lothian Admin Team

A discussion on the process for confirmation of CD support for applications for SCAN medicines to the ERFC followed. To be raised at the next SCAN meeting for formal agreement that the previous approach for applications to the LJF should remain in place for applications to the ERFC.

ACTION: NHS Lothian Associate Director of Pharmacy

3.1.6 FAF2 Ceftazidime-avibactam: Zavicefta

The ERFC noted that the FAF2 application for Ceftazidime-avibactam: Zavicefta was not required and the application was withdrawn from the agenda.

3.1.7 FAF2 DEKA plus

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. CD support was received from NHS Fife and NHS Lothian. There were no supporting pharmacist details on the application.

Indication: vitamin supplementation in adult Cystic Fibrosis where a multivitamin preparation is required and high dose vitamin K is not desirable.

No local treatment protocol has been developed. The finance template was included with the FAF. The proposed place in therapy is second choice within a treatment pathway (first choice will remain vitamins A+D plus vitamin E). DEKA would be used in patients with a high pill burden who do not require high dose vitamin K. It is proposed that DEKA would be initiated in Clinic and prescribing would be continued in Primary Care.

The ERFC noted that this patient group would be treated in NHS Lothian however there would be ongoing Primary Care prescribing within the three Boards.

A discussion on the requirement for CD support from all three Boards for specialist medicines that are entirely dealt with in one Health Board ensued and the ERFC agreed that further clarification was required.

The ERFC agreed that clarification around CD support for applications for specialist medicines was required.

ACTION: NHS Lothian Associate Director of Pharmacy

The ERFC requested separate applicant/supporting pharmacist details and confirmation of NHS Borders CD support.

ACTION: ERFC Meeting Admin

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

ACTION: NHS Lothian Admin Team

3.1.8 FAF3 Mycophenolate Mofetil

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

Indication: Immunobullous disorders; Eczema

A local treatment protocol has not been developed. The finance budget template was included with the FAF. The draft ERF pathways for Autoimmune Bullous Dermatoses and Eczema were also included with the FAF.

It was noted that mycophenolate mofetil is a licensed product; the proposed indications for use are unlicensed.

The proposed place in therapy is moderate to severe immunobullous disorders alongside conventional therapies such as potent topical corticosteroids and systemic corticosteroids and moderate to severe eczema when other preferred options (topical corticosteroids, ciclosporin, methotrexate, azathioprine and dupilumab) are contraindicated or subtherapeutic. There was no information provided on cost of replacement therapies for use in eczema.

The ERFC discussed the evidence for use. The proposed delivery route would be via shared care agreement. The ERFC noted that the intention is that these indications are included in the existing Shared Care Agreement for mycophenolate mofetil. The proposed 12 week supply period however is not in line with the existing Shared Care Agreement for mycophenolate mofetil (8 weeks supply).

The ERFC discussed the proposed place in therapy. Information on dose titration to minimise side effects was also highlighted. It was noted that the methylprednisolone products in the ERF pathway for autoimmune bullous dermatoses are all injectable formulations and it was suggested that consideration be given to addition of an oral formulation. It was noted that the ERF pathways are out for discussion and are subject to further refinement.

The ERFC agreed that further refinement of the pathways and clarification of place in therapy was required.

ACTION: ERWG/NHS Lothian Formulary Pharmacist

The ERFC agreed to classify Mycophenolate Mofetil as Routinely available in line with 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: NHS Lothian Admin Team

3.2 Formulary Amendment Forms

3.2.1 Benilexa

The ERFC noted and discussed the previously circulated formulary amendment form. One personal non-specific declaration of interest was received. Clinical and Pharmacist support received from all three Boards.

Indication: Contraception, Heavy Menstrual Bleeding

Application to include Benilexa Hormone-releasing Intrauterine Device (IUD)/System in the ERF. Benilexa is a one-handed insertion device and is cost effective compared to Mirena and Kyleena. Levosert is more cost effective compared to Benilexa however Levosert is a two-handed insertion device and potentially more technical to use. The proposed ERF position is joint first choice alongside current 52mg Levonorgestrel-releasing IUDs. Benilexa would not replace an existing ERF medicine.

The ERFC agreed to classify Benilexa as Routinely available in line with regional prescribing guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

3.2.2 Dapagliflozin

The ERFC noted and discussed the previously circulated formulary amendment form. One personal non-specific declaration of interest was received. NHS Borders and NHS Fife were not consulted on the proposed amendment.

Indication: In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

Application to include dapagliflozin in the ERF to align diabetes therapy with other current formulary approved indications for SGLT2 inhibitors and to simplify prescribing. The proposed position is second choice within a treatment pathway. The amendment was discussed at the Lothian diabetes prescribing group and agreed as a way of simplifying drug prescribing within the SGLT2i class. An SBAR – Managing Cross Specialty Prescribing in the SGLT2i Drug Class in Lothian was included with the FAF. There are no anticipated cost implications.

The ERFC noted that the proposal is that dapagliflozin would not replace another ERF medicine and requested that consideration be given to potential rationalisation to two products going

forward. The ERFC also requested clarification that the formulary amendment request is in line with SMC approval.

The ERFC noted that NHS Borders and NHS Fife were not consulted on the proposed amendment. Feedback from NHS Borders representatives at the meeting was that NHS Borders would be supportive of the proposed amendment. The ERFC requested confirmation of support from NHS Fife.

The ERFC requested confirmation of NHS Fife support for the proposed Formulary amendment and confirmation that the amendment is in line with SMC approval.

ACTION: NHS Fife Formulary Pharmacist/ERFC Meeting Admin

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

ACTION: NHS Lothian Admin Team

3.2.3 Famotidine

The ERFC noted and discussed the previously circulated formulary amendment form. One personal non-specific declaration of interest was received. Support received from all three Boards.

Indication: Gastric and duodenal ulceration

Application to replace ranitidine with famotidine due to supply issues with ranitidine. An alternative ERF H2 receptor antagonist medication is required.

The ERFC noted that there was no supporting pharmacist details on the application. The NHS Borders Formulary Pharmacist confirmed support for the application.

The ERFC agreed to classify Famotidine as Routinely available in line with regional prescribing guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Borders Formulary Pharmacist

3.2.4 Fondaparinux

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

Indication: Heparin induced thrombocytopenia

Application to change Specialist Use only Formulary flag to Specialist Initiation due to practical issues regarding ongoing prescribing in Secondary Care.

The majority of patients eligible for treatment would be under review in NHS Lothian. Fondaparinux would be initiated by a specialist with ongoing prescribing in Primary Care. All follow up would be done by the specialist clinic. The ERFC discussed whether a Shared Care Agreement was required and agreed that this would be a decision for individual Boards.

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

ACTION: NHS Lothian Admin Team

3.2.5 Sodium hyaluronate 0.2% eye drops preservative free

The ERFC noted and discussed the previously circulated formulary amendment form. One personal non-specific declaration of interest was received. Support received from all three Boards.

Indication: Severe Dry Eyes (adult and children's indications)

Application to replace Hylo-forte brand with generic sodium hyaluronate 0.2% eye drops preservative free.

The ERFC noted that there are other brands of sodium hyaluronate 0.2% eye drops preserve free available that are most cost effective compared to Hylo-forte.

The ERFC noted that the same individual has signed the application as both applicant and supporting pharmacist.

The ERFC requested that the applicant be made aware that separate applicant and supporting pharmacist details are required. It was agreed that the application did not require to be brought back to the ERFC.

ACTION: ERFC Meeting Admin

The ERFC agreed to classify Sodium hyaluronate 0.2% eye drops preservative free as Routinely available in line with regional prescribing guidance. Included on the ERF. The formulary website will be updated.

ACTION: NHS Lothian Admin Team/NHS Borders Formulary Pharmacist

3.3 Ultra-Orphan Pathway

3.3.1 Burosumab: Crysvita (SMC2514)

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

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.4 SMC not recommended advice

3.4.1 There was no SMC not recommended advice for noting.

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Estradiol / micronised progesterone: Bijuve (SMC2502)

The ERFC noted the SMC abbreviated submission Estradiol / micronised progesterone: Bijuve (SMC2502).

Indication: Continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.

The ERFC noted that the SMC advice was published in September 2022 and at that time there was no request for ERF inclusion. Following further discussion with specialists ERF inclusion has now been requested and the pathway has been developed for review by the ERWG.

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

ACTION: NHS Lothian Admin Team/NHS Fife Formulary Pharmacist

3.5.2 Upadacitinib: Rinvoq (SMC2532)

The ERFC noted the SMC abbreviated submission Upadacitinib: Rinvoq (SMC2532).

Indication: Treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) in adult patients with objective signs of inflammation (OSI) as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

The ERFC noted that NHS Lothian and NHS Fife are supportive of ERF inclusion. At the time of the ERFC meeting there was no feedback from NHS Borders however a recent application for upadacitinib for active radiographic ankylosing spondylitis was supported by NHS Borders. It was proposed that active nr-axSpA be added to the existing ERF pathway for active radiographic ankylosing spondylitis and the pathway name be amended to reflect both indications.

The ERFC requested that the pathway be shared with the three Boards for agreement on the terminology used.

ACTION: **ERWG/NHS Borders Formulary Pharmacist**

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

ACTION: NHS Lothian Admin Team

3.5.3 Eptinezumab: Vyepti (SMC2547)

The ERFC noted the SMC abbreviated submission Eptinezumab: Vyepti (SMC2547).

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

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

The ERFC agreed to classify Eptinezumab: Vyepti as Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.6 Paediatric licence extensions

3.6.1 N/A.

3.7 Non-submissions within 90 days of SMC publishing

The ERFC noted the non-submissions within 90 days of SMC publishing.

3.7.1 Pembrolizumab: Keytruda (SMC2501)
3.7.2 Nintedanib: Ofev (SMC2513)
3.7.3 Bulevirtide: Hepcludex (SMC2520)
3.7.4 Pralsetinib: Gavreto (SMC2496)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3 and 3.7.4 as Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

4 Central Alerting System COVID-19 Alerts

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

5 National Cancer Medicines Advisory Group

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

6 Board specific information

6.1 NHS Borders
None raised.

6.2 NHS Fife
The ERFC noted that a Formulary Amendment for mesalazine: Pentasa is being finalised for review at the June meeting.

6.3 NHS Lothian
None raised.

7 Any other competent business
None raised.

8 Date of next meeting
The next ERFC meeting is scheduled for Wednesday 7 June 2023. NHS Lothian will be hosting the meeting.
FAF3s should be submitted by 2 May 2023 (for discussion at the ERWG meeting on 17 May 2023).
FAF1s and FAF2s should be submitted by 23 May 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