East Region Formulary

East Region Formulary Committee
Minutes

Date: 24 November 2021
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	Lead Pharmacist, ERF Project Team
Dr Maria Corretge	Consultant Geriatrician, NHS Lothian
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Gillian Donaldson	Nurse – Cardiology, NHS Borders
Steven Fenton	Project Manager, ERF Project Team
Anne Gilchrist	Lead Pharmacist, NHS Lothian
Fiona Grant	Physiotherapist, NHS Borders
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Dr Nicola Henderson	GP, NHS Borders
Carol Holmes	Pharmacist – Primary care, NHS Lothian
Liz Leitch	Formulary Pharmacist, NHS Borders
Kirsty MacFarlane	Regional Formulary Pharmacist, ERF Project Team
Dr Linda McGourty	GP, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Fraser Notman	Formulary Pharmacist, NHS Fife
Euan Reid	Lead Pharmacist, NHS Fife
Angela Sinclair	Pharmacist – Rheumatology, NHS Fife
Dr Lucy Wall	Consultant – Oncology, NHS Lothian
Dr Andrew Watson	Consultant – Psychiatry (Co-chair), NHS Lothian – in the Chair
Alison Wilson	Director of Pharmacy (Co-chair), NHS Borders

In Attendance:

Moira Ross	Information Officer, NHS Lothian – Minutes
Erin McKay	Student, NHS Fife

Apologies:

Dr Sarah Hailwood	Consultant – Rheumatologist, NHS Fife

1 Project update

1.1 Welcome and Apologies

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

- **Declarations of interest**

ERFC members were reminded to return their Declaration of Interest (DOI) forms. DOI forms will be requested yearly. Completed DOIs will be retained by the project team and shared with the individual's board.

ACTION: ALL

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

The ERFC noted that Chapter Expert Working Groups (CEWGs) have been established. Currently, 3 groups: Gastroenterology (GI), Infections and Skin have met and prepared chapters for approval of the ERFC. Updates have also been prepared for the Pharmacy First chapter to align to the 01/10/2021 NHS Scotland approved list of products. There is good progress with the next 3 chapters: each of the CEWGs have met and work is under review for Cardiovascular, Diabetes and Respiratory chapters. The aim is to have this work completed for next ERFC meeting in February 2022. Alongside the Diabetes chapter review, a virtual review of the Endocrine section is taking place.

An opportunity to promote the work of the East Region Formulary (ERF) allowed for 2 posters to be presented at the Scottish Practice Pharmacy & Prescribing Advisers (SP_3A) conference.

The main challenge so far has been scheduling the paediatric review work which is progressing at a slower pace than originally planned.

The ERFC were updated on the risk register for the ERF project. The next steps of the ERF project are recruitment of an additional formulary pharmacist to increase the pace of the reviews. From January 2022 the number of chapter reviews per group will increase from 3 to 4 CEWG reviews.

1.3 Matters arising

- **Dupilumab: Dupixent (SMC2317)**

The clinical team provided clarification on patient numbers and costs which were agreed by all 3 boards.

- **Casirivimab and Imdevimab: Ronapreve - in the treatment of COVID-19 in hospitalised patients 04 November 2021**

All 3 boards worked together on a formulary amendment request for use of Ronapreve for the treatment of COVID-19 in hospitalised patients. The amendment is in line with new national guidance issued on 04 November 2021 but with an additional local restriction to have a negative baseline serology in patients with hospital onset COVID-19 pending clarification from the national body. It was agreed by the ERFC Co-Chairs to amend the existing formulary decision for Ronapreve to note the latest update for Ronapreve coronovirus (COVID-19) alerts issued by the MHRA Central

Alerting System – 04 November 2021 (Ronapreve). Local prescribing guidance will be updated and reviewed at board level.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 29 September 2021

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

2.2 East Region Working Group (ERWG) meeting minutes 03 November 2021

The minutes of the ERWG meeting were noted for information.

2.3 East Region Formulary (ERF) amendments

Gastroenterology (GI) chapter

It was noted that meetings had taken place to discuss the GI chapter and that there was good consensus from all 3 board's participants. The finalised draft of the GI chapter was sent to the ERWG. Feedback was then shared with the GI CEWG for action. Edits were presented in the paper shared with the ERFC.

The ERFC discussed how infection pathways were presented in the PDF word documents with some antimicrobial recommendations for GI appearing only in the GI chapter and others in the infections chapter. It was noted that antimicrobial recommendations sitting in the content of chapters for the body systems rather than the infection chapter will be relevant for review by infection specialists. When the PDF word documents are approved the antimicrobial pathways can be linked to the infection chapter on the website. The ERFC discussed infection specialist involvement for input around antimicrobial recommendations. Further refinement of master chapters will be made to ensure all pathways relating to infection are reviewed by the Infections CEWG.

ACTION: ERF Project Team

Feedback on the content of the GI chapter was provided in the meeting with some points raised for further review by the CEWG. There was discussion around the number of side effects added to prescribing notes. The ERFC were of the view that prescribing notes should be succinct with salient points. The website has icons for quick links to resources such as the BNF for extra information including side-effects. In some cases, it may be appropriate to draw attention to key points. The CEWG and ERWG will provide guidance around which side-effects require inclusion in the prescribing notes.

The ERFC approved the new chapter content with the points raised in the meeting to be concluded by approval of the GI CEWG. The formulary website will be updated.

ACTION: ERF Project Team

Infections chapter

The meeting went well and took into consideration different working practices across all 3 boards and best practice.

There was discussion around the Infections chapter covering mostly primary care. The ERFC agreed that consideration should be taken to the inclusion of secondary care formulary recommendations for infections in ERF pathways.

The ERFC approved the chapter on the basis of being a primary care chapter. The ERFC agreed that formulary governance includes antimicrobials used in secondary care.

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

ACTION: ERF Project Team

Pharmacy First chapter
The ERF Pharmacy First chapter reflects the medicines included in the national Pharmacy First Approved List.

Feedback on the content of the prescribing notes of the Pharmacy First chapter was provided in the meeting and the amendments were agreed for update.

Inclusion of Lactulose in the Pharmacy First approved list was questioned by the ERFC, there are other preferred options for the management of constipation. The inclusion of Lactulose is due to it being listed as an option on the Pharmacy First approved list and therefore cannot be removed by local ERFC agreement.

The ERFC agreed to write to the national Pharmacy First group expressing concerns around the inclusion of Lactulose for consideration when Pharmacy First is next reviewed.

ACTION: ERF Project Team

The ERFC approved the changes to this chapter. The formulary website will be updated.

ACTION: ERF Project Team

Skin chapter
The group met 3 times and had lots of good collaboration across all 3 boards.

The new chapter content takes account recent NICE guidance on the management of Acne.

The infection specialists provided feedback on antimicrobial recommendations for the management of secondary bacterial infection in inflammatory skin conditions (e.g. eczema) – with final approval of the changes by infection specialists outstanding.
Feedback on the content of the Skin chapter was provided in the meeting with the correction agreed in the meeting.
The ERFC approved the new chapter content and changes agreed in the meeting subject to approval by infection specialists as noted. The formulary website will be updated.

ACTION: ERF Project Team

2.4 Generic and Branded Prescribing - ERF Position Statement

A brief position statement was presented to the ERFC outlining the ERF position on generic prescribing, branded prescribing and branded generic prescribing. There were some minor edits discussed and taken into consideration upon approval. The brief refers to the Specialist Pharmacy Service (SPS) document which is noted for review in Spring 2022, but not expected to change.

ACTION: KM

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Buprenorphine transdermal patch: Sevodyne

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific declaration of interest was received. Proposed use of this medicine is as per SMC approved indication and restriction for Buprenorphine transdermal patch: Butec (SMC1213/17). The patches proposed for formulary inclusion have subsequently been changed by the clinical team to the Sevodyne brand, therefore this application is now considered via a local application route as this product is considered out with SMC remit.

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

The committee agreed that branded prescribing is appropriate in this case due to the variety of available products and that the most cost-effective preparation would be preferred for formulary inclusion. In the local protocol, the named patches will need to be updated – the patch name Butrans is currently referenced.

Feedback from all boards noted agreement around positioning of buprenorphine patches, but not around the need for inclusion in the formulary.

The ERFC considered the potential for inappropriate prescribing of buprenorphine patches rising following formulary inclusion. The ERFC noted the recommendation for monthly review in primary care to assess for effectiveness with consideration to stopping. The ERFC noted that as a partial agonist if additional strong opioid pain relief is required, the response to add-on analgesia may be unpredictable.

ERFC decision:

Name	Buprenorphine transdermal patch: Sevodyne
Source	Local application
Therapeutic Area	Central nervous system
Generic Medicine	Buprenorphine transdermal patch
Brand Name	Sevodyne
Formulation	5, 10, 15 and 20 microgram/hour transdermal patch
Indication	In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. Restriction: for use in elderly patients (over 65 years).

Conclusion and Formulary Status	November 2021 - Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 02 February 2022.
Other Comments	The ERFC requested the clinical team to look at their referencing in the protocol as Butrans is referenced. The ERFC recommend that the proposals set out in the local protocol for starting, stopping and monitoring are consulted with primary care representatives in the region to ensure use as described can be managed in practice and that proposals for ongoing monitoring in a primary care setting are feasible. The ERFC requested the clinical team to provide clarification on these points along with evidence of support from primary care colleagues in the 3 boards. The ERFC are happy to receive an updated application.
Flags (website)	N/A
Reference Number	N/A
Link to SMC Advice	N/A
Date Advice Published	N/A
SMC Submission type	N/A
SMC Status	N/A

3.1.2 FAF1 Ofatumumab: Kesimpta (SMC2357)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Proposed use of this medicine is as per SMC approved indication and restriction. The local treatment protocol and finance budget template were included with the FAF.

ERFC decision:

Name	Ofatumumab: Kesimpta (SMC2357)
Source	SMC
Therapeutic Area	Central nervous system
Generic Medicine	Ofatumumab
Brand Name	Kesimpta
Formulation	20mg/0.4mL solution for injection in pre-filled syringe/pen
Indication	Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. SMC restriction: treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.
Conclusion and Formulary Status	November 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.

Other Comments	The ERFC requested the clinical team to clarify patient numbers and costings. There were differences noted in how the drug will be used between the boards. One board intends to start new patients on this medicine and another board intends to start new patients and switch patients from their current treatment to this medicine.
Flags (website)	SUO
Reference Number	SMC2357
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/ofatumumab-kesimpta-full-smc2357/
Date Advice Published	12/07/2021
SMC Submission type	Full
SMC Status	Restricted

3.1.3 FAF1 Guselkumab: Tremfya (SMC2360)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Proposed use of this medicine is as per SMC approved indication and restriction. The local treatment protocol and finance budget template were included with the FAF. NHS Borders and NHS Fife have already included Guselkumab: Tremfya (SMC2360) on the formulary.

ERFC decision:

Name	Guselkumab: Tremfya (SMC2360)
Source	SMC
Therapeutic Area	Musculoskeletal and joint diseases
Generic Medicine	Guselkumab
Brand Name	Tremfya
Formulation	100mg solution for injection in pre-filled pen or syringe
Indication	Alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. 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.
Conclusion and Formulary Status	November 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.

Other Comments	The ERFC agreed to link to each of the 3 board prescribing guidelines when the section is reviewed by the ERF CEWG.
Flags (website)	SUO
Reference Number	SMC2360
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/guselkumab-tremfya-full-smc2360/
Date Advice Published	09/08/2021
SMC Submission type	Full
SMC Status	Restricted

3.1.4 FAF1 Filgotinib: Jyseleca (SMC2365)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Proposed use of this medicine is as per SMC approved indication and restriction. The local treatment protocol and finance budget template were included with the FAF.

ERFC decision:

Name	Filgotinib: Jyseleca (SMC2365)
Source	SMC
Therapeutic Area	Musculoskeletal and joint diseases
Generic Medicine	Filgotinib
Brand Name	Jyseleca
Formulation	100mg and 200mg film-coated tablets
Indication	Filgotinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). SMC restriction: in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate.
Conclusion and Formulary Status	November 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments	None
Flags (website)	SUO
Reference Number	SMC2365
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/filgotinib-jyseleca-full-smc2365/
Date Advice Published	13/09/2021

SMC Submission type	Full
SMC Status	Restricted

3.1.5 FAF1 Cabotegravir: Vocabria (SMC2376)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Proposed use of this medicine is as per SMC approved indication and restriction. The local treatment protocol and finance budget template were included with the FAF. The ERFC commented that the SMC detailed advice document did not make it clear that the submission includes approval of the oral tablets of Cabotegravir and Ripilvirine for lead in to assess tolerability of Vocabria and Rilpivirine prior to administration of long acting Cabotegravir injection plus long acting Rilpivirine injection. The ERFC were advised that the tablets are considered as approved for use in the national guidance (SMC2376).

ERFC decision:

Name	Cabotegravir: Vocabria (SMC2376) + Rilpivirine: Rekambys
Source	SMC
Therapeutic Area	Infections
Generic Medicine	Cabotegravir
Brand Name	Vocabria + Rekambys
Formulation	600mg prolonged-release suspension for injection. In combination with Rilpivirine: Rekambys 900mg prolonged-release suspension for injection. Cabotegravir: Vocabria 30mg film-coated tablets.*
Indication	In combination with Rilpivirine prolonged-release injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. *Cabotegravir: Vocabria 30mg film-coated tablets and Rilpivirine 25mg film coated tablets are given as oral lead in prior to the initiation of prolonged release injection (see Vocabria manufacturers summary of product characteristics for full details).
Conclusion and Formulary Status	November 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments	None
Flags (website)	SUO
Reference Number	SMC2376
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/cabotegravir-vocabria-full-smc2376/
Date Advice Published	11/10/2021
SMC Submission type	Full
SMC Status	Accepted

3.1.6 FAF2 Etoricoxib

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. A finance budget template was included with the FAF.

ERFC decision:

Name	Etoricoxib (Local application)
Source	Local application
Therapeutic Area	Musculoskeletal and joint diseases
Generic Medicine	Etoricoxib
Brand Name	Etoricoxib
Formulation	60-90mg tablet daily
Indication	For axial spondyloarthritis. Restriction to second line therapy for patients unable to tolerate NSAIDs due to gastro-intestinal side-effects.
Conclusion and Formulary Status	November 2021 - Routinely available in line with local prescribing guidance. Included on the ERF.
Other Comments	None
Flags (website)	None
Reference Number	N/A
Link to SMC Advice	N/A
Date Advice Published	N/A
SMC Submission type	N/A
SMC Status	N/A

3.1.7 Formulary amendment form Forceval

The ERFC noted and discussed the previously circulated formulary amendment form. No declarations of interest were received. A finance budget template was not included with the FAF.

ERFC decision:

Name	Forceval: Forceval (Local application)
Source	Local application
Therapeutic Area	Nutrition and blood
Generic Medicine	Forceval
Brand Name	Forceval
Formulation	Oral capsules and soluble tablets
Indication	Maldigestion following oesophagogastric surgery and micronutrient replacement in patients undergoing bariatric surgery.
Conclusion and Formulary Status	November 2021 - Routinely available in line with local guidance. Included on the ERF for Specialist initiation.
Other Comments	Forceval is already on NHS Borders and NHS Fife formulary.

	The ERFC note that when the Nutrition CEWG meet in 2022 the place in therapy recommendations will require further discussion and agreement for the region.
Flags (website)	SI
Reference Number	SMC
Link to SMC Advice	N/A
Date Advice Published	N/A
SMC Submission type	N/A
SMC Status	N/A

3.1.8 FAF3 Metformin

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. A finance budget template was included with the FAF. The FAF3 was reviewed by the ERWG, feedback was shared with the applicants and clarification was provided on all points. Metformin is already in use for the proposed indication in one board. There were differences noted in the patient selection criteria in the application and the place in therapy between the board already using Metformin. In the board already using the treatment, treatment is considered when there is evidence of weight gain associated with antipsychotic treatment only, rather than for the additional proposal for the prevention of weight gain when antipsychotics are initiated in selected patient groups.

ERFC decision:

Name	Metformin: Metformin (Local application)
Source	Local application
Therapeutic Area	Central nervous system
Generic Medicine	Metformin
Brand Name	Metformin
Formulation	500mg tablets
Indication	For use in weight gain associated with antipsychotic treatment.
Conclusion and Formulary Status	November 2021 - Routinely available in line with local guidance. Included on the ERF for Specialist use only.
Other Comments	The ERFC requested the clinical team to clarify the eligibility criteria for use in the East region. The ERF team will draw up a pathway and share this with local experts for approval, the final draft will be shared with the ERWG and then the ERFC.
Flags (website)	SUO
Reference Number	N/A
Link to SMC Advice	N/A
Date Advice Published	N/A
SMC Submission type	N/A

SMC Status	N/A

3.2 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.2.1 Amikacin: Arikayce (SMC2369)
3.2.2 Selpercatinib: Retsevmo (SMC2371)
3.2.3 Mercaptamine: Procysbi (SMC2374)
3.2.4 Liraglutide: Saxenda (SMC2378)
3.2.5 Elotuzumab: Empliciti (SMC2407)
3.2.6 Isatuximab: Sarclisa (SMC2423)
3.2.7 Avapritinib: Ayvakyt (SMC2424)
3.2.8 Vericiguat: Verquvo (SMC2425)
3.2.9 Asfotase alfa: Strensiq (SMC2433)
3.2.10 Durvalumab: Imfinzi (SMC2434)
3.2.11 Olaparib: Lynparza (SMC2435)
3.2.12 Olaparib: Lynparza (SMC2436)
3.2.13 Sebelipase alfa: Kanuma (SMC2437)

3.3 Abbreviated submissions

3.3.1 Doravirine: Pifeltro (SMC2332)

ERFC decision:

Name	Doravirine: Pifeltro (SMC 2332)
Source	SMC
Therapeutic Area	Infections
Generic Medicine	Doravirine
Brand Name	Pifeltro
Formulation	100mg film-coated tablets
Indication	In combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.
Conclusion and Formulary Status	November 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments (e.g. other action needed)	An updated document on cost-sensitive prescribing of anti-retrovirals supported by all 3 boards provides answers to previously noted points for clarification on the place in therapy requested by the Lothian Formulary Committee in August 2021.
Flags	SUO
Reference Number	SMC2332
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/doravirine-pifeltro-abb-smc2332/
Date Advice Published	08/03/2021
SMC Submission Type	Abbreviated
SMC Status	Accepted

3.3.2 Patiromer sorbitex calcium: Veltassa (SMC2381)

ERFC decision:

Name	Patiromer sorbitex calcium: Veltassa (SMC2381)
Source	SMC
Therapeutic Area	Nutrition and blood
Generic Medicine	Patiromer sorbitex calcium
Brand Name	Veltassa
Formulation	8.4g and 16.8g powder for oral suspension
Indication	For treatment of hyperkalaemia in adults. SMC restriction: patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia).
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2381
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/patiromer-sorbitex-calcium-veltassa-abb-smc2381/
Date Advice Published	09/08/2021
SMC Submission Type	Abbreviated
SMC Status	Restricted

3.3.3 Ponesimod: Ponvory (SMC2384)

ERFC decision:

Name	Ponesimod: Ponvory (SMC2384)
Source	SMC
Therapeutic Area	Central nervous system
Generic Medicine	Ponesimod
Brand Name	Ponvory
Formulation	Ponesimod titration pack and 20mg film-coated tablets
Indication	The treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. SMC restriction: Adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment.

Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2384
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/ponesimod-ponvory-abb-smc2384/
Date Advice Published	08/11/2021
SMC Submission Type	Abbreviated
SMC Status	Restricted

3.3.4 Cabozantinib: Cabometyx (SMC2386)

ERFC decision:

Name	Cabozantinib: Cabometyx (SMC2386)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Cabozantinib
Brand Name	Cabometyx
Formulation	20mg, 40mg and 60mg film-coated tablets
Indication	In combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2386
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/cabozantinib-cabometyx-abb-smc2386/
Date Advice Published	11/10/2021
SMC Submission Type	Abbreviated
SMC Status	Accepted

3.3.5 Midazolam: Ozalin (SMC2392)

ERFC decision:

Name	Midazolam: Ozalin (SMC2392)
Source	SMC
Therapeutic Area	Anaesthesia
Generic Medicine	Midazolam
Brand Name	Ozalin
Formulation	2mg/mL oral solution in single-dose container
Indication	In children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anaesthesia.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2392
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/midazolam-ozalin-abb-smc2392/
Date Advice Published	11/10/2021
SMC Submission Type	Abbreviated
SMC Status	Accepted

3.3.6 Empagliflozin: Jardiance (SMC2396)

ERFC decision:

Name	Empagliflozin: Jardiance (SMC2396)
Source	SMC
Therapeutic Area	Cardiovascular system
Generic Medicine	Empagliflozin
Brand Name	Jardiance
Formulation	10mg film-coated tablets
Indication	In adults for treatment of symptomatic chronic heart failure with reduced ejection fraction.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2396
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/empagliflozin-jardiance-abb-smc2396/
Date Advice Published	11/10/2021

SMC Submission Type	Abbreviated
SMC Status	Accepted

3.3.7 Bempedoic acid / Ezetimibe: Nustendi (SMC2406)

ERFC decision:

Name	Bempedoic acid / Ezetimibe: Nustendi (SMC2406)
Source	SMC
Therapeutic Area	Cardiovascular system
Generic Medicine	Bempedoic acid / Ezetimibe
Brand Name	Nustendi
Formulation	180mg / 10mg film-coated tablets
Indication	In adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe • alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone • in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin. SMC restriction: for use in patients who are: • statin intolerant or for whom a statin is contra-indicated • where ezetimibe alone does not appropriately control LDL-C • where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate. SMC has previously accepted bempedoic acid for restricted use in combination with ezetimibe for this indication. Nustendi (bempedoic acid / ezetimibe) provides a single tablet alternative to bempedoic acid plus ezetimibe.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	The local clinical team intend to submit an application at the next ERFC meeting.
Flags	N/A
Reference Number	SMC2406
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/bempedoic-acidezetimibe-nustendi-abb-smc2406/
Date Advice Published	11/10/2021
SMC Submission Type	Abbreviated
SMC Status	Restricted

3.3.8 Bimekizumab: Bimzelx (SMC2410)

ERFC decision:

Name	Bimekizumab: Bimzelx (SMC2410)
Source	SMC
Therapeutic Area	Skin
Generic Medicine	Bimekizumab
Brand Name	Bimzelx
Formulation	160mg solution for injection in pre-filled syringe and pre-filled pen
Indication	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	The local clinical team intend to submit an application at the next ERFC meeting.
Flags	N/A
Reference Number	SMC2410
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/bimekizumab-bimzelx-abb-smc2410/
Date Advice Published	08/11/2021
SMC Submission Type	Abbreviated
SMC Status	Restricted

3.4 Paediatric licence extensions

None noted for this meeting.

3.5 Non-submissions within 90 days on SMC publishing

3.5.1 Avatrombopag: Doptelet (SMC2345)

ERFC decision:

Name	Avatrombopag: Doptelet (SMC2345)
Source	SMC
Therapeutic Area	Nutrition and blood
Generic Medicine	Avatrombopag
Brand Name	Doptelet
Formulation	20mg film-coated tablets
Indication	Treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids or immunoglobulins).

	SMC restriction: to use in patients with severe symptomatic ITP or a high risk of bleeding.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2345
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/avatrombopag-doptelet-full-smc2345/
Date Advice Published	09/08/2021
SMC Submission Type	Full
SMC Status	Restricted

3.5.2 Inclisiran: Leqvio (SMC2358)

ERFC decision:

Name	Inclisiran: Leqvio (SMC2358)
Source	SMC
Therapeutic Area	Cardiovascular system
Generic Medicine	Inclisiran
Brand Name	Leqvio
Formulation	284mg solution for injection in pre-filled syringe
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.

Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2358
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/inclisiran-leqvio-full-smc2358/
Date Advice Published	09/08/2021
SMC Submission Type	Full
SMC Status	Restricted

3.5.3 Olaparib: Lynparza (SMC2366)

ERFC decision:

Name	Olaparib: Lynparza (SMC2366)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Olaparib
Brand Name	Lynparza
Formulation	100mg and 150mg film-coated tablets
Indication	As monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2366
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/olaparib-lynparza-full-smc2366/
Date Advice Published	11/10/2021
SMC Submission Type	Full
SMC Status	Accepted

3.5.4 Selpercatinib: Retsevmo (SMC2370)

ERFC decision:

Name	Selpercatinib: Retsevmo (SMC2370)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Selpercatinib

Brand Name	Retsevmo
Formulation	40mg and 80mg hard capsules
Indication	Selpercatinib as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib. Selpercatinib as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2370
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/selpercatinib-retsevmo-tc-full-smc2370/
Date Advice Published	13/09/2021
SMC Submission Type	Full
SMC Status	Interim acceptance

3.5.5 Chloroprocaine hydrochloride: Ampres (SMC2373)

ERFC decision:

Name	Chloroprocaine hydrochloride: Ampres (SMC2373)
Source	SMC
Therapeutic Area	Anaesthesia
Generic Medicine	Chloroprocaine hydrochloride
Brand Name	Ampres
Formulation	10mg/mL solution for injection
Indication	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes. SMC restriction: for use in day-case anaesthetic pathways.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2373
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/chloroprocaine-hydrochloride-ampres-resub-smc2373/

Date Advice Published	11/10/2021
SMC Submission Type	Resubmission
SMC Status	Restricted

3.5.6 Pembrolizumab: Keytruda (SMC2375)

ERFC decision:

Name	Pembrolizumab: Keytruda (SMC2375)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Pembrolizumab
Brand Name	Keytruda
Formulation	25mg/mL concentrate for solution for infusion
Indication	As monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	The boards will consider if they intend to submit a FAF as patient numbers may be small.
Flags	N/A
Reference Number	SMC2375
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/pembrolizumab-keytruda-cc-full-smc2375/
Date Advice Published	13/09/2021
SMC Submission Type	Full
SMC Status	Restricted

3.5.7 Atezolizumab: Tecentriq (SMC2379)

ERFC decision:

Name	Atezolizumab: Tecentriq (SMC2379)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Atezolizumab
Brand Name	Tecentriq
Formulation	840mg and 1,200mg concentrate for solution for infusion
Indication	As monotherapy is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC.

Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2379
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/atezolizumab-tecentriq-full-smc2379/
Date Advice Published	08/11/2021
SMC Submission Type	Full
SMC Status	Accepted

3.5.8 Pembrolizumab: Keytruda (SMC2380)

ERFC decision:

Name	Pembrolizumab: Keytruda (SMC2380)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Pembrolizumab
Brand Name	Keytruda
Formulation	25mg/mL concentrate for solution for infusion
Indication	As monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2380
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/pembrolizumab-keytruda-full-smc2380/
Date Advice Published	08/11/2021
SMC Submission Type	Full
SMC Status	Restricted

3.5.9 Osimertinib: Tagrisso (SMC2383)

ERFC decision:

Name	Osimertinib: Tagrisso (SMC2383)
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Osimertinib
Brand Name	Tagrisso
Formulation	40mg and 80mg film-coated tablets
Indication	As monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions (Ex19del) or exon 21 (L858R) substitution mutations. SMC restriction: treatment with osimertinib is subject to a three-year clinical stopping rule.
Conclusion and Formulary Status	November 2021 - 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.
Other Comments (e.g. other action needed)	None
Flags	N/A
Reference Number	SMC2383
Link to SMC Advice	https://www.scottishmedicines.org.uk/medicines-advice/osimertinib-tagrisso-full-smc2383/
Date Advice Published	08/11/2021
SMC Submission Type	Full
SMC Status	Restricted

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

None raised.

4.3 NHS Lothian

- ADTC Approval of medicines governance applications and forms flowcharts via ADTC and accompanying SBAR noted by the ERFC.

- Link to updated flowcharts medicines governance applications and forms October 2021 shared post meeting. The Chair requested ERFC members send comments on the flowchart.

ACTION: ALL

- ADTC Procedure SMC Not Recommended Advice older than 10 years October 2021. Until the process has been approved by all 3 boards, applications via this route cannot be reviewed by the ERFC. Discussion on the proposed process to review group applications for SMC Not Recommended Advice older than 10 years at board level are ongoing. One of the board's informed that it had applications for future consideration in this category and one board has medicines on formulary which fall into this criteria. An update on this subject will be added to the agenda of the next meeting.

  ACTION: ERF project team

5 Any other competent business

None raised.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 02 February 2022.

FAF3s should be submitted by 28 December 2021 (for discussion at the ERWG meeting on 12 January 2022).

FAF1s and FAF2s should be submitted by 18 January 2022.

All FAFs need to include information from all 3 boards to be added to the agenda.

Apologies for the meeting to be sent to prescribing@nhslothian.scot.nhs.uk.