East Region Formulary

East Region Formulary Committee
Minutes

Date: 29th September 2021
Time: 2pm – 4pm
Location: MS Teams

Present:

Jane Browning	Lead Pharmacist, ERF Project Team
Ruth Cameron	Advanced Clinical Nurse Specialist – Urology, NHS Fife
Nicole Cromar	Pharmacist – Neurology, NHS Lothian
Gillian Donaldson	Nurse – Cardiology, NHS Borders
Anne Gilchrist	Lead Pharmacist, NHS Lothian
Dr Jane Goddard	Consultant – Renal, NHS Lothian
Fiona Grant	Physiotherapist, NHS Borders
Dr David Griffith	Consultant – Microbiologist (Co-chair), NHS Fife
Dr Sarah Hailwood	Consultant – Rheumatologist, 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
Diane Murray	Formulary Pharmacist, NHS Lothian
Euan Reid	Lead Pharmacist, 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, Medicines Management Team, NHS Lothian – Minutes

Apologies:

Dr Emma Christmas	GP, NHS Fife
Dr Maria Corretge	Consultant Geriatrician, NHS Lothian
Steven Fenton	Project Manager, ERF Project Team
Dr Peter Hall	Consultant – Oncology, NHS Lothian
Dr Linda McGourty	GP, NHS Fife
Fraser Notman	Formulary Pharmacist, NHS Fife
Angela Sinclair	Pharmacist – Rheumatology, NHS Fife

Meeting Goals/ Purposes/ Objectives:

- Agree terms of reference for ERFC, ERWG and CEWG
- Approve formulary application form templates
- Discuss and agree process for new medicines submissions
- Review new medicines applications

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1 Project update

1.1 Welcome and Apologies

The Chair welcomed everyone to the first meeting of the East Region Formulary Committee (ERFC) and thanked everyone for all their work in getting to this point in the process for the development of the East Region Formulary (ERF).

- ***Membership***

Membership has been drawn from the existing Formulary Committees (FC) (Borders, Fife and Lothian) to build on the expertise that these committees had. The intention is to add to the membership as any gaps in expertise are identified or as members leave.

- ***Chairs***

Three Co-Chairs volunteered to become chair. Dr David Griffith, Dr Andrew Watson and Ms Alison Wilson will each chair on a 6 month rotational model. The selection of the Co-Chairs has been sent to the ADTCs of each of the Boards for ratification.

- ***Declarations of interest***

Committee 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 project progress

Expert working groups have been established and 3 chapter reviews for Skin, GI and Infections are nearly complete. A presentation slide outlining the scheduling for future reviews was presented to the ERFC.

Updates and improvements to the new formulary website and app are on-going. The Risk Register is updated regularly and will be reported back to the ERFC.

2 Governance

2.1 Terms of Reference

The Terms of Reference (ToR) for the ERFC, East Region Working Group (ERWG) and Chapter Expert Working Group (CEWG) were circulated with the meeting papers.

ToRs are based on existing documentation from all 3 Boards. The ToRs had been circulated and commented on extensively over the last year, amongst the 3 Board formulary teams. The aim was to finalise the ToRs at the ERFC meeting.

The ERFC highlighted that the ERFC ToR needed a minor amendment to include that there may be a requirement to allow for a change to the Co-Chair arrangement and that in the future, the ERFC may require a Chair and a Vice Chair.

It was requested that the membership of ERFC and ERWG should also include a non-medical prescriber. This also applies for CEWG where appropriate.

It was suggested adding a member from one of the Board's Antimicrobial Management Teams (AMT) to the membership of the ERFC and ERWG. An existing ERFC member who is also part of an AMT clinical team informed that they could fulfil this role.

It was agreed that the quorum for the ERFC would be representation from all 3 Boards, a clinician representative from acute, a clinician representative from primary care, a pharmacist and at least 50% of members in attendance.
The ERFC suggested clarification on the wording regarding administrative support (which is shared between the 3 Boards) in case of a difference of opinion.
Subject to the changes outlined, the ERFC approved the ToRs. The ToRs will be added to the formulary website.

ACTION: KM

2.2 Formulary application form templates

The new formulary application form (FAF) templates were circulated with the ERFC meeting papers.
The FAF templates were designed based on the existing paperwork used in the 3 Boards.
It was suggested that some of the options in section J of the FAF1 form could be removed to avoid users inadvertently ticking these options.
The ERFC noted that there may be forms completed where it would be appropriate for the medicine to only be approved for use in a tertiary centre.
The ERFC suggested that the formulary amendment request form should be broadened to cover requests for both addition, replacement or deletion requests and to include a prompt to provide details relating to implementation.
The future intention is for the FAFs to be made available for completion as online forms.
Subject to the changes outlined, the FAF templates were approved for use. The FAF templates will added to the formulary website.

ACTION: ERF project team

2.3 ERWG minutes

The ERWG will meet a few weeks before the ERFC and will inform some ERFC agenda items.
The first ERWG meeting held, had an abbreviated membership. (The meeting notes from the ERWG were included with the ERFC papers for information.) The next meeting will be with attendees from ERWG's full membership.
The ERFC questioned what the process is if there is a disagreement between the ERWG and ERFC. It was clarified that the role of the ERWG and ERFC are complementary but differ and that a conflict of opinion is not foreseen. The ERFC is the committee that approves all formulary content.

2.4 ERF amendments

None.

3 New Medicines

3.1 Process for new medicines

A flowchart will be produced to explain the new process.
When SMC advice is sent out, the wording will explain that a joint application to the ERFC is expected. Any FAF1s received that only include details for one Board will not be accepted for the agenda until information from all 3 Boards is available from the applicants. The 3 Board's Formulary Pharmacists will help applicants with contact details for clinicians from each of the Boards.
FAF2s and FAF3s should also come with information from all 3 Boards.
All completed FAFs should be submitted directly to the ERFC. The only exception will be for unlicensed medicines, which will go to the ERWG first and then to the ERFC meeting.
The FAFs now ask for Clinical Directors to support the application and the clinical effectiveness of the proposal. Governance of medicine budget available is very complex across the Boards and HSCPs. Budget templates will be continue to be vital and will be used to inform all relevant bodies of the likely impact of formulary changes.

The Chair action may be required for urgent issues. However this process relates to groups of patients. Requests for individual patients should still go to the individual health Board. The flowchart will highlight the distinction between individual patients and patient group requests.
The ERFC raised a query in that Dumfries and Galloway are not part of the ERF but are part of SCAN. This is correct at this time and is something that will need to be taken in to account moving forward.
The ERFC asked if the ERF is part of the Single National Formulary. It was explained that the development of the ERF follows on from the early work of the Single National Formulary project but is separate. Further plans are not yet known but there is an expectation that any learning from the ERF project will be shared with the other Boards.
The ERFC agreed that a flowchart will be prepared to illustrate the new process for applications to use new medicines.

ACTION: JB

3.2 Formulary Application Forms

3.2.1 FAF1 avelumab (SMC 2359)

The committee noted and discussed the previously circulated FAF1 submission. One non-personal specific declaration of interest was 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 application has been submitted on behalf of SCAN.

ERF Decision:

Name	Avelumab: Bavencio
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Avelumab
Brand Name	Bavencio
Formulation	20mg/mL concentrate for solution for infusion
Indication	Avelumab is indicated as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.
Conclusion and Formulary Status	September 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments	None
Flags (website)	SUO
Reference Number	SMC2359
Link to SMC Advice	avelumab (Bavencio) (scottishmedicines.org.uk)
Date Advice Published	09 August 2021
SMC Submission type	Full
SMC Status	Accepted

3.2.2 FAF1 dupilumab (SMC 2317)

The committee noted and discussed the previously circulated FAF1. No declarations of interest were received. Proposed use of this medicine is as per SMC approved indication and restriction. There was no local treatment protocol included with the FAF. A finance budget template was included with the FAF.
Dupilumab had previously been discussed at NHS Fife FC and was approved subject to the approval of a guideline. This FAF was included for information.

ERF Decision:…/

ERF Decision:

Name	Dupilumab: Dupixent
Source	SMC
Therapeutic Area	Respiratory
Generic Medicine	Dupilumab
Brand Name	Dupixent
Formulation	200mg and 300mg solution for injection in pre-filled syringe and pen
Indication	In adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.
Conclusion and Formulary Status	September 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments	• Clarify discrepancies between the two forms around patient numbers and costs. • Guidelines to be approved in due course. • Check on estimated numbers for NHS Borders. • CEWG for respiratory to agree a pathway when reviewing Respiratory advice.
Flags (for website)	SUO
Reference Number	SMC2317
Link to SMC Advice	dupilumab (Dupixent) (scottishmedicines.org.uk)
Date Advice Published	12 April 2021
SMC Submission type	Full
SMC Status	Restricted

3.2.3 FAF1 nivolumab (SMC 2362)

The committee 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 application has been submitted on behalf of SCAN.

ERFC decision:

Name	Nivolumab: Opdivo
Source	SMC
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Nivolumab
Brand Name	Opdivo
Formulation	10mg/mL concentrate for solution for infusion
Indication	As monotherapy for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum based combination chemotherapy.
Conclusion and Formulary Status	September 2021 - Routinely available in line with national guidance. Included on the ERF for Specialist use only.
Other Comments	None
Flags (for website)	SUO
Reference Number	SMC2362

Link to SMC Advice	nivolumab (Opdivo) (scottishmedicines.org.uk)
Date Advice Published	09 August 2021
SMC Submission Type	Full
SMC Status	Accepted

3.3 SMC not recommended advice

3.3.1 None for this meeting – will catch up at the next meeting.

3.4 Abbreviated submissions

3.4.1 None for this meeting – will catch up at the next meeting.

3.5 Paediatric licence extensions

3.5.1 None for this meeting – will catch up at the next meeting.

3.6 Non-submissions within 90 days on SMC publishing

3.6.1 None for this meeting – will catch up at the next meeting.

4 Board specific information

4.1 NHS Borders

Borders FC last met on 25th August 2021.
Nothing to approve at this meeting.

4.2 NHS Fife

Fife FC last met on 22nd September 2021.
Nothing to approve at this meeting.

4.3 NHS Lothian

Lothian FC last met on 25th August 2021.
Matters arising from last meeting all noted and approved at this meeting.

Rituximab: Ruxience

A formulary amendment request was submitted from Lothian to switch to Ruxience biosimilar to replace Truxima biosimilar. No declarations of interest were received.
The committee reviewed and noted the proposal from Lothian with additional confirmation from Fife, and Borders to include Rituximab: Ruxience as the preferred rituximab preparation for all approved haematology indications currently on formulary.
The pathway malignant disease – antilymphocyte monoclonal antibodies treatment will be edited to include Ruxience instead of Truxima.

ERFC decision:

Name	Rituximab: Ruxience
Source	Local application
Therapeutic Area	Malignant disease and immunosuppression
Generic Medicine	Rituximab
Brand Name	Ruxience
Formulation	Concentrate for solution for infusion
Indication	In line with product licence and in line with SMC approved haematology indications. SMC advice 33/03, 135/04, 330/06, 540/09, 591/09, 675/11, 975/14, NICE TA243.
Conclusion and Formulary Status	September 2021 – Routinely available in line with local guidance for prescribing. Included on the ERF for Specialist use only.

Other Comments	The pathway malignant disease – antilymphocyte monoclonal antibodies treatment will be edited to include Ruxience instead of Truxima. The Truxima formulary decisions entry will be deleted.
Flags (for 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

Two new urgent requests for medicines for use in the treatment of COVID-19 were submitted to the ERFC:

Sarilumab: Kevzara
A formulary amendment form was submitted for Sarilumab. No declarations of interest were received. The amendment is to update the existing formulary committee decision in line with guidance from the coranovirus (COVID-19) alerts issued by the MHRA Central Alerting System - 12 September 2021 (interleukin-6 inhibitors).

The 3 Boards have guidelines for treatment of adults hospitalised with COVID-19. These need to be updated and approved locally. It was agreed that the decision is for ERF, with the Boards updating their guidelines for use in line with their previous process for approving medicines for use during the pandemic.

ERF Decision:

Name	Sarilumab: Kevzara
Source	Local application
Therapeutic Area	Infection
Generic Medicine	Sarilumab
Brand Name	Kevzara
Formulation	200mg solution for injection in prefilled syringe
Indication	For hospitalised patients with COVID-19 (adults) in line with local guidance for prescribing and coronovirus (COVID-19) alerts issued by the MHRA Central Alerting System – 12 September 2021 (interleukin-6 inhibitors)
Conclusion and Formulary Status	September 2021 – Routinely available in line with local guidance for prescribing. Classified for use under policy for the use of unlicensed Medicines. Included on the ERF for Specialist use only.
Other Comments	None
Flags (for 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

Casirivimab + Imdevimab: Ronapreve
A formulary amendment form was submitted for Casirivimab + Imdevimab. No declarations of interest were received. The medicine in question is a new medicine for inclusion on the formulary for the treatment of COVID 19, the proposed use of the medicine is off-label. The application is to include casirivimab and imdevimab in line with guidance from the coronovirus (COVID-19) alerts issued by the MHRA Central Alerting System - 17 September 2021 (Ronapreve)
The correct paperwork for this application would usually be a FAF3. In view of the urgent nature of the request and the comprehensive information provided in the coronovirus (COVID-19) alerts issued by the MHRA Central Alerting System the committee agreed to accept the paperwork for the proposal to use Ronapreve for the off-label dose recommended.

The 3 Boards have guidelines for treatment of adults hospitalised with COVID-19. They need to be updated and approved locally.

It was agreed that the decision is for ERF, with the Boards updating their guidelines for use in line with their previous process for approving medicines for use during the pandemic.
ERFC Decision:

Name	Casirivimab + Imdevimab: Ronapreve
Source	Local application
Therapeutic Area	Infection
Generic Medicine	Casirivimab + Imdevimab
Brand Name	Ronapreve
Formulation	120mg/ml solution for infusion
Indication	For hospitalised patients with COVID-19 (adults and children aged 12 and over) in line with local guidance for prescribing and coronovirus (COVID-19) alerts issued by the MHRA Central Alerting System – 17 September 2021 (Ronapreve)
Conclusion and Formulary Status	September 2021 – Routinely available in line with local guidance for prescribing. Classified for use under policy for the use of unlicensed Medicines. Included on the ERF for Specialist use only.
Other Comments	None
Flags (for 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

5 Any other competent business
None raised.

6 Date of next meeting
Wednesday 24th November 2021 – any papers to be submitted by 9 November 2021.
Apologies for the meeting to be sent to prescribing@nhslothian.scot.nhs.uk