NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 September 2025 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Mr Y Al-Obaidi	Mrs S O'Beirne	
Ms L Cameron	Mr R Sivewright	
Dr V Chieng		
Ms F Doney		
Dr L Elliot (Chair)		
Mrs M Galvin		
Mrs G McKerron		
Mrs E Milne		
Mr M Paterson		
Dr K Simpson		

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.
Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

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WELCOME
The Chair opened the meeting, welcomed members, and confirmed that a quorum was present.

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 19 AUGUST 2025

Members endorsed the draft note of the meeting, pending minor typographical amendments.

The final approved minute will be made publicly available within 21 days of formal approval. **FD**

2.2. FORMULARY GROUP DECISIONS AUGUST 2025 - PUBLISHED 01/09/2025

Members formally ratified the August 2025 decisions document as published.

3. MATTERS ARISING

3.1. ACTION LOG

The Action log was noted.

3.2. PREFERRED FOSTAIR®/LUFORBEC® PMDI

There were no declarations of interest recorded in relation to this product.

Ms Doney reported that Respiratory Managed Clinical Network (MCN) Prescribing Subgroup has changed its preferred combination inhaled corticosteroid (ICS) plus long-acting beta2 agonist (LABA) inhaler choice. The MCN supports replacing Luforbec® pressurised metered-dose inhaler (pMDI) with Proxor® pMDI.

The latest update of the NHS Grampian Respiratory MCN asthma prescribing guidance promotes anti-inflammatory reliever (AIR) and maintenance and reliever therapy (MART)

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regimens. The previous guidance will remain available for those not using the AIR regimen.

The Group supported the change proposed by the Respiratory MCN, noting that Luforbec® will no longer be promoted as a preferred product.

Proxor® 100micrograms/6micrograms, 200micrograms/6micrograms pressurised inhalation solution (beclometasone dipropionate/ formoterol fumarate dihydrate) is routinely available in line with local guidance.
Indication under review: for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:

- **patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or**
- **patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists**

Restriction: use is subject to inclusion in the Respiratory MCN framework for inhaled medicines.
It was classified 1a – available for general use and 8e – treatment may be initiated in either hospital or community. **FTEAM**

4. DISCUSSION

None.

5. NEW PRODUCT REQUESTS

5.1. FG1SMC 2750 - RUXOLITINIB (ACUTE GRAFT VERSUS HOST DISEASE)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for ruxolitinib for the treatment of patients aged 12 years and older with acute graft versus host disease (aGvHD) who have inadequate response to corticosteroids.

The Group noted that:

- ruxolitinib is a Janus Associated Kinase (JAK) inhibitor with selectivity for JAK1 and JAK2
- graft versus host disease (GvHD) is a major complication following allogenic haematopoietic stem cell transplantation. Systemic treatment with corticosteroids is recommended first-line for patients with moderate to severe aGvHD [ref SMC]
- there is no standard of care for patients with steroid-refractory aGvHD and the service stated that currently sirolimus or methotrexate are used off-label
- ruxolitinib:
  - [for this indication] meets SMC end of life and orphan equivalent criteria
  - [for this indication] was accepted for use in NHS Scotland only in the context of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
  - is the first licensed treatment for aGvHD in patients with an inadequate response to corticosteroids
  - is given orally as 10mg twice a day
- evidence comes from REACH2:
  - patients were randomised to receive oral ruxolitinib (n=154) or investigator's choice of best available therapy (BAT) (n=155)
  - the primary outcome of overall response rate (ORR) at day 28 was 62% for ruxolitinib vs 39% for BAT (complete response 34% vs 19% and partial response 28% vs 20% for ruxolitinib vs BAT respectively)
  - at day 56, the ORR was 40% versus 22% for ruxolitinib versus BAT respectively

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- the regulator noted that there is some uncertainty regarding the duration of benefit of ruxolitinib, as the overall response rate decreased between day 28 and day 56
- patient numbers are expected to be small
- in REACH2, the median duration of treatment in the ruxolitinib group was 63 days (ref SMC)
- the service stated that ruxolitinib will be preferred over other immunosuppressants such as sirolimus and methotrexate
- minimal cost off-set available, however some costs may already be in the system as some patients have received ruxolitinib via individual patient requests
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ruxolitinib

The Group accepted the restricted local need for ruxolitinib for the treatment of patients aged 12 years and older with aGvHD who have inadequate response to corticosteroids.

SMC 2750 - Ruxolitinib 5mg, 10mg tablets (Jakavi®) is routinely available in line with national guidance (SMC 2750).
Indication under review: for the treatment of patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids.
In a randomised, open-label, phase III study, ruxolitinib treatment resulted in a statistically significant improvement in overall response rate compared with best available therapy in patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Ruxolitinib treatment should only be initiated by a physician experienced in the administration of anti-cancer medicinal products. **FTEAM**

5.2. FG1SMC 2698 - BIMEKIZUMAB (HIDRADENITIS SUPPURATIVA)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for bimekizumab for the treatment of active moderate to severe hidradenitis suppurativa (HS) in adults for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.

The Group noted:
- bimekizumab:
  - is a monoclonal antibody designed to attach to interleukins IL-17A, IL-17F and IL-17AF, which are messenger molecules in the body's immune system
  - is administered subcutaneously as 320mg every 2 weeks up to week 16 then every 4 weeks thereafter
  - is already included on the formulary for other indications
- other treatments already included on the formulary for HS include the tumour necrosis factor (TNF) inhibitors adalimumab and infliximab, and the interleukin 17 inhibitor secukinumab
- evidence comes from BE HEARD I and II which compared bimekizumab to placebo:
  - the primary outcome was the proportion of patients with HiSCR50 (hidradenitis suppurativa clinical response) at week 16
  - BE HEARD 1: HiSCR50 48% vs 29% for bimekizumab vs placebo respectively
  - BE HEARD II: HiSCR50 52% vs 32% for bimekizumab vs placebo respectively

- there is no direct evidence comparing bimekizumab and secukinumab
- patient numbers treated in the first year are expected to be small, but may increase in subsequent years
- the service plans to supply bimekizumab via a manufacturer-commissioned homecare service, therefore costs will not include VAT
- treatment will be long term so costs will be cumulative
- some cost offset will be available from displacement of other biologic/biosimilar medicines
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of bimekizumab

The Group accepted the restricted local need for bimekizumab as an additional treatment option for active moderate to severe hidradenitis suppurativa (HS) in adults for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.

SMC 2698 – Bimekizumab 160mg, 320mg solution for injection in pre-filled pen, pre-filled syringe (Bimzelx®)▼ is routinely available in line with national guidance (SMC 2698).
Indication under review: for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy and for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.
In two phase III studies in patients with moderate to severe HS, significantly more patients achieved a clinical response (defined as ≥50% decrease in abscess and inflammatory nodule [AN] count with no increase in the number of abscesses and/or in the number of draining fistulae) with bimekizumab (every two weeks) compared with placebo at week 16.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Bimekizumab is indicated. FTEAM

5.3. FG1SMC 2751 - CLADRIBINE (ACTIVE RELAPSING-REMITTING MULTIPLE SCLEROSIS)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for cladribine tablets for the treatment of adults with active relapsing-remitting multiple sclerosis (RRMS).

The Group noted that:

- cladribine:
  - is administered orally at a recommended dose of 3.5mg/kg body weight over two years, administered as one treatment course of 1.75mg/kg per year. Each treatment course consists of two treatment weeks, one at the beginning of the first month and one at the beginning of the second month of the respective treatment year.
  - as Mavenclad®, is already included on the formulary for adults with two subgroups of patients with highly active relapsing MS (rapidly evolving severe relapsing-remitting MS and sub-optimal therapy relapsing-remitting MS), so the service has experience prescribing cladribine
- evidence comes from CLARITY:
  - patients were randomised to cladribine or placebo

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  - the primary outcome was annualised rate of relapse (ARR) at 96 weeks. The ARR was 0.14 versus 0.33 for cladribine versus placebo respectively
  - an indirect treatment comparison indicated that cladribine is at least as effective as the other disease modifying treatments for all the efficacy outcomes
- patient numbers are expected to be small
- the current formulary indications would be included in the RRMS population
- the service plans to supply cladribine by a homecare arrangement, so costs will not include VAT
- the service plans to use cladribine as an alternative choice in patients who are needle-phobic, live in a remote geographical area or would find it difficult to attend for regular infusions and are intolerant of treatment options. In some older patients cladribine is seen as a better tolerated option.

The Group accepted the restricted local need for cladribine for the treatment of adults with active RRMS, as outlined in SMC 2751.

SMC 2751 – Cladribine 10mg tablets (Mavenclad®) is routinely available in line with national guidance (SMC 2751).
Indication under review: for the treatment of adults with active relapsing-remitting multiple sclerosis (RRMS) as defined by clinical or imaging features.
In a phase III study, cladribine showed statistically significant improvements in the annualised relapse rate in adults with active relapsing-remitting MS, compared with placebo.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment must be initiated and supervised by a physician experienced in the treatment of MS. **FTEAM**

Items 5.5 and 5.5 were taken together.

5.4. FG1SMC 2569 - FENFLURAMINE (SEIZURES ASSOCIATED WITH DRAVET SYNDROME)

5.5. FG1SMC 2723 - FENFLURAMINE (SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME)

There were no declarations of interest recorded in relation to this product.

The Group considered the requests for fenfluramine, as add-on therapy to other anti-epileptic medicines, for the treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome where seizures have not been controlled after trying two or more anti-seizure medicines.

The Group noted that:
- fenfluramine is a serotonin releasing agent, which stimulates multiple 5-hydroxytryptamine (5-HT) receptor subtypes
- Dravet syndrome is a severe, lifelong and genetic form of epilepsy. It usually presents in the first year of life with recurrent, prolonged convulsive seizures.
- Lennox–Gastaut syndrome (LGS) is a severe, lifelong and treatment-resistant form of epilepsy that begins in early childhood, generally before the age of 8 years.
- Dravet syndrome and LGS are rare diseases with limited treatment options. Fenfluramine used in addition to other antiseizure medicines has been shown to reduce the frequency of seizures in children and young adults with these diseases.
- fenfluramine meets SMC orphan criteria for both Dravet and LGS
- fenfluramine is administered orally. The dose is titrated up to 0.35mg/kg twice daily (maximum 26mg daily) or to 0.2mg/kg twice daily (maximum 17mg daily) with concomitant stiripentol.
- patients must undergo an echocardiogram to establish a baseline prior to initiating treatment, then every 6 months for the first 2 years and annually thereafter
- evidence for use in Dravet syndrome:

  - three studies involving patients with Dravet syndrome compared fenfluramine with placebo, or fenfluramine plus stiripentol with placebo, all were given in addition to the patient's standard of care
  - at all doses fenfluramine was more effective than placebo for the primary and key secondary outcomes
- evidence for use in LGS:
  - a study involving 263 patients with LGS compared fenfluramine with placebo, both given in addition to the patient's standard of care
  - the study found that the median frequency of drop seizures reduced by 26.5% in the 87 patients receiving fenfluramine compared with 7.6% in those receiving placebo (87 patients)
- there are no direct evidence comparing fenfluramine with other potential add-on treatment options but, unless there are tolerability issues, treatments are generally added to current antiseizure medicines rather than replacing medicines
- there are a lack of long-term data (efficacy and safety), evidence is based on short term studies that have a 2 or 3 week titration period and 12-week maintenance period
- patient numbers are expected to be small but may be cumulative
- dosing is weight-based so costs will increase as a person's weight increases. The maximum daily dose is 26mg daily.
- patients will trial treatment for six months, treatment may be discontinued if seizure frequency is not reduced by 50% or there are adverse events of concern
- unless there are tolerability issues, antiseizure medicines are often added to current treatment rather than replacing
- there are some costs already in the system for people with Dravet syndrome
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of fenfluramine

The Group accepted the restricted local need for fenfluramine as add-on therapy to other anti-epileptic medicines, for the treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome for patients 2 years of age and older where seizures have not been controlled after trying two or more anti-seizure medicines.

SMC 2569 – Fenfluramine 2.2mg/mL oral solution (Fintepla®)▼ is routinely available in line with national guidance (SMC 2569).
Indication under review: for the treatment of seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older where seizures have not been controlled after trying two or more anti-seizure medicines.
In three phase III studies compared with placebo, the addition of fenfluramine significantly reduced convulsive seizure frequency in children aged 2 to 18 years with Dravet syndrome that was inadequately controlled by current anti-epileptic medicines.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by physicians with experience in the treatment of epilepsy. FTEAM

SMC 2723 - Fenfluramine 2.2mg/mL oral solution (Fintepla®)▼ is routinely available in line with national guidance (SMC 2723).
Indication under review: treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older whose seizures have not been controlled after trying two or

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more anti-epileptic medicines.
In a randomised, double-blind, phase III study, fenfluramine significantly reduced drop seizure frequency in patients (aged 2 to 35 years) with Lennox-Gastaut syndrome that was inadequately controlled by current anti-epileptic medicines, compared with placebo.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by physicians with experience in the treatment of epilepsy. **FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES SEPTEMBER 2025

There were no declarations of interest recorded in relation to these products.

DEBRANDING

Ms Bruce reported that Pfizer Limited has debranded Provera®, which will now be marketed as medroxyprogesterone acetate.

Members supported updating the formulary entry to remove the brand name, only the generic name will be noted on the formulary. **FTEAM**

DISCONTINUATIONS

Ms Bruce reported that:
- Bayer plc has discontinued estradiol 50micrograms/24hours, 100micrograms/24hours transdermal patches (Progynova TS®)
- sodium fusidate/fusidic acid:
  - Leo Laboratories Limited has ceased manufacturing sodium fusidate 250mg tablets and fusidic acid 250mg/5mL oral suspension as the brand Fucidin®
  - Essential Pharma Limited has ceased manufacturing sodium fusidate intravenous infusion
  - the Antimicrobial Management Team is aware of the discontinuation and considers the situation manageable as alternative agents would be available, or requests could be handled on a case-by case basis
- Sandoz Limited has discontinued topotecan capsules, the infusion remains available

The changes are considered low impact discontinuations.

Members supported update of the formulary entries to note the discontinuations. **FTEAM**

6.2. ORAL NUTRITIONAL SUPPLEMENTS FORMULARY UPDATE

The Chair reported that the oral nutritional supplement choices have been updated. The first choice is now Ensure® Shake following the discontinuation of the previous first choice product, Fresubin® Powder Extra.

DIABETES MANAGED CLINICAL NETWORK FORMULARY CHOICE METERS AND TEST STRIPS

Ms Doney reported that the current choice of meters and strips for self-monitoring of capillary blood glucose [for people with Type 2 diabetes mellitus] is under review with an update planned for the Grampian Diabetes Managed Clinical Network (MCN) Professional Conference tomorrow.

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6.3. RYBELSUS® (ORAL SEMAGLUTIDE): RISK OF MEDICATION ERROR DUE TO INTRODUCTION OF NEW FORMULATION WITH INCREASED BIOAVAILABILITY

Ms Doney reported that a new higher bioavailability formulation of oral semaglutide tablets, as the brand Rybelsus®, will be introduced and there is a risk of medication error while the old and new formulations are available.

The Medication Safety Officer and Medicines Management Team are aware of the issue and this will become a 'live' issue when both the old and new formulations are available in prescribing and/or dispensing systems.

The new strength tablets will be added to the formulary in alignment with the existing formulary positioning, subject to the product's market availability.

Semaglutide 1.5mg, 4mg, 9mg tablets (Rybelsus®) is routinely available in line with local guidance.
Indication under review: in addition to other oral anti-diabetic medicines, for adults with type 2 diabetes mellitus, where glycaemia is insufficiently controlled, as an adjunct to a reduced-calorie diet and increased physical activity and who have a BMI >30kg/m^2 (adjust for ethnicity).
Restriction: as a fourth-line choice, generally after a trial of an injectable GLP-1 RA. Consider if triple therapy with metformin and two other drugs not effective/not tolerated/contraindicated.
It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist (specialist to include GPs/independent prescribers with a specialist interest in diabetes). **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED SEPTEMBER 2025

The Group noted the SMC advice published September 2025.

Following publication of the non-submission statements for belzutifan (Welireg®▼ - SMC 2864) and encorafenib (Braftovi® - SMC 2865), these medicines will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2808 blinatumomab (Blincyto®)▼ (submission expected)
- SMC 2799 rucaparib (Rubraca®)

Local advice for these medicines and indications will be included in the September 2025 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED SEPTEMBER 2025

The Group noted the SMC provisional advice issued September 2025.

If the SMC issues negative recommendations or non-submission statements next month, these medicines will not be included on the formulary for the specified indications. **FTEAM**

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9. OTHER BUSINESS

9.1. POSITION STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE (AI) IN MEDICINES INFORMATION (MI) OR MEDICINES ADVICE SERVICES

The Chair highlighted the position statement as an interesting document that members should read as it is important to be aware of the pit falls and dangers of using these technologies, especially as they become incorporated into our working lives.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (MHRA Safety Round-up August 2025), 10.2 (MedWatch Vol.6:Issue 3 August 2025), 10.3 (Grampian Acute and Mental Health Medicines meeting minute April 2025), 10.4 (Grampian Area Drug and Therapeutics Committee meeting minute July 2025), 10.5 to 10.8 (Antimicrobial Management Team meeting minute April 2025, May 2025, June 2025, July 2025), were noted.

11. AOCB

THANK YOU AND GOODBYE

Ms Doney, on behalf of the Group, expressed sincere thanks to Mr Bob Sivewright for his longstanding contribution as the finance representative for the Group. His expertise and commitment, to this and other medicines management meetings, have been greatly valued over the years, and he leaves with the Group's warmest wishes for a fulfilling retirement.

DATE OF NEXT MEETING

Tuesday 21 October 2025 starting at 14.30 via Microsoft Teams.

Signature on file

CHAIR'S SIGNATURE **Dr Louise Elliot** **DATE 21 OCTOBER 2025**