East Region Formulary

East Region Formulary Committee
Minutes

Date: 28 September 2022
Time: 2pm – 4pm
Location: MS Teams

Present:

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

Guests/Observing:
Dr Prabath Amarasinghe
Sandra MacDonald, NHS Fife
Kirsten Thomson, NHS Borders
Dr Kapila Wickramanayake

Apologies:
Ruth Cameron, Advanced Clinical Nurse Specialist – Urology, NHS Fife
Gillian Donaldson, Nurse – Cardiology, NHS Borders
Dr Peter Hall, Consultant – Oncology, NHS Lothian
Kirsty Macfarlane, Regional Formulary Pharmacist, ERF Project Team

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 - Sandra MacDonald, NHS Fife; Kirsten Thomson, NHS Borders; Dr Prabath Amarasinghe and Dr Kapila Wickramanayake, both from Sri Lanka, guests of Dr Watson, NHS Lothian.
- Welcome - Alison Casey, Senior Pharmacist Cancer Services, NHS Fife.
- Leaving - Fiona Grant, NHS Borders.
- 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. Adult Chapters still to be completed are Malignant Disease, Wound Care and Nutrition & Blood; expected by the end of the year.

1.3 Matters arising

1.3.1 ERFC 27.07.22 item 3.1.1 FAF1 Formoterol fumarate dihydrate / glycopyrronium / budesonide: Trixeo Aerosphere (SMC2321) was reviewed at the ERFC July meeting. The ERFC had requested response to two questions: 1) a clear indication for addition to ERF of Trixeo in addition to the other triple MDI Trimbow, and 2) was there clinical benefit in the ERF choice changing to Trixeo. The ERFC heard a summary of the responses received. There is support from three Boards as well as from an Advanced Physiotherapist Practitioner and a Practice Nurse, both NHS Lothian. The ERFC agreed that the questions had been answered and that the additional evidence shows benefit in outcome.

<u>The proposed place in therapy is as an alternative triple therapy MDI to Trimbow.</u>

<u>The ERFC agreed to classify Formoterol fumarate dihydrate / glycopyrronium / budesonide: Trixeo Aerosphere as Routinely available in line with national guidance. Included on the ERF. The formulary website will be updated.</u>

ACTION: ERF Project Team

1.3.2 ERFC 27.07.22 item 3.1.5 FAF 1 Pembrolizumab: Keytruda (SMC2420) no declarations of interest confirmed for pharmacist applicant.

1.3.3 ERFC 27.07.22 item 3.1.7 FAF1 Abrocitinib: Cibinqo (SMC2431) the clinical experts clarified the treatment pathway.

1.3.4 ERFC 27.07.22 item 3.1.8 FAF 1 Relugolix, estradiol, norethisterone acetate tablets: Ryeqo (SMC2442) – NHS Fife CD support and figures provided.

1.3.5 ERFC 27.07.22 item 3.1.9 FAF 2 Tenofovir AF/Emtricitabine: Descovy – response to confirm that national guidelines are currently under review and will include Tenofovir AF/Emtricitabine: Descovy for this indication. Service delivery will be with the Sexual Health teams in Fife and Borders and leads of services have seen and approve the guideline - completed.

1.3.6 ERFC 27.07.22 item 3.2.3 Fidaxomicin 40mg/ml oral suspension NHS Fife and NHS Borders support the application.

1.3.7 ERFC 27.07.22 item 4.1 Barcitinib: Olumiant (Local application). A formulary amendment form has been completed from NHS Lothian and supplied numbers for patients.
Indication: For hospitalised patients with COVID-19 (Adults aged 18 and over) in line with local or regional guidance and coronavirus (COVID-19) alerts issued by the MHRA Central Alerting System. The most up to date national CMO guidance can be found here: https://www.cas.mhra.gov.uk/Help/CoronavirusAlerts.aspx. The adult guideline in Lothian has been updated; Fife has guideline and Borders are in process of updating their guideline. The ERFC approved formulary inclusion of Baricitinib in line with CMO guidance for adult patients only. For use in paediatrics discuss with paediatric specialists and follow local board non-formulary procedures.

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

ACTION: ERF Project Team

1.3.8 ERFC 27.07.22 item 6.1 FAF2 Gadobutrol: Gadovist – ERF Project Team confirmed that Gadobutrol: Gadovist has been included on ERF website in Formulary Decisions section and noted that it is not yet included in the therapeutic area section of the website. The ERFC agreed that future pathway development will be noted for review.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 27 July 2022.

The minutes of the previous meeting were approved as an accurate record with the following changes - update iperacillin with Tazobactam item 3.1.12 to reflect use in the critical care population and incorporate comments highlighted by ERWG to be updated.

The ERFC 27.07.2022 minute to be updated as above.

ACTION: Meeting Admin

2.2 East Region Working Group (ERWG) meeting minutes 7 September 2022

The minutes of the ERWG meeting were noted for information.

2.2.1 SBAR for noting from ERWG - SMC Ultra-Orphan Initial Assessment: Formulary Decisions. Wording to be used for ultra-orphan medicine decisions was outlined and the ERFC approved.

2.2.2 SBAR for noting from ERWG - NCMAG National Cancer Medicines Advisory Group: Formulary Applications and Decisions. The ERWG agreed to continue to use FAF 2 for off-patent and FAF 3 for off label applications. The ERFC approved this decision.

2.3 East Region Formulary (ERF) sections for approval

2.3.1 Anaesthesia

It was noted that there was a discussion around safety of formulations and vial and ampoule sizes of all the different anaesthetics; a decision was made to reduce the number of dose and formulation options for preparations which were available so that we would reduce the number of vial sizes for practitioners to select in theatres. Also reviewed dosage regimen for all the specialist anaesthetic agents and felt there was no benefit in adding the dosing instructions; these have been omitted throughout the document. Outstanding discussion on this draft was regarding ethyl chloride; specialists agreed that it was useful to have available for assessment of regional block and also as a topical analgesia in Paediatrics. Proposing to approve chapter as shared and add ethyl chloride spray into relevant pathway. Question was raised about Nitrous Oxide and why this was on formulary and once more information is received from NHS Lothian colleagues, the ERFC will review. The ERFC agreed to change the category for methoxyflurane to SUO. Detailed development notes are included at 2.3.8. The ERFC approved with amendments and actions as noted.

Forward email trail on nitrous oxide to be discussed with the chapter expert group.

ACTION: N Cromer

Confirm whether Penthrox methoxyflurane is restricted to use in neurosurgery .

ACTION: ERF Project Team

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

ACTION: ERF Project Team

CNS 3 was split into different CEWGs as shown in the sections below. Detailed development notes are included at 2.3.9.

2.3.2 CNS 3 – Dementia, Parkinson's, MS and Neuro-muscular

It was noted that, once developed, there will links to all three Boards MS guidelines. In RRMS pathway Diroximel fumarate was flagged as Specialist Initiation with everything else in pathway flagged as Specialist Use only and the ERFC agreed that Diroximel fumarate should be changed to Specialist Use only.

Propranolol has a warning for risk in overdoes and this should be repeated in the essential tremor. Parkinson's section – agreed to change to generic rather than branded products Sinemet and Madopar. Pathway for dementia prescribing has a repeat of wording 'refer to specialist services' to be reviewed.

ACTION: Chapter Expert Working Group – CNS 3

The ERFC approved the new chapter content with changes as noted. The formulary website will be updated.

ACTION: ERF Project Team

2.3.3 CNS 3 – Nausea and Vertigo

It was noted that chemo induced nausea and vomiting will be covered with Chapter 8 with Malignant Disease. Issues surrounding peri-operative nausea and vomiting are still under discussion with work on-going.

The ERFC approved the new chapter content. The formulary website will be updated when on-going work is completed.

ACTION: ERF Project Team

2.3.4 CNS 3 – Poisoning

It was noted that no drugs are included in this section – directing prescribers to Toxbase.

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

ACTION: ERF Project Team

2.3.5 CNS 3 – Migraine

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

ACTION: ERF Project Team

2.3.6 CNS 3 – Epilepsy

Prescribing bullet points relating to requirement for brand prescribing of antiepileptic medicines have been simplified with a link to MHRA for further detail. Added Everolimus for partial onset seizures which was omitted from original draft; with dosage instructions as directed by the Specialist. Buccal midazolam changed to general use when used by GPs for emergency treatment of seizures.

The ERFC approved the new chapter content with changes noted above. The formulary website will be updated.

ACTION: ERF Project Team

2.3.7 CNS 4 – Pain

It was noted that badging of IV Paracetamol to specialist use only has been agreed. The ERFC discussed branded vs generic of strong opioids morphine and oxycodone MR formulation. The current practice in the three Boards was reviewed and the formulary entry is a compromise which includes all options – generic preparations, Zomorph brand, Oxypro MR and Long tec. Agreed that safe advice for patients who weigh less than 50kg the maximum dose would be 500mg Paracetamol regardless of route – oral or IV; same applies when in combination with Dihydrocodeine or Codeine. Fentanyl patches included; no brand specified with matrix, as the formulary option, to enable them to be cut for dose titration. The ERFC approved these updates.

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

ACTION: ERF Project Team

2.3.8 Chapter development notes document for Anaesthesia

The ERFC noted the development notes.

2.3.9 Chapter development notes document covering all CNS 3

Obesity pathway will be covered in Nutrition & Blood.
The ERFC noted the development notes.

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Inclisiran: Leqvio (SMC2358)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific interest and one non-personal non-specific declaration of interest were received. CD support received from all three Boards.

Indication: for 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 who are 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 are statin intolerant, or for whom a statin is contraindicated.

SMC restriction: for specialist use only in patients at high cardiovascular risk as follows:

- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or,
- patients with HeFH and LDL-C≥3.5mmol/L, for secondary prevention of cardiovascular events or,
- patients with high risk due to previous cardiovascular events and LDL-C≥4.0mmol/L or,
- patients with recurrent/polyvascular disease and LDL-C≥3.5mmol/L.

In three phase III studies, both the percentage reduction in LDL-C to day 510 and the time-adjusted percentage in LDL-C from day 90 to day 540 were significantly larger with inclisiran compared with placebo.

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

The ERFC agreed to classify Inclisiran: Leqvio 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 Empagliflozin: Jardiance (SMC2396)

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

Indication: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

Empagliflozin offers an additional treatment choice in the therapeutic class of sodium glucose co-transporter 2 inhibitors in this indication.

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

There is good evidence available; Empagliflozin reduces the risk of cardiac death and hospitalisation for heart failure. It is included now in the European and American guidelines for treatment of heart failure and is very much accepted within the cardiovascular community. It is an SGLT2 inhibitor and is second one used after Dapagliflozin. Patient numbers discussed. No cost difference noted. Patient information leaflet included with application.

The ERFC agreed to classify Empagliflozin: Jardiance 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/Meeting Admin

3.1.3 FAF1 Atezolizumab: Tecentriq (SMC2267)

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

Indication: Atezolizumab in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received prior chemotherapy for metastatic disease.

In a randomised, double-blind, phase III study, the addition of atezolizumab to nab-paclitaxel significantly improved progression-free survival and numerically improved overall survival in patients with locally advanced or metastatic triple-negative breast cancer with PD-L1 expression ≥1% who had not received prior chemotherapy for metastatic disease.

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

The ERFC questioned the wording of the SMC advice – no prior treatment for metastatic TNBC. The treatment is not meant for third and fourth line use, ERFC requested clarification on the SMC approval. Should SMC approval state that approval was for treatment in patients who had received no previous treatment for locally advanced or metastatic treatment?

Clarification required on SMC approval.

ACTION: ERF Chair

The ERFC agreed to classify Atezolizumab: Tecentriq 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 Chair

3.1.4 FAF1 Olaparib; Lynparza + Bevacizumab: Aybintio (SMC2368)

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

Indication: in combination with bevacizumab for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability.

In a phase III study, maintenance treatment with olaparib plus bevacizumab significantly prolonged progression-free survival (PFS) compared with placebo plus bevacizumab in patients with advanced ovarian cancer who responded to first-line standard therapy including bevacizumab.

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

Formulations and evidence outlined. First choice in treatment pathway. Route of supply will differ between Boards.

The ERFC agreed to classify Olaparib; Lynparza + Bevacizumab: Aybintio as Routinely available in line with national guidance. Included on the ERF for Specialist use only. The formulary website will be updated.

ACTION: ERF Project Team

3.1.5 FAF1 Sacituzumab Govitecan: Trodelvy (SMC2446)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest was received. CD support received from all three Boards.

Indication: Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease.

Sacituzumab govitecan, compared with a range of single-agent chemotherapies, significantly improved progression free survival and overall survival in adults with mTNBC, without brain metastases, who had received at least two prior chemotherapy regimens including a taxane.

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

Patient selection criteria, is noted as “or second line in patients that received neo adjuvant therapy within the last 12 months” the ERFC requests clarification that this is intended as patients who had relapsed after at least two prior lines of chemotherapies (one of which could be in the neoadjuvant or adjuvant setting provided progression occurred within a 12 month period. The ERFC noted that patient numbers are higher than predicted in the SMC budget impact assessment and therefore requested confirmation that patient numbers are correct for the region.

The ERFC requested clarification that the place in therapy of the medicine will be updated in clinical management guidelines.

The ERFC asked for confirmation of place in therapy, patient criteria wording and patient numbers.

ACTION: Meeting Admin

The ERFC agreed to classify Sacituzumab Govitecan: Trodelvy 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 FAF2 Dermatonics Once Heel Balm

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

Indication: very dry skin conditions affecting the feet.

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

Prescribing note would need to be changed from hands and feet to just feet. No additional guidelines available; a 25% Urea foot cream was previously on NHS Fife formulary for use where a step up from 10% is required.

The ERFC agreed to classify Dermatonics Once Heel Balm as Routinely available in line with local or regional guidance. Included on the ERF. The formulary website will be updated.

ACTION: ERF Project Team

3.1.7 FAF3 Loperamide 2mg orodispersible tablets sugar free: Imodium Instant Melts and Loperamide 2mg capsules

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

Indication: Reduction in stoma output (high output stomas).

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

Application discussed by the ERWG who supported ERFC approval. The ERWG asked whether orodispersible and capsules are to be both made available (orodispersible has a sweetener that some patients may need to avoid). Lothian and Fife wish to have both preparations; Borders to follow this up with the service. Monitoring would be indicated for patients are on high dose long term use. Guideline and patient information available in Lothian which Fife and Borders acknowledge would be appropriate to use.

Confirm if Borders require both orodispersible and capsules.

ACTION: NHS Borders Formulary Pharmacist

The ERFC agreed to classify Loperamide 2mg orodispersible tablets sugar free: Imodium Instant Melts and Loperamide 2mg capsules as Routinely available in line with local guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: ERF Project Team

3.2 Formulary Amendment Forms

3.2.1 Emollin aerosol spray

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

Indication: Dermatitis – contact requiring treatment with emollients (special circumstances) & eczema requiring treatment with emollients (special circumstances)

Application to remove Dermamist 10% spray, which is being discontinued, and replace with Emollin aerosol spray.

The ERFC agreed to classify Emollin aerosol spray as Routinely available in line with local prescribing guidance. Included on the ERF. The formulary website will be updated.

ACTION: ERF Project Team

3.2.2 Alendronic acid 70mg effervescent tablets

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

Indication: Osteoporosis.

Change in treatment pathway from first line along with standard non effervescent 70mg tablet to restricted to use in patients who cannot swallow tablets.

The ERFC agreed to classify Alendronic acid 70mg effervescent tablets as Routinely available in line with local prescribing guidance. Included on the ERF. The formulary website will be updated.

ACTION: ERF Project Team

3.2.3 Aspirin 75mg dispersible tablets

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

Indication: Management of peripheral arterial disease.

Included in Cardiovascular section as non-dispersible option. Request to change this to dispersible.

The formulary website will be updated.

ACTION: ERF Project Team

3.2.4 Losartan

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

Indication: Use in the management of heart failure.

Formulary has a maximum dose of 100mg; the BNF has a maximum dose of 150mg for this indication. The ERFC agreed to change formulary to match BNF.

The formulary website will be updated.

ACTION: ERF Project Team

3.2.5 Metolazone: Xaqua

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

Indication: Resistant oedema.

Remove 2.5mg tablet as it is unlicensed; there is a licensed 5mg tablet now available; called Xaqua. There is a caution that it is not interchangeable with other metolazone preparations. It has twice the bio-availability of the other metolazone preparations that are currently in use. The current metolazone preparations are unlicensed. Concerns were discussed about the switch to the licensed preparation and the CEWG will discuss and advise a plan. The ERFC agreed that this change would not be approved currently and that a warning/information note should be added to the current formulary entry; to issue prescribing bulletin information and awareness to community pharmacies regarding the associated dangers.

To come back to November ERFC after the chapter expert working group have agreed; immediate warning note to be issued in meantime.

ACTION: NHS Borders Formulary Pharmacist

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

ACTION: ERF Project Team

3.2.6 Prednisolone

The ERFC noted and discussed the previously circulated formulary amendment form. One non-personal, non-specific declaration of interest was received.

Indication: Idiopathic pulmonary fibrosis (IPF) and other chronic fibrosing interstitial lung diseases.

Prednisolone to be first line; with Nintedanib or MMF as second line for chronic fibrosing ILD (IPF not included). Formulary amendment as Prednisolone was not in the pathway of treatment approved at previous FAF for MMF.

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

ACTION: ERF Project Team

3.2.7 Bevacizumab: Zirabev

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

Indication: various cancer indications approved by the SMC for the originator product SMC 1135/16, SMC 806/12, and SMC 1063/15.
Application on behalf of SCAN team to replace one biosimilar with another; replacing existing formulary choice of bevacizumab with Zirabev brands.

The ERFC agreed to classify Bevacizumab: Zirabev 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

3.3 Ultra-Orphan Pathway

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

3.3.1 Velmanase alfa: Lamzede (SMC2466)

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

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Zanubrutinib: Brukinsa (SMC2452)3.4.2 Remimazolam: Byfavo (SMC2454)

The ERFC agreed to classify each of these medicines as Not routinely available as not recommended for use in NHSScotland. The formulary website will be updated.

ACTION: ERF Project Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions 3.5.1 – 3.5.4. There has been request to use three of the medicines form Borders but no response from Fife and Lothian. How can the applications progress for Borders if there is no engagement elsewhere. We would lose engagement of clinicians if this is not progressed. Until the clinicians apply they would be stated as Not Routinely available on website.

The ERFC agreed that the local clinical experts should be contacted to confirm whether these items have a place on the ERF and the necessary amendments to the website. The communication with clinical experts should be progressed as follows: Skin – Diane Murray; Respiratory – Fraser Notman; HRT – Liz Leitch

ACTION: Formulary Pharmacists to progress amendments / discuss with teams.

3.5.1 Trifarotene: Aklief (SMC2441)

The ERFC noted the SMC abbreviated submission Trifarotene: Aklief (SMC2441).

Indication: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. Trifarotene provides an additional treatment choice in the therapeutic class of topical retinoids.

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

ACTION: ERF Project Team

3.5.2 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. Estradiol / micronised progesterone (Bijuve®) offers an additional treatment choice of continuous combined hormone replacement therapy.

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

ACTION: ERF Project Team

3.5.3 Somatrogon: Ngenla (SMC2493)

The ERFC noted the SMC abbreviated submission Somatrogon: Ngenla (SMC2493).

Indication: for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone. Somatrogon offers an additional treatment choice in the therapeutic class of recombinant human growth hormones for this indication.

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

ACTION: ERF Project Team

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

The ERFC noted the SMC abbreviated submission Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium: Trimbow (SMC2334).

Indication: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium (Trimbow®) offers an additional treatment choice of high dose inhaled corticosteroid (ICS), long-acting beta2-agonist (LABA) and long-acting muscarinic antagonist (LAMA) in a single inhaler. SMC has previously accepted an alternative LAMA as an add-on treatment to ICS and LABA in asthma.

The ERFC agreed to classify Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium: Trimbow as Not routinely available as local implementation plans are being developed or the ERFC is waiting for further advice from local clinical experts. The formulary website will be updated.

ACTION: ERF Project Team

3.6 Paediatric licence extensions

3.6.1 No paediatric licence extensions were requested for formulary inclusion by local clinical teams at the time of the ERFC meeting.

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 Potassium citrate - potassium hydrogen carbonate: Sibnayal (SMC2409)
3.7.2 Imlifidase: Idefirix (SMC2445)
3.7.3 Daratumumab: Darzalex (SMC2447)
3.7.4 Nivolumab: Opdivo (SMC2458)
3.7.5 Roxadustat: Evrenzo (SMC2461)
3.7.6 Tofacitinib: Xeljanz (SMC2463)
3.7.7 Apalutamide: Erleada (SMC2472)
3.7.8 Atezolizumab: Tecentriq (SMC2492)

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.

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 - FAF1 Delta-9 tetrahydrocannabinol: Sativex (SMC2473)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from NHS Borders only.

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

Indication: As treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

In four phase III/IV studies, Sativex® was associated with greater improvements in patient reported spasticity symptom numerical rating score (NRS) and response rate compared with placebo.

Application from Borders, sent to Lothian and Fife with no response from either on numbers or CD support, although support from Lothian confirmed in email to be forwarded. Patient numbers for Borders of 6 patients and estimated 12 numbers in Lothian. The ERFC heard from both Boards on the current situation with receiving support.

Information from all Boards is required for decision making. If waiting for clinical information, non-formulary request forms to be used until information is clarified and it can be approved. Discussed if the applicant submitting should get consensus with discussion with specialist teams from Boards and that submission is incomplete until this is done. Contact with all three Boards is routinely done as part of the process. Formulary pharmacists are routinely involved in the submission process. The ERFC agreed there was a difference between no response and not wanting to use.

The ERFC agreed that, for this particular FAF1, information needs to come from Boards in an email, as an audit trail copying in clinicians and clinical director who supports, and then the application can be amended and completed.

The ERFC requested information from Lothian and Fife to be forwarded by email to Borders formulary pharmacist at which time approval can be given.

ACTION: Lothian and Fife Formulary Pharmacists/ERF Meeting Admin/ERF Project Team

The ERFC agreed to classify Delta-9 tetrahydrocannabinod: Sativex as Routinely available in line with national prescribing guidance. Included on the ERF for Specialist Use only. The formulary website will be updated once above information is received.

ACTION: ERF Project Team

6.2 NHS Fife - FAF1 Liraglutide: Saxenda (SMC2455)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from NHS Fife only.

No local treatment protocol has been developed, for NHS Fife a treatment pathway was included with the application, and finance budget template was included with the FAF.

Indication: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:

- ≥30kg/m² (obese), or
- ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

SMC restriction: BMI ≥35kg/m²* (obesity class II and above) with:

- Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either:
  - Fasting plasma glucose level of 5.5 to 6.9mmol/L or
  - HbA1c of 6.0 to 6.4% (42 to 47mmol/mol), and
- High risk of cardiovascular disease (CVD):
  - Total cholesterol >5mmol/L, or
  - High-density lipoprotein (HDL) <1.0mmol/L for men and <1.3mmol/L for women, or
  - Systolic blood pressure (SBP) >140mmHg

Patients should be treated in a specialist weight management service.

In a phase III study, liraglutide, as an adjunct to diet and exercise, was associated with significant reduction in body weight compared with placebo in patients with BMI ≥30kg/m² or ≥27kg/m² if they had dyslipidaemia or hypertension.

*a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.

The ERFC discussed the patient numbers, prescribing and weight management service support. Concern raised about the number of patients already asking for this drug. The ERFC agreed that they could not approve until the above concerns were addressed. CD support is required from each Board. The ERFC did not approve inclusion on the formulary, any individual requests for prescribing to follow local board non-formulary process..

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

ACTION: ERF Project Team/Meeting Admin

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 30 November 2022.
The ERFC agreed that NHS Fife would host November meeting.
FAF3s should be submitted by 25th October 2022 (for discussion at the ERWG meeting on 9th November 2022).
FAF1s and FAF2s should be submitted by 15th November 2022.

All FAFs need to include information on proposed use and confirmation of clinical director (or equivalent medical manager) support from all three boards, 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