East Region Formulary

East Region Formulary Committee
Minutes

Date: 25th May 2022
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	Lead Pharmacist, ERF Project Team
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Steven Fenton	Project Manager, ERF Project Team
Jane Goddard	Consultant – Renal, NHS Lothian
Fiona Grant	Physiotherapist, NHS Borders
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
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant Cardiologist, 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:

Andrew Crawford	Foundation Pharmacist, NHS Borders
Lesley Macher	Pharmacist, NHS Lothian
Jayne Stuart	Support Formulary Pharmacist, NHS Lothian

Apologies:

Dr Peter Hall	Consultant – Oncology, NHS Lothian
Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Gillian Donaldson	Nurse – Cardiology, 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) and thanked previous Chair. New members Dr Elliot Longworth, GP and Dr Paul Neary, Consultant Cardiologist, both from NHS Borders were welcomed. Observing - guest Andrew Crawford, Foundation Pharmacist, NHS Borders, and Lesley Macher, Pharmacist, NHS Lothian and Jayne Stuart, Support Formulary Pharmacist, NHS Lothian. ERFC noted that the meeting is being recorded.

- **Declarations 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)

Eye and ENT chapters included for approval. Progress on chapter reviews to-date was reviewed. CNS sections are progressing towards ERFWG stage and are expected to be on July ERFC agenda with the final four chapters on September ERFC agenda. Paediatric chapters will be progressed separately; plans under development. Progress on the adult chapters is as expected to-date.

1.3 Matters arising

1.3.1 There are no immediate plans for SAPG to develop Covid19 treatment guidance; this may be considered for development in future. Current treatment guidance from NHS Lothian is available in the formulary decision section of the website and can be searched by drug name with links to Covid therapeutic alert guidance. There is no link to the viral section of the ERF; this could be considered for future development and discussion.

1.3.2 Letter sent to CMO regarding treatment of erectile dysfunction and regulations around prescribing. The medicines policy team have agreed to review guidance and would welcome a discussion on the scope of a review. Plan to confirm volunteers from CEWGs to review; to await future developments.

1.3.3 Galcanezumab: Emgality (SMC2313) discussed at previous meetings – original restrictions differed to SMC advice; agreed to classify as routinely available in line with local prescribing guidance for Specialist Use only. There is a difference with this and SMC guidance; post-meeting decision to request approval from ADTCs in East Region for the formulary entry, noting additional local restriction which was highlighted. Borders approved virtually and noted at ADTC meeting on 25th May; Fife ADTC to review at meeting on 22 June; Lothian to review at meeting 10 June. Final update by next ERFC meeting and migraine formulary will be taken forward as part of the development of the CNS section of the ERF and any decisions incorporated. Prescribing of Galcanezumab before approval received from all Boards was discussed as it had been approved in ERFC March meeting and then discussed after the meeting to go to ADTCs; in essence the formulary application has gone through and just requires this further clarification.

1.3.4 Tralokinumab: Adtralza – CD support from three Boards has been received.

1.3.8 Naltrexone – CD support from three Boards has been received as part of the review of Substance Misuse chapter; CD from Borders was present in that meeting and gave support; Fife have on formulary already; chapter to come to next meeting. Noted that there were no numbers for Fife – 14-15 patients for Naltrexone – this will come to the next meeting.

1.3.5 Forceval - Completed

1.3.6 Metformin – Completed.

1.3.7 Cinacalcet – Lothian local application for Paediatric use; edit to minute and formulary decision "specialist initiation" - Completed

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 30 March 2022.

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

2.2 East Region Working Group (ERWG) meeting minutes 5 May 2022

The minutes of the ERWG meeting were noted for information.

2.3 East Region Formulary (ERF) sections for approval

- **Eye Chapter (Adult)**

  It was noted that meetings had taken place to discuss the Eye chapter; no specific issues; attention to detail and careful thought on positioning and choice of medicines; thanks to the experts. Top line of meeting content was reviewed and areas highlighted including dry eyes; aligning with Pharmacy First choices; CEWG met to agree separate Glaucoma section content and this worked well; FAF submissions from previous ERFC were incorporated into the final formulary section.. GP/Primary Care asked about inclusion of preservative free preparations and if this was required in all instances – clinicians felt this was relevant as options needed for individual patients – hence the range. The finalised draft of the Eye chapter had been through the ERWG.

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

  ACTION: ERF Project Team

- **ENT Chapter (Adult)**

  There was a high level of overlap with three Boards and this was created as a virtual document. Good engagement and top areas were allergic rhinitis product choices, dry mouth options and potential pathways for future FAFs highlighted. Updated chapter was re-reviewed with comments received and will be reviewed later in summer if required. Thanks to the teams involved.

  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 Polatuzumab vedotin: Polivy (SMC2282)

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 bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant. In a phase Ib/II study polatuzumab vedotin in combination with bendamustine and rituximab significantly increased complete response rate compared to bendamustine and rituximab alone.

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

Discrepancies in financial figures was pointed out. The ERFC discussed SMC interim advice subject to on-going evaluation and future reassessment. The ERFC agreed that local monitoring would not be possible and that SMC would provide updates on the status of medicines approved through this route. If there are conditional authorisations they are reviewed through chapter group process.

The ERFC requested that the Fife patient number and cost per annum and sub-total be clarified.

ACTION: Meeting Admin

The ERFC agreed to classify Polatuzumab vedotin: Polivy 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 Isatuximab: Sarclisa (SMC2303)

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 pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy.

SMC restriction: patients receiving fourth-line therapy. Addition of isatuximab to pomalidomide plus dexamethasone significantly increased progression-free survival (PFS) in adults with RRMM who had received at least two prior lines of therapy including lenalidomide and a PI.

The local treatment protocol and finance budget template were included with the FAF. Differences in costs were noted.

The ERFC requested that the net total costs be clarified.

ACTION: Meeting Admin

The ERFC agreed to classify Isatuximab: Sarclisa 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 Brigatinib: Alunbrig (SMC2314)

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

Indication: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. Brigatinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors for this indication. Medicines within this therapeutic class have been accepted via the orphan process for this indication.

The local treatment protocol and finance budget template were included with the FAF. SMC advice is for treatment naïve patients; criteria for patient selection in the FAF also includes patients who have had previous treatment and this is out with the SMC advice. For this approved as Specialist Use only.

The ERFC will request clarification on why application includes prior treatment patients as SMC advice is for naïve patients only and application to use out with the SMC approval cannot be included in FAF1 submissions. Patient numbers may require to be amended.

ACTION: Meeting Admin

The ERFC agreed to classify Brigatinib: Alunbrig 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 Acalabrutinib: Calquence (SMC2347)

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

Indication: as monotherapy or in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). SMC restriction: as monotherapy for the treatment of adult patients with previously untreated CLL without a del(17p) or TP53 mutation and who are ineligible for fludarabine, cyclophosphamide and rituximab (FCR) therapy. Acalabrutinib, compared with chlorambucil-obinutuzumab, significantly improved progression-free survival in adults with previously untreated CLL with co-morbidities.

The local treatment protocol and finance budget template were included with the FAF. An email has been sent to clarify patient numbers to check calculated costs. A plan for switch to long term supply through Homecare was mentioned in the application but there were no figures in relation to this in the application.

The ERFC requested clarification on patient numbers and costs.

ACTION: Meeting Admin

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

ACTION: ERF Project Team

3.1.5 FAF 1 Cabozantinib: Cabometyx / Nivolumab: Opdivo (SMC2386)

The ERFC noted and discussed the previously circulated FAF1 submission. One Non-personal, non-specific declaration of interest was received – as applicant on advisory boards but also on boards for alternatives and therefore no bias noted. CD support received from all three Boards.

Indication: in combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults. Cabozantinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors given in combination with a PD-1 inhibitor for this indication. Medicines within this therapeutic class have been accepted under the end of life process for this indication.

The local treatment protocol and finance budget template were included with the FAF. Questioned sub total cost and cost per annum is incorrect (Borders and D&G).

The ERFC requested clarification on costs from applicant.

ACTION: Meeting Admin

The ERFC agreed to classify Cabozantinib: Cabometyx / 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: ERF Project Team

3.1.6 FAF 1 Tirbanibulin: Klisyri (SMC2395)

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

Indication: field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults. In two phase III studies, a greater proportion of adults with actinic keratosis affecting an area of 25cm2 on the face or scalp achieved complete clearance when treated with tirbanibulin ointment 1% compared with vehicle.The proposed use of this medicine is as per SMC approved indication and restriction for Tirbanibulin: Klisyri.

The finance budget template was included with the FAF.

Second line, primary care use; one concern to be noted was in this pre-cancerous condition, second line agent could be used and may delay specialist referral. Patient numbers discussed as there are fewer patients in Fife to Borders and that Borders has equal use in primary and

secondary care; Lothian and Fife more in primary care. Referral patterns and access to secondary care services may be reflected in numbers.

The ERFC agreed to classify Tirbanibulin: Klisyri as Routinely available in line with national guidance. Included on the ERF with no formulary flags. The formulary website will be updated.

ACTION: ERF Project Team

3.1.7 FAF 1 Upadacitinib: Rinvoq (SMC2417)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest was received with no concerns. CD support received from all three Boards.

Indication: for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

SMC restriction: patients who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable. In patients with moderate to severe atopic dermatitis eligible for systemic therapy, upadacitinib was associated with significantly greater improvements in the signs and symptoms of atopic dermatitis in adults and adolescent patients in three placebo-controlled phase III studies and in adult patients in one phase III comparative study with a monoclonal antibody.

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

The ERFC discussed first and second line choices and criteria for patient selection and if there should be joint options. On application there will be monitoring in secondary care – there is no Shared Care Agreement in place; pre-treatment screens and bloods after 12 weeks – no monitoring stated to be done in primary care.

The ERFC requested clarification from Dermatology Team on joint options as above.

ACTION: Meeting Admin

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

ACTION: ERF Project Team

3.1.8 FAF 1 Dapagliflozin: Forxiga (SMC2428)

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 chronic kidney disease.

SMC Restriction: in patients with an estimated glomerular filtration rate of ≥25 to ≤75 mL/min/1.73m² at treatment initiation, and are receiving an angiotensin converting enzyme

inhibitor or angiotensin receptor blocker (unless these are not tolerated or contraindicated), and have a urine albumin creatinine ratio of at least 23mg/mmol, or type 2 diabetes mellitus or both. In a randomised, double-blind, phase III study in patients with chronic kidney disease, treatment with dapagliflozin added to standard of care significantly reduced the risk of first occurrence of ≥50% sustained decline in estimated glomerular filtration rate, end stage renal disease, cardiovascular death or renal death when compared with standard of care alone.

The links to the local treatment protocol and finance budget template were included with the FAF. The ERFC noted that there is an interim Lothian ADTC approval for use of this pending SMC advice and formulary. Full review of the submission and practicalities for use locally resulted in three requests to change patient inclusion criteria from the SMC restrictions. ACR not used – to use PCR; remove upper eGFR limit as not reported by labs above 60 – this may need to be Specialist Initiation as it is deviating from the restrictions. It is requested to be routinely available with EDREN support. Request for educational need for GPs was agreed – EDREN, email-shots, renal community to flag this to GPs when on formulary. Local prescribing amendments to SMC advice were agreed.

The ERFC agreed to classify Dapagliflozin; Forixiga as Routinely available in line with local guidance. Included on the ERF for Specialist Initiation with criteria added in addition to SMC advice. The formulary website will be updated.

ACTION: ERF Project Team

3.1.9 FAF 1 Amikacin: Arikayce (SMC2432)

The ERFC noted and discussed the previously circulated FAF1 submission. Two Non Personal Specific and two Non personal, non-specific declarations of interest were received. CD support received from all three Boards.

Indication: Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. The addition of amikacin liposomal nebuliser dispersion to standard oral guideline-based therapy for MAC NTM lung infections significantly increased the proportion of patients achieving sputum culture conversion at 6 months and post-treatment at 3 months.

The finance budget templates were included with the FAF with link to national guidance replacing the local treatment protocol.

The ERFC agreed to classify Amikacin: Arikayce 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

3.1.10 FAF 1 Filgotinib: Jyseleca (SMC2467)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. CD support received from all three Boards – NHS Fife support was indicated by email and should be confirmed.

Indication: for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Filgotinib provides an additional treatment choice in the therapeutic class of janus kinase (JAK) inhibitors.

The links to the local treatment protocol and finance budget template were included with the FAF. Finance table to be updated to 15 for Fife in the FAF. Replacement therapy is Toficitinib.

The ERFC requested that the Fife CD support be confirmed and finance table to be updated on application.

ACTION: Meeting Admin

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

ACTION: ERF Project Team

3.1.11 FAF2 Cinacalcet

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

Indication: Hypercalcaemia in Primary Hyperparathyroidism [in patients where parathyroidectomy is inappropriate].
Concerns raised included approval of a SMC non submission and that applicant has suggested including as prescribing note. The ERFC agreed to approve for specialist use and hand on to discussion in nutrition and blood CEWG for pathway.

The ERFC agreed to classify Cinacalcet 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

3.1.12 FAF3 Physostigmine: Anticholium

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received.

Indication: Specialist use only for management of antimuscarinic toxicity on advice of Consultant Toxicologist.

The finance budget template was included with the FAF. No local treatment protocol was available. This has been discussed by ERWG; use would bring us in line with rest of world. Patient safety discussed and should only be in acute service on advice of a Consultant Toxicologist.

The ERFC agreed to classify Physostigmine: Anticholium 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

3.2 Formulary Amendment Forms

3.2.1 Trimbow: NEXThaler

The ERFC noted and discussed the previously circulated formulary amendment form. Two Personal Specific declarations of interest were received which were not raised as a concern as there is support from Fife and Borders. CD support received from all three Boards.

Indication: COPD.
Available for patients who find easier to use than MDI – no cost implications and would be second choice in treatment pathway; no formulary flags.

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

ACTION: ERF Project Team

3.2.2 Trientine: Cuprior tablets

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

Indication: Wilson's Disease.
Discussed Cuprior and Cufence and changes required in change – dose, monitoring and availability through Homecare. Patients currently on Cufence to be continued and Cuprior for new patients. Currently as Specialist use only – GI team requesting change to Specialist Initiation, as in BNF, to enable it to be prescribed in community.

The ERFC agreed to classify Trientine: Cuprior 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 Daratumumab: Darzalex (SMC2416

3.3.2 Ropeginterferon alfa-2b : Besremi (SMC2421)
3.3.3 Belimumab: Benlysta (SMC2483)
3.3.4 Carfilzomib: Kyprolis (SMC2484)
3.3.5 Ibrutinib: Imbruvica (SMC2485)
3.3.6 Cemiplimab: Libtayo (SMC2489)
3.3.7 Mepolizumab: Nucala (SMC2488)
3.3.8 Mepolizumab: Nucala (SMC2490)
3.3.9 Mepolizumab: Nucala (SMC2491)

3.4 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions

3.4.1 Risankizumab: Skyrizi (SMC2459)

The ERFC discussed the request from local clinical teams for the formulary inclusion of Risankizumab: Skyrizi in line with the SMC abbreviated submission SMC2459.

Indication: alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

SMC restriction: (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated.

Risankizumab offers an additional treatment choice in the therapeutic class of interleukin-23 (IL-23) inhibitor in this setting.

No applications had been received from the three Boards. The number of biologics available was commented on and that when a new SMC Abbreviated is received for a new biologic that a full FAF is submitted so that benefits over current treatment can be reviewed. The ERFC agreed that the Rheumatology Team should submit a FAF if they wish Risankizumab: Skyrizi to be considered for addition to ERF.

The ERFC agreed to classify Risankizumab: Skyrizi as Not routinely available; to be submitted as a FAF1 if local clinical experts wish to add the medicine to the formulary.

ACTION: ERF Project Team

3.4.2 Fedratinib: Inrebic (SMC2462)

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

Indication: for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib. Fedratinib provides an additional treatment choice in the therapeutic class of JAK inhibitors. Another medicine within this therapeutic class has been accepted via the orphan medicine process.

Haematology Team would like added to formulary; proposing routinely available in line with national guidance; anticipated patient numbers highlighted and cost implications were discussed. Compared to existing treatments this was not considered to be a cost effective option and the ERFC agreed a full FAF should be submitted for consideration.

The ERFC agreed to classify Fedratinib: Inrebic as Not routinely available; to be submitted as a FAF1 if local clinical experts wish to add the medicine to the formulary.

ACTION: ERF Project Team

3.5 Paediatric licence extensions

3.5.1 No paediatric licence extensions were noted for this meeting. 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 Oritavancin: Tenkasi (SMC2285)

3.6.2 Venetoclax: Venclyxto (SMC2412)

3.6.3 Atidarsagene autotemcel: Libmeldy (SMC2413) *Validated as ultra-orphan but noted as non-submission, see correction below.

3.6.4 Pembrolizumab: Keytruda (SMC2420)

3.6.5 Venetoclax: Venclyxto (SMC2427)

3.6.6 Liraglutide: Saxenda (SMC2455)

3.6.7 Nivolumab: Opdivo (SMC2429)

***New Ultra Orphan Pathway - For information only**

Atidarsagene autotemcel: Libmeldy (SMC2413)

4 Central Alerting System COVID-19 Alerts

4.1 Baricitinib for Patients Hospitalised Due to COVID-19 (Adults and Children Aged 2 Years and Over). Discussed with clinical teams and have requested full FAF application to the ERFC. Local guidance is being worked on and expecting as a virtual review. With other Covid medicines we had realigned entries to be in line with national advice – specifically looking for

adult group and another application at a later date for paediatric group. The ERFC agreed that they would need to have as formulary applications for these drugs rather than amendments.

5 Board specific information

5.1 NHS Borders

None raised.

5.2 NHS Fife

None raised.

5.3 NHS Lothian

None raised.

6 Any other competent business

6.1 CEL2012_26 Gender Reassignment Protocol update

Specialist clinic provide over labelled packs of hormones from clinics and following review and centralisation of over labelling it was agreed they should be on formulary. There is also a shared care agreement coming to Lothian GPPC in June for approval. The ERFC have discussed considering FAF3s for a lot of products or we can use the national guidance on gender reassignment protocol alongside the shared care agreements, seek approval and sign off at formulary committee. Submit pathways to ERWG and sign off at ERFC. ERWG were in agreement with this approach. Off label indications questioned: as gender reassignment protocol has government backing this is already accepted as national practice. All the medicines will be off label; control over governance with limited evidence based but has been through a governance process at a national level. The ERFC agreed that this will go through ERWG and back to ERFC.

6.1 **Micronized Progesterone**

SBAR prepared for ADTCs for an alternative route to have micronized progesterone approved; to address current issues and to enable a consensus to be reached across the Boards. Board differences were discussed; Borders ADTC approved through evidence based new medicines application. This will be sent virtually for approval to ADTCs.

7 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 27 July 2022.

FAF3s should be submitted by 21 June 2022 (for discussion at the ERWG meeting on 6 July 2022).

FAF1s and FAF2s should be submitted by 12 July 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