East Region Formulary

East Region Formulary Committee
Minutes

Date: 11 October 2023
Time: 2.00pm – 4.30pm
Location: MS Teams

Present:

Alison Casey	Senior Pharmacist Cancer Services, NHS Fife
Carla Capaldi	Senior Practice Pharmacist, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Steven Fenton	Project Manager, NHS Lothian
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Nikki Gilluley	Lead Pharmacist - Regional Formulary Development
Liz Leitch	Formulary Pharmacist, NHS Borders
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist, NHS Lothian
Alice Mathew	Formulary Pharmacist, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Dr Paul Neary	Consultant – Cardiology, NHS Borders
Fraser Notman	Senior Pharmacist – Medicines Management, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian – in the Chair
In attendance:	Caitlin Satti, Information Officer, NHS Lothian
Guests/Observing:	Karen Burke, Lead Pharmacist - Medical Paediatrics, NHS Lothian
Apologies:	Jane Browning, (Acting) Associate Director of Pharmacy, NHS Lothian Ruth Cameron, Advanced Clinical Nurse Specialist - Urology, NHS Fife Gillian Donaldson, Nurse – Cardiology, NHS Borders Dr Jane Goddard, Consultant – Renal, NHS Lothian Dr Peter Hall, Consultant - Oncology, NHS Lothian Carol Holmes, Pharmacist - Primary Care, 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 – Karen Burke, NHS Lothian
- Welcome - Nikki Gilluley, NHS Lothian
- Leaving – Liz Leitch, NHS Borders and Alison Wilson, NHS Borders; the Chair noted that this is LL and AW's last ERFC with both due to retire. The Chair thanked them for their contributions to the East Region Formulary.

1.2 Update on progress with Chapter Expert Working Groups (CEWG)

The ERFC received an update on progress with the Chapter Expert Working Groups.

The Paediatric Gastrointestinal and Respiratory ERF chapters have been completed and launched on the ERF website and app. Three out of the four CNS chapters are included in this meeting, item 2.3 for discussion. The fourth CNS chapter to be reviewed covers topics such as anxiety, depression, sleep disorders and psychosis, with the content expected to come to the next East Region Working Group.

Further chapters for review include Infections and Endocrine, with preliminary meetings scheduled for late October 2023, and the intention of these Chapters coming to ERFC in December 2023.

The ERFC noted the update on progress with the Paediatric ERF chapters and had no further comments.

1.3 Matters arising

1.3.1 ERFC 07 June 2023 item 3.1.1 - FAF1 daratumumab: Darzalex (SMC2447) was reviewed at the ERFC June meeting. A typo error within the finance budget was noted, and it was unclear whether the updated PAS for daratumumab was reflected in the financial section. The ERFC requested that the financial budget template be reviewed and updated as required.

The ERFC noted that the requested information had been received. Action completed.

1.3.2 ERFC 07 June 2023 item 3.1.5 - FAF1 empagliflozin: Jardiance (SMC2523) was reviewed at the ERFC June meeting. The ERFC requested confirmation of NHS Fife CD support.

The ERFC confirmed that Fife CD support was received. Action completed.

1.3.3 ERFC 09 August 2023 item 3.1.1 - FAF1 pembrolizumab: Keytruda (SMC2526) was reviewed at the ERFC August meeting. The ERFC noted that the SMC approval for use includes treatment in adolescents aged 12 years and older, however, there was no supporting local protocol presented regarding use in this age-group. The ERFC requested clarification on potential use in adolescents aged 12 years and older, and input from paediatric oncology specialists if appropriate.

The ERFC noted that the proposed 6-weekly dosing interval was not in line with SMC advice (3-weekly) and no clinical evidence was presented to support this variation. The ERFC requested clarification/further information on the proposed 6-weekly dosing interval. The ERFC also requested confirmation of the finance detail as the finance template included with the FAF1 is based on 3-weekly dosing.

The ERFC noted that further dosing interval information was received. The adult clinical team did not present additional information for age 12-17 year and support in the East region is for adults only. Further information is awaited from local paediatric oncology specialists for ages 12-17 years of age.

ACTION: NHS Lothian Formulary Pharmacist

The ERFC agreed to classify pembrolizumab: Keytruda as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use Only. For adults > 18 years. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

The ERFC noted that a minor cost correction is required. The clinical team are requested to respond with information on the recommended actions by 28 Nov 2023.

ACTION: NHS Lothian Admin Team

1.3.4 ERFC 09 August 2023 item 3.1.2 - FAF1 pembrolizumab: Keytruda (SMC2144) was reviewed at the ERFC August meeting. The ERFC noted that the proposed 6-weekly dosing interval is not in line with the SMC

advice (3-weekly) and no clinical evidence was presented to support this variation. The ERFC requested clarification/further information on the proposed 6-weekly dosing interval. The ERFC also requested confirmation that the finance detail in the FAF1 is correct.

The ERFC noted that further dosing interval information was received.

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

ACTION: NHS Lothian Admin Team

The ERFC noted that a minor cost correction is required as a total of 36 vials will be used instead of 34. The clinical team are requested to respond with information on the recommended actions by 28 Nov 2023.

ACTION: NHS Lothian Admin Team

1.3.5 ERFC 09 August 2023 item 3.1.6 FAF1 venetoclax: Venclyxto (SMC2293 + SMC2427) was reviewed at the ERFC August meeting. The ERFC noted that the comparator treatment in the FAF1 (acalabrutinib) was different to the comparator treatment in the SMC advice (chlorambucil venetoclax). The ERFC requested clarification on the evidence base and rationale for the comparator treatment (acalabrutinib) and a review of the modelling/finance section to reflect the potential implications of longer-term treatment with acalabrutinib compared to venetoclax: Venclyxto.

The ERFC noted that the requested information had been received. Action completed.

The ERFC agreed to classify venetoclax: Venclyxto 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

1.3.6 ERFC 09 August 2023 item 3.1.7 polatuzumab vedotin: Polivy (SMC2524) was assigned as 'Not Routinely Available' after a non- submission within the required 90-day period. The ERFC noted that polatuzumab vedotin: Polivy SMC2282 is a previously agreed item, but was, in fact, interim advice awaiting an update from the SMC who have issued a new number for the update. NHS Lothian Cancer teams have confirmed it's the same indication as before; polatuzumab vedotin: Polivy SMC2282, the ERFC supported with the update to the new SMC number. Action completed.

The ERFC agreed to classify polatuzumab vedotin: Polivy as Routinely available in line with existing guidance for the same indication. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

1.3.7 ERFC 09 August 2023 item 3.1.8 FAF1 trifarotene: Aklief (SMC2441) was reviewed at the ERFC August meeting. The ERFC noted that the NHS Lothian Dermatology team have provided clarity on cost and position in pathway for trifarotene: Aklief which has now been considered and agreed through ERWG. Action completed.

1.3.8 ERFC 09 August 2023 item 3.1.4 FAF1 atezolizumab: Tecentriq (SMC2492) was reviewed at the ERFC August meeting. The ERFC noted that atezolizumab: Tecentriq is in the clinical management guideline in line with SMC advice. Action completed.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 9 August 2023

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

2.2 East Region Working Group (ERWG) meeting minutes 20 September 2023

The minutes of the ERWG meeting on 20 September 2023 were noted for information.

2.3 East Region Formulary (ERF) sections/amendments for review

- **CNS Chapter B (Paediatric)**

The ERFC discussed the key points in the ERF CNS Chapter B (Paediatric).

The CEWG for this review was quorate, with representation from all three Boards. However, it was lean on specialist attendance, thus, several further meetings have been carried out.

The ERFC discussed the chapter content and the rationale for any variations between the Adult and Paediatric chapter content/pathways.

The key points were noted as:

- Status epilepticus pathway – the local experts agreed the inclusion of the unlicensed Midazolam 10mg per ml Oromucosal Solution 5ml bottle, Veriton Pharma Ltd – the preparation that is issued by the Royal Hospital for Sick Children & Young People; this preparation has the brand name Epistatus on the packaging and includes graduated syringes which allows for administration of doses not available as a licensed pre-filled syringe. The licensed pre-filled syringes are only suitable when the dose to be administered matches the dose in the syringe. The Epistatus 10mg per ml prefilled syringe, in all strengths, are also included. Prescribers/dispensers are recommended to confirm the patient has received training on the preparation to be supplied. It was noted that there was a prescribing note amendment with the unlicensed 5ml bottle preparation found by ticking the special box on Vision GP ePrescribing systems, used by some GP practises in the East region.
- A new section on epilepsy syndrome was added with all drugs classified as Specialist Initiation.
- Ataluren was proposed for inclusion under additional treatment for Duchenne muscular dystrophy, however, is currently undergoing initial assessment in the Ultra-Orphan Pathway. When SMC issue advice on use in NHS Scotland formulary status, it will be reconsidered. The ERFC agreed to add signposts to the information on Ataluren's availability within the ultra-orphan pathway in the interim.
- A new pathway has been developed for the treatment of dystonia which includes several medicines that were not previously on the Board child formularies for this indication. The following medicines are confirmed as established use for the treatment of dystonia by local paediatric specialists, ERFC approved inclusion of the following items on the ERF: Trihexyphenidyl, Chlorol hydrate, Cloral betaine, Co-careldopa and Baclofen.
- Nusinersen and Risdiplam are proposed for inclusion under the neuromuscular disorders > Treatment of spinal muscular atrophy pathway as equal first choice, both as Specialist-Use Only.
- The abdominal migraine section and cyclical vomiting syndrome sections are both with respective specialists for further comments and confirmation, and will come to a future ERFC for approval.
- For prophylaxis of migraine, Amitriptyline and Riboflavin have been added and to be used alongside Propranolol and Topiramate. Pizotifen noted to only be used in children lower than twelve years.

<u>The ERFC requested clarity on the formulary flags used for medicines listed in the prophylaxis of migraine pathway, and the addition of further information relating to prescribing in 12–16-year-olds in the prescribing notes.</u>

ACTION: NHS Borders Formulary Pharmacist

The ERFC noted that Onasemnogene abeparvovec (SMC2311) with SMC accepted restricted advice, and Risdiplam (SMC2401) with SMC accepted advice are currently included in the national Ultra-Orphan

Drug Risk Share. Formulary applications have been invited from local clinical teams, but no submission has been made to ERFC to include these medicines on the formulary to date. Use is currently approved for individual patients on a case-by-case basis through established board non-formulary medicines governance approval routes. The clinical team is advised to submit FAF1 applications for these medicines to include these medicines as routinely available on the formulary. The pathway will be revised to remove these items pending future formulary submissions and signpost to local board medicines governance procedures for non-formulary prescribing.

The ERFC noted that Nusinersin SMC 1318/18 has SMC accepted restricted advice, and was previously included on the LJF additional list as routinely available SUO for the Treatment of 5q spinal muscular atrophy - SMC restriction to patients with symptomatic type 1 SMA (infantile onset).
The ERFC agreed to include Nusinersin with the formulary pathway revised to show the restriction and existing formulary approval.

Nusinersen can also be prescribed for patients with types 2 and 3 SMA under the ultra-orphan pathway on a case-by-case basis. As this use is currently undergoing initial assessment within the Ultra-Orphan pathway, when the SMC issue advice on use in NHS Scotland, formulary status will be reconsidered. The ERFC agreed to add signposts to the information on Nusinersen availability for type 2 and type 3 SMA within the ultra-orphan pathway in the interim.

The ERFC discussed the proposal to include Fenfluramine for licensed and off-label indications, and agreed that the ERFC did not have sufficient information to support routine availability of Fenfluramine on the formulary, at present. The ERFC agreed the FAF1 for Fenfluramine (SMC2569) should be submitted prior to formulary inclusion for treatment of seizures associated with Dravet syndrome. The ERFC agreed that there is a possibility of future licence approvals for other indications and subsequent health technology appraisals, and that this should be clarified prior to consideration of formulary inclusion of Fenfluramine for the other indications via established East Region Formulary application procedures.

The ERFC agreed that the pathways will be revised to remove Fenfluramine for all proposed indications. In the meantime, access for individual patients shall continue to be approved via local Board medicines governance procedures for non-formulary prescribing.

The ERFC approved the new chapter content presented with the recommended changes. The formulary website will be updated.

ACTION: NHS Borders Formulary Pharmacist/ ERF Project Manager

- **CNS Chapter C (Pain and Nausea - Paediatric)**

The ERFC discussed the key updates to the ERF CNS Chapter C (Pain and Nausea - Paediatric).

Pain specialists at the Royal Hospital for Children & Young People provided secondary care comments, with a section added for chemotherapy-induced nausea as crossover specialists were present at the CEWG.

The ERFC discussed the chapter content and the rationale for any variations between the Adult and Paediatric chapter content/pathways.

The key points were noted as:

- Hyoscine patches, Granisetron patches and Nabilone capsules were added for chemotherapy-induced nausea and vomiting. These medicines were not previously on the Board child formularies for this indication, and are confirmed as established use for the treatment of CINV by local paediatric specialists, ERFC approved inclusion of these items.

- Diamorphine for use in emergency departments by nasal administration, which is established use in emergency departments in all three Boards. This will replace a discontinued licensed product Ayendi, which was previously used in NHS Lothian only.
- Addition of Fentanyl patches for acute pain which is established use for a subset of patients in the spinal surgery pathway.
- For neuropathic pain, Lidocaine patches, Capsaicin cream, and Menthol in Aqueous cream to be added to the pathway, reflecting the Adult chapter content. It was highlighted that the specific Menthol in Aqueous cream strength for this indication in adults is not specified, the recommendation is included in the prescribing notes only.

The ERFC recommend the formulation details for Menthol in Aqueous cream are confirmed and updated in the medicine choices of the adult neuropathic pain pathway.

ACTION: NHS Lothian Formulary Pharmacist/ ERF Project Manager

The ERFC noted the occasional use of Pregabalin for oncology and palliative care patients, however, the local pain specialists agreed not to propose inclusion on the formulary due to lack of evidence base, and any future use will be considered on a case-by-case basis via non-formulary routes.

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

ACTION: NHS Lothian Formulary Pharmacist/ERF Project Manager

- **CNS Chapter D (Paediatric)**

The ERFC discussed the key updates to the ERF CNS Chapter D.

The ERFC discussed the chapter content and the rationale for any variations between the Adult and Paediatric chapter content/pathways.

The key points were noted as:

- ADHD and Tourette's were reviewed in the joint Adult and Child section, and, thus, no further proposed changes.
- Minor changes were recommended to the Poisoning section by local experts.
- Smoking Cessation, which mainly mirrors Adults, sent out for comments. Addition of 1mg Nicotinell lozenges to the pathway, with the intention to add it to Adults also.

The ERFC approved the change to the Adult Smoking Cessation pathway. The formulary website will be updated.

ACTION: NHS Lothian Formulary Pharmacist/ERF Project Manager

The ERFC noted that whilst initially sitting within the CNS pathways, Adult and Child Obesity will now sit within the Nutrition chapter with a joint Adult/Child formulary condition review to be planned. The ERFC also noted the importance of a psychiatric input in the Obesity chapter review to ensure appropriate prescribing guidance.

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

ACTION: NHS Lothian Formulary Pharmacist/ERF Project Manager

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 apalutamide: Erleada (SMC2579)

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: Hormonal treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) in adults who are at high risk of developing metastatic disease.

The local treatment protocol and finance budget template were included with the FAF. The ERFC notes the inclusion of treatment criteria within the application, with the proposal of treating 5 new patients per year - patients with a PSA doubling time of less than 10 months and a PSA of greater than two nanograms per mil.

The ERFC discussed the supporting evidence. The proposed place in therapy is first line, in place of Darolutamide as a more cost-effective drug, however, the application states Enzalutamide as the comparator which isn't approved for non-metastatic indications.

The ERFC requested a review of the finance section to reflect Darolutamide as the cost comparator instead of Enzalutamide.

The applicants are requested to respond with information on the recommended actions by 28 Nov 2023.

ACTION: NHS Lothian Admin Team

The ERFC agreed to classify apalutamide: Erleada (SMC2579) 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

3.1.2 FAF1 apalutamide: Erleada (SMC2472)

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: For the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

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

The ERFC discussed the supporting evidence. The proposed place in therapy is first line in conjunction with Doectaxel, Abiraterone, Enzalutamide, with primary treatment option based upon disease bulk and comorbidity of the patient.

The ERFC agreed to classify apalutamide: Erleada (SMC2472) 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 pembrolizumab: Keytruda (SMC2538)

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

Indication: In combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, for the treatment of adults with locally advanced, or early-stage triple-negative breast cancer (TNBC) at high risk of recurrence.

The local treatment protocol and finance budget template were included with the FAF. The treatment protocol is line with SMC advice.

The ERFC discussed the supporting evidence. The ERFC noted that there is currently no adjuvant or neoadjuvant treatment at present, with pembrolizumab: Keytruda proposed to fill an unmet need because of the aggressive nature of the disease and lack of responsiveness to treatment.

The ERFC requested a review of the finance budget template to provide clarity on the cost per annum for all patients.

ACTION: NHS Lothian Admin Team

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

ACTION: NHS Lothian Admin Team

3.1.4 FAF3 Zoledronic Acid

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

Indication: For treatment of osteoporosis in men and women post-low trauma hip fracture. IV 5mg vial, now generically available, to be used as an off-label indication.

The local treatment protocol and finance budget template were included with the FAF, with proposed patient numbers of 1090 per annum.

The ERFC reviewed the supporting evidence. The ERFC discussed concerns regarding patient follow ups and the primary/secondary care interface, and the need for a robust process to be in place in all three Boards as to the clear communication of doses given to prevent therapeutic duplication, and to ensure recall of patients for planned follow-up doses. The ERFC noted that some patients are already receiving this medicine for this indication in one of the Boards via non-formulary routes.

The ERFC requested information on operational arrangements for Zoledronic Acid in the post-op period from each Board to ensure effective continuation of treatment and patient safety.

The applicants and the representative from the individual Board clinical teams are requested to liaise with the following Board contacts to clarify operational arrangements at Board level: Lead Pharmacist - Medicines Governance and Guidance NHS Lothian; Senior Pharmacist – Medicines Management, NHS Fife, and NHS Borders Formulary Pharmacist.

ACTION: NHS Lothian Admin Team

The ERFC noted the advent of generic Zoledronic Acid allowing for more cost-effective treatment options. The ERFC, however, discussed discrepancies in the finance budget template, with figures denoting a single-use treatment rather than long-term treatment costs. The ERFC noted and questioned whether there were disproportionate numbers given the size of the population in each of the Boards, and noted that there should be an oral bisphosphonate comparator. The ERFC accept that the prices will vary depending on the formulation of Zoledronic Acid and the oral bisphosphonate comparator. The ERFC agreed that the finances in the form are not correct, but instead of a revision of the patient numbers and costs in the form, the ERFC agreed that Boards should note the discrepancy and calculate local Board-specific financial impact.

The ERFC agreed that a new formulary pathway will need to be developed with input from local experts with guidance included on the operational arrangements including recommendations for ongoing doses, monitoring and follow-up of patients. The ERFC note that operational arrangements for individual Boards are still to be confirmed and may vary.

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

ACTION: NHS Fife Formulary Pharmacist/NHS Lothian Admin Team

3.1.5 FAF3 Pemetrexed and cisplatin (NCMAG109)

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

Indication: For use as an adjuvant treatment for patients with completely resected stage IIA to IIIA non-squamous, non-small-cell lung cancer.

The finance budget template was included with the FAF. The National Cancer Medicines Advisory Group provided an approved cost effectiveness case.

The ERFC noted the supporting evidence.

The ERFC agreed to classify Pemetrexed and cisplatin as routinely available in line with national guidance. Included on the ERF for Specialist Use only. Classified for use under policy for the use of unlicensed medicines. Refer to NCMAG109 Pemetrexed and cisplatin advice document. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.6 FAF3 Droperidol acute behavioural disturbance in critical care

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

Indication: To be used as rapid tranquilisation in acute behavioural disturbance in critical care environments, either by intravenous or intramuscular use.

The finance budget template was included with the FAF.

The ERFC noted that Droperidol is currently licensed for nausea and vomiting. This application is to approve Droperidol for off-label use for the rapid tranquilisation of patients who have been risk-assessed as an immediate danger to themselves and to staff, for acute behavioural disturbance within violence and aggression pathways for immediate urgent control only.

The proposed place in therapy is second-line treatment, with Ketamine used as another option in critical care environments.

The ERFC recommended submission of a FAF3 for Ketamine for rapid tranquilisation in acute behavioural disturbance in locally approved settings (e.g. ED resus/critical care) by appropriately trained personnel i.e. in environments where there is immediate access to someone with advanced airway skills and equipment.

The ERFC noted the DROM study provided, a randomised control trial, which shows that Droperidol is comparative to the use of Midazolam; it is safe, and not inferior. There was also the inclusion of a peer-assessed guideline which has been approved through the Critical Care and Quality Improvement teams

within NHS Lothian, which assures the safe procurement and usage of the medicine within the Board. NHS Fife provided their guideline which is used in wider areas, not just Critical Care, but in Emergency Departments also, for extended monitoring requirements.

The ERFC discussed the existing guidelines including those for NHS Lothian adult critical care, and NHS Fife across more locally approved clinical settings including emergency departments. The ERFC note there is further work ongoing to develop supporting guidance for the management of acute behavioural disturbance in various clinical settings in NHS Lothian. The ERFC welcomed the sharing of guidance developed and approved in individual Boards that it may be considered as a resource in the development of guidance for use in other Boards in the East region. Approval of supporting clinical guidelines remains a matter for local Board medicines governance committees.

The ERFC agreed that the development of a formulary pathway will be revisited when there are formulary approvals for the medicines to be included in the pathway, and approved local Board clinical guidelines supporting the use of the medicines in question. Appropriate clinical representatives from the relevant specialties in each of the Boards will be required to input on the pathway development.

ACTION: ERWG/Lead Pharmacist - Regional Formulary Development

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

ACTION: NHS Lothian Team

3.1.7 FAF3 Neridronate: Nerixia

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

Indication: For treatment of Paget's disease of bone (PDB) (intramuscular use, 25mg injection weekly for 8 doses).

The finance budget template was included with the FAF. The ERFC noted that the addition of Neridronate would have little to no additional service impact as there is already an existing service in an outpatient clinic in NHS Lothian.

The ERFC noted that Risedronate is currently the only medicine choice approved for use in the pathway for Paget's disease, with the applicants request to have Neridronate sit within the prescribing notes – Zoledronic Acid is in the prescribing notes of the pathway for the indication in question. The ERFC discussed the place in therapy of Neridronate, with the medicine to be used in secondary care only, and to treat patients with Paget's who are intolerant of oral bisphosphonates or when Zoledronic acid is unsuitable (patients who have trouble with IV access).

The ERFC noted that a condition pathway is currently in draft and in receipt of comments.

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

ACTION: NHS Lothian Formulary Pharmacist/NHS Lothian Admin Team

3.2 Formulary Amendment Forms

3.2.1 Kliniderm Foam Silicone Sacrum Border

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

Indication: Bordered foam dressing shaped to conform to the sacrum. For moderate to highly exuding wounds.

Application to include Kliniderm Foam Silicone Sacrum Border various sizes as first line sacral option in the silicone foam dressings – with border pathway treatment pathway. Mepilex sacrum would remain as second line option as it can be used as part of a sheer/friction reduction care plan in exceptional circumstances.

The ERFC agreed to classify Kliniderm Foam Silicone Sacrum Border as routinely available in line with local guidance. Included on the ERF. The formulary website will be updated.

ACTION: ERF Project Manager

3.2.2 Venlafaxine MR tablets

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: For treatment of major depression: generalised anxiety disorder, and social anxiety disorder.

Application to include Venlafaxine MR tablets (added to the Scottish Drug Tariff on July 2023) as a more cost-effective alternative to the modified release capsules that are already on the formulary, with local procedures in place to direct on the most cost-effective option at a given time.

The ERFC reviewed the supporting evidence. The ERFC noted the volatility of the Drug Tariff and reasoned that both Venlafaxine MR capsules and MR tablets should remain on the formulary.

The formulary website will be updated.

ACTION: NHS Fife Formulary Pharmacist/NHS Lothian Admin Team

3.3 Ultra-Orphan Pathway

3.3.1 Eladocagene exuparvovec: Upstaza (SMC2586)

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

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.3.2 Olipudase alfa: Xenpozyme (SMC2560)

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

The ERFC noted the SMC not recommended advice for information.

3.4.1 Mosunetzumab: Lunsumio (SMC2542)
3.4.2 Lutetium (177Lu) vipivotide tetraxetan: Pluvicto (SMC2517)
3.4.3 Nivolumab: Opdivo (SMC2620)
3.4.4 Crizotinib: Xalcori (SMC2621)

The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.5 Abbreviated submissions

The ERFC noted the SMC abbreviated submissions.

3.5.1 Vutrisiran: Amvuttra (SMC2596)

The ERFC noted the SMC abbreviated submission Vutrisiran: Amvuttra (SMC2596).

Indication: For the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.

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

The ERFC agreed to classify Vutrisiran: Amvuttra 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

3.5.2 Atogepant tablets: Aquipta (SMC2599)

The ERFC noted the SMC abbreviated submission Atogepant tablets: Aquipta (SMC2599).

Indication: for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

The ERFC agreed to classify Atogepant tablets: Aquipta 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

3.5.3 Zanubrutinib: Brukinsa (SMC2600)

The ERFC noted the SMC abbreviated submission Zanubrutinib: Brukinsa (SMC2600).

Indication: as monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL).

The ERFC agreed to classify Zanubrutinib: Brukinsa 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 None.

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 Daratumumab: Darzalex (SMC2536)
3.7.2 Ibrutinib: Imbruvica (SMC2543)
3.7.3 Rimegepant: Vydura (SMC2603)

3.7.4 Olaparib: Lynparza (SMC2518)
3.7.5 Fenfluramine: Fintepla (SMC2569)
3.7.6 Regorafenib: Stivarga (SMC2562)
3.7.7 Brexucabtagene autoleucel: Tecartus (SMC2548)
3.7.8 Belzutifan: Welireg (SMC2587)
3.7.9 Voclosporin: Lupkynis (SMC2570)
3.7.10 Maribavir: Livtencity (SMC2576)
3.7.11 Darolutamide: Nubeqa (SMC2604)
3.7.12 Semaglutide: Wegovy (SMC2497)

The ERFC agreed to classify items 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, 3.7.6, 3.7.7, 3.7.8, 3.7.9, 3.7.10, 3.7.11, 3.7.12 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

3.8 Central Alerting System COVID-19 Alerts

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

The ERFC agreed to remove Central Alerting System COVID-19 Alerts as an agenda point moving forward as the Alerts are now available through normal channels.

ACTION: NHS Lothian Admin Team

3.9 National Cancer Medicines Advisory Group

None.

4 Board specific information

4.1 NHS Borders

None.

4.2 NHS Fife

None.

4.3 NHS Lothian

None.

5 Any other competent business

The ERFC noted a Clopixol accuphase formulary application in development by lead applicants based in NHS Borders, support from Board CDs in NHS Fife and NHS Lothian was noted. Details to be shared with Borders applicants, ERFC welcome submission of the completed formulary application at the next meeting.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 13 December 2023 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 7 November 2023 (for discussion at the ERWG meeting on 22 November 2023).

FAF1s and FAF2s should be submitted by 28 November 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