NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 January 2025 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Dr D Culligan	
Dr V Chieng	Mrs M Galvin (and deputy Mrs S Howlett)	
Ms A Davie (from item 5.1)	Mrs E Milne (and deputy Mrs B Tiesman)	
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Mrs G McKerron (from item 3)		
Mr M Paterson		
Mr R Sivewright (from item 2.2)		
Mrs S O'Beirne		
Dr K Simpson		

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.

ITEM	SUBJECT	ACTION

WELCOME

The Chair welcomed members, opened the meeting, and noted 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 NOVEMBER 2024

The Chair reported that the draft minute was not available for the meeting. It would be shared after the meeting with members given until 07 February to return comments to Ms Doney. **ALL**

Once agreed the final approved minute will be in the public domain within 21 days of final approval. **FD**

2.2. FORMULARY GROUP DECISIONS NOVEMBER 2024 - PUBLISHED 02/12/2024

Members ratified the decisions of the November 2024 meeting as published.

3. MATTERS ARISING

3.1. Action LOG

The Chair reported that the Action log was not available for the meeting.

ACTION FROM NOVEMBER 2024 MEETING - SMC 2670 FOLLITROPIN DELTA (REKOVELLE®)

The Chair confirmed that the Marketing Authorisation Holder (MAH), of follitropin delta (Rekovelle®), confirmed that the Rekovelle® Dose Calculator app has gone through the relevant assessment process/conformity assessment and it is registered by the Medicines and Healthcare products Regulatory Agency (MHRA).

Item closed. **FTEAM**

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4. PRESENTATION/DISCUSSION

None.

5. NEW PRODUCT REQUESTS

5.1. SMC 2697 - TENECTEPLASE (THROMBOLYTIC TREATMENT OF ACUTE ISCHAEMIC STROKE)

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

The Group considered the request for tenecteplase 5,000 units (25mg) in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.

The Group noted that:

- tenecteplase:
  - is a recombinant fibrin-specific plasminogen activator that is derived from native tissue plasminogen activator (t-PA). It binds to the fibrin component of the thrombus and selectively converts thrombus-bound plasminogen to plasmin, which degrades the fibrin matrix of the thrombus. The treatment effect is time-dependent; therefore, earlier treatment increases the probability of a favourable outcome.
  - [for this indication] was accepted for use in NHS Scotland following an abbreviated submission reviewed by the SMC executive
  - [for this indication] is administered as a single intravenous bolus over approximately 5 to 10 seconds, with a maximum single dose of 5000 units (25mg tenecteplase)
- alteplase:
  - is an alternative antithrombotic agent licensed for acute ischaemic stroke
  - is administered as an initial intravenous bolus, immediately followed by the remainder of the total dose infused intravenously over 60 minutes
  - is the most relevant comparator for the submission
- evidence for tenecteplase in acute ischaemic stroke comes from phase II and phase III studies:
  - AcT demonstrated non-inferiority against alteplase for the proportion of patients with modified Rankin Scale (mRS) score of 0 to 1 at 90 to 120 days after treatment, and no meaningful differences observed between tenecteplase and alteplase in key safety outcomes
  - EXTEND-IA TNK Part 1 (phase II study) showed that tenecteplase resulted in a better 90-day functional outcome than alteplase (primary endpoint met in 22% (22 patients) of patients in the tenecteplase group versus 10% (10 patients) in the alteplase group (incidence difference, 12 percentage points; 95% CI, 2 to 21; incidence ratio, 2.2; 95% CI, 1.1 to 4.4; P = 0.002 for non-inferiority).
- that the British and Irish Association of Stroke Physicians:
  - supports tenecteplase (dose 0.25mg/kg) as a safe alternative to alteplase for patients with acute ischaemic stroke eligible for thrombolysis within 4.5 hours of onset and should become the standard of care
  - recommends that it is reasonable for Stroke Services to consider a complete switch from alteplase to tenecteplase for the treatment of acute ischaemic stroke in both the conventional and extended time window to simplify treatment pathways and avoid potential dosing errors which may occur if both alteplase and tenecteplase were to be available

Members accepted the practical advantages, ease of administration (single bolus delivery), time- and cost-savings, involved with the introduction of tenecteplase (5,000units (25mg)) for acute ischaemic stroke.
To simplify treatment pathways and avoid potential dosing errors, which may occur if both alteplase and tenecteplase were available, members supported the service's plans to

implement a complete switch from alteplase to tenecteplase only for acute ischaemic stroke. Alteplase will remain on formulary for other indications.

Members recognised the training/educational need for colleagues across NHS Grampian, NHS Shetland and NHS Orkney to ensure the safe introduction and implementation of tenecteplase as the preferred thrombolytic agent for the treatment of acute ischaemic stroke.

The Group accepted the restricted local need for tenecteplase as outlined in SMC 2697, for use in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.
The Medication Safety Advisor will liaise with the Service and Pharmacy colleagues to support the safe introduction of tenecteplase for this indication. **LC**

SMC 2697 - Tenecteplase 5,000 units (25mg) powder for solution for injection (Metalyse®) is routinely available in line with national guidance (SMC 2697).
Indication under review: in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.
Tenecteplase offers an additional treatment choice in the therapeutic class of antithrombotic agents.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Tenecteplase must be prescribed by physicians experienced in neurovascular care and the use of thrombolytic treatment, with the facilities to monitor that use. The appropriate presentation of tenecteplase product should be chosen carefully and in line with the indication. The 25mg presentation of tenecteplase is only intended for use in acute ischaemic stroke.
Tenecteplase should be administered on the basis of body weight, with a maximum single dose of 5,000 units (25mg tenecteplase) for the indication acute ischaemic stroke.
Benefit-risk of tenecteplase treatment should be carefully evaluated in patients weighing 50kg or less due to limited availability of data. **FTEAM**

Items 5.2 and 5.3 were taken together.

5.2. SMC 2614 - GLOFITAMAB (RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA)

5.3. SMC 2632 - EPCORITAMAB (RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA)

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

The Group considered the requests for glofitamab infusion and epcoritamab injection, both as monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy.

The Group noted that:
- DLBCL is a cancer that affects B cells, a type of white blood cell
- glofitamab and epcoritamab are 'bispecific' agents. They are described as 'bispecific' because they recognise and attach to two targets simultaneously: CD20, a protein that is present on the surface of B cells (including the cancer cells), and CD3, a protein found on the surface of healthy T cells. By binding to the CD20 and CD3 proteins, the drugs bring together the cancer cells and T cells. This encourages the T cells to destroy the cancer cells and helps control the disease.
- evidence for glofitamab comes from NP30179, an ongoing open-label, multicentre,

single-arm, phase I/II study evaluating glofitamab in patients with relapsed or refractory DLBCL. The primary outcome was complete response (CR), secondary outcomes were DOCR = duration of complete response; DOR = duration of response; ORR = objective response rate; OS = overall survival; PFS = progression-free survival. Glofitamab was given for 12 treatment cycles and was not compared with other medicines.

- NP30179 - results in the intention-to-treat population (N=155):
  - CR rate was 39% (95% CI, 32–48) and the ORR was 52% (95% CI, 43–60). At the time of primary analysis, the primary efficacy endpoint was met in the primary efficacy population (n=108) with an IRC-assessed CR rate of 35% (95% CI, 26–45), which was significantly greater than the pre-specified 20% historical control CR rate (p<0.001)
  - the median duration of response in responders was 18.4 months (95% CI, 13.7–not reached) and the median duration of CR was not reached (95% CI, 16.8–not reached)
  - CR was achieved within an average of 42 days after starting treatment, and of those patients who achieved a CR, 75% maintained this response 12 months after starting treatment
  - patients received a median of 5 cycles of glofitamab treatment (range: 1 to 13 cycles) with 34.7% receiving 8 or more cycles and 25.7% receiving 12 cycles, ref SmPC
- evidence for epcoritamab comes from EPCORE NHL-1, an open-label, single-arm, multicentre, phase I/II study evaluating epcoritamab, as monotherapy, in patients with relapsed or refractory DLBCL after two or more lines of systemic therapy. The primary outcome was ORR = overall response rate (IRC-assessed, using Lugano criteria). Secondary outcomes were DOCR; DOR; OS; PFS. Epcoritamab was administered by subcutaneous injection in 28-day cycles of 4 week until disease progression or unacceptable toxicity.
- EPCORE NHL-1 - efficacy was evaluated in 139 patients:
  - the overall response rate (ORR) was 62% (82/139) in patients with DLBCL, with 39% of patients in complete response
  - updated analysis (data cut-off 30 June 2022) supported the primary analysis and showed that patients maintained these responses for an average of ~16 months, with a median OS of 18.5 months
  - the median duration of exposure to epcoritamab was 3.7 months (range: 0 to 25 months), ref SmPC
- limitations of the evidence were:
  - the studies were single-arm phase I/II study, so there could be biases in reporting side effects or outcomes
  - no direct evidence comparing either medicine with any of the comparator treatments
  - small patient numbers
  - long-term efficacy and safety data are limited
- patient numbers are expected to be small
- the SMC advice for both glofitamab infusion and epcoritamab injection take account of the benefits of PASs that improve the cost-effectiveness of treatment, and were accepted for use only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
- the requestor confirmed that:
  - it would be beneficial to have both treatments on the formulary because they have different treatment courses (fixed duration versus ongoing until progression/unacceptable toxicity) and are administered by different routes (infusion versus injection)
  - patient fitness will determine treatment choice, the ‘fitter’ patients would be offered a bispecific agent

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The Group accepted the restricted local need for both glofitamab infusion and epcoritamab injection, as monotherapy for the treatment of adults with relapsed or refractory DLBCL after two or more lines of systemic therapy, as outlined in SMC 2614 and SMC 2632 respectively.

SMC 2614 – Glofitamab 1mg/mL concentrate for solution for infusion (Columvi®)▼ is routinely available in line with national guidance (SMC 2614).
Indication under review: as monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.
In a phase I/II open-label study, 40% of patients treated with glofitamab who had R/R DLBCL after two or more lines of systemic therapy had a complete response.
This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements 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.
Glofitamab must only be administered under the supervisions of a healthcare professional experienced in the diagnosis and treatment of cancer patients and who has access to appropriate medical support to manage severe reactions associated with cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). **FTEAM**

SMC 2632 – Epcoritamab 4mg/0.8mL concentrate for solution for injection, 48mg solution for injection (Tepkinly®)▼ is routinely available in line with national guidance (SMC 2632)
Indication under review: as monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.
In a phase I/II open-label study, 62% of patients treated with epcoritamab who had R/R DLBCL after two or more lines of systemic therapy achieved objective response.
This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements 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.
Epcoritamab must only be administered under the supervisions of a healthcare professional qualified in the use of anti-cancer therapies with access to appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS). **FTEAM**

5.4. SMC 2587 - BELZUTIFAN (ADULTS WITH VON HIPPEL-LINDAU (VHL) DISEASE

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

The Group considered the request for belzutifan for the treatment of adults with von Hippel-Lindau (VHL) disease who require therapy for VHL associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable.

The Group noted that:

- VHL disease is a rare, potentially life-threatening genetic disease which causes tumour growth in multiple organ systems. Tumours can grow in several different sites at the same time and are often heavily vascularised. Tumours can predominantly affect the brain, spine, eyes, kidneys, pancreas, adrenal glands and inner ears.
- tumours are often benign, but they have the potential to cause pressure on the brain, nerves, and spinal tissue. They can lead to permanent damage, disability, or death in some cases. Some tumours can become cancerous, such as those found in the kidneys and pancreas.
- VHL tumours are unlikely to spontaneous regress
- throughout their lifetime patients diagnosed with VHL face regular surveillance and multiple surgeries to resect VHL-associated tumours and prevent metastasis or manage symptoms. As there is a risk of further tumours, organ-sparing surgery is recommended if feasible.
- the surgeries and procedures may lead to morbidity including renal insufficiency, pancreatic insufficiency and neurological deficits. After tumours have metastasized, standard therapies for advanced malignancies are used.
- belzutifan:
  - is an inhibitor of hypoxia-inducible factor 2 alpha (HIF-2α). In healthy cells, HIF-2α plays a role in helping the body respond to low oxygen levels. But in certain cancers, including those linked to VHL disease, this protein can become overactive, allowing tumours to grow and spread more easily.
  - works by blocking this HIF-2α protein, which helps to stop or slow down the growth of tumours
  - is the first medicine licensed for VHL
  - [for this indication] treatment should continue until disease progression or unacceptable toxicity
  - [for this indication] meets SMC orphan criteria and was accepted for use only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
- evidence comes from LITESPARK-004 an open-label, multicentre, single-arm, phase II study. At the data cut-off (1 April 2022), for primary and secondary outcomes, LITESPARK-004 showed:
  - high overall response rates for RCC and pNET (64% (39/61) and 91% (20/22) respectively); a partial response in a large proportion of patients with VHL-associated RCC (57%; 35/61) and pNET (59% 13/22), stable disease for many patients with CNS hemangioblastomas (46%; 23/50).
  - approximately 70% of people with VHL develop RCC
- limitations:
  - open-label study so there could be biases in reporting side effects or outcomes
  - patient numbers are small, but this is not unexpected for a rare condition
  - no direct evidence comparing belzutifan with standard of care - a matched adjusted indirect comparison (MAIC) was used to inform the economic analysis
  - long-term efficacy and safety data are limited
- this would be a new cost to the system, and in the studies the median length of treatment has not been reached so costs will be cumulative
- patient numbers are small, VHL is a variable disease and patient care is complex
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of bulzetifan

Members acknowledged that belzutifan provides the opportunity to preserve quality of life, control the disease and spare patients from surgeries or procedures that may compromise organ function.

The Group accepted the restricted local need for belzutifan as outlined in SMC 2587, for the treatment of adults with VHL disease who require therapy for VHL associated RCC,

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CNS hemangioblastomas, or pNETs, and for whom localised procedures are unsuitable or undesirable.

SMC 2587 – Belzutifan 40mg tablets (Welireg®)▼ is routinely available in line with national guidance (SMC 2587)
Indication under review: for the treatment of adults with von Hippel-Lindau (VHL) disease who require therapy for VHL associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable.
In a single-arm, phase II study, belzutifan was associated with overall response rates of at least 64%, 44% and 91% in RCC, CNS and pNET, respectively.
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.
Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTEAM**

5.5. SMC 2655 - ETRASIMOD (ULCERATIVE COLITIS)

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

The Group considered the request for etrasimod tablets for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

The Group noted that:

- UC is a chronic inflammatory bowel disease, which affects the rectum and colon and is characterised by remissions and exacerbations. Symptoms include recurrent episodes of diarrhoea, rectal bleeding and abdominal pain, and patients are at an increased risk of perforated bowel, toxic megacolon and colorectal cancer. The treatment goal for patients with active disease is to induce and maintain remission and mucosal healing.
- a significant number of patients with moderate to severe UC do not respond, lose response or are intolerant to currently available therapies
- June 2024, following an abbreviated submission reviewed by the SMC executive, etrasimod was accepted for use within NHS Scotland for the treatment of patients 16 years of age and older with moderately to severely active UC who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent (SMC 2655)
- etrasimod is the second sphingosine-1-phosphate (S1P) receptor modulator licensed for UC. Licensing limits use to patients who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.
- the mechanism by which S1P receptor modulators exert their therapeutic effects in UC is unknown but may involve the reduction of lymphocyte migration into sites of inflammation
- there is no direct evidence comparing etrasimod with relevant comparators. The submitting company conducted a network meta-analysis (NMA) to compare the efficacy of etrasimod to comparators (ozanimod, tofacitinib, filgotinib, upadacitinib, vedolizumab, infliximab, adalimumab, golimumab and ustekinumab) in adults with moderately to severely active UC with and without prior exposure to biologic therapy. SMC concluded that etrasimod is an efficacious treatment for patients with moderately to severely active ulcerative colitis and is comparable to currently available therapies

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used in the advanced treatment of UC.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of etrasimod
- the costing error within the submission
- the additional pressures expected, including on other services - a baseline electrocardiogram (ECG), and the need for consultation with cardiology for some people. People with diabetes, uveitis, or retinal disease require a pre-treatment ophthalmologic examination.

Members queried the error in the costings submitted and the potential for drug interactions with medications changes in Primary Care.

The Group deferred decision-making pending confirmation of the queries posed in the reviews, and confirmation of the monitoring arrangements.

SMC 2655 - Etrasimod 2mg film-coated tablets (Velsipity®) ▼ decision deferred to future meeting.
Indication under review: for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.
Etrasimod offers an additional treatment choice in the therapeutic class of sphingosine 1-phosphate (S1P) receptor modulators.
This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.
Decision deferred to future meeting. **FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES – DISCONTINUED MEDICINES

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

Ms Doney reported that:
- Eli Lilly and Company Limited has discontinued the originator duloxetine brands, Cymbalta® and Yentreve®. Generic products remain available.
- Emerade® 150mg, 300mg, 500mg solution for injection in pre-filled pen has been discontinued, this follows a long period of being unavailable after the precautionary recall in 2023
- Novo Nordisk Ltd has discontinued Insulatard® Penfill 100units/mL suspension for injection in cartridge (human isophane insulin). Discontinuation is due to the company consolidating its portfolio and supplies are expected to be exhausted by March 2025.
- Thornton & Ross Ltd has confirmed that Metanium Nappy Rash Ointment has been discontinued and is out of stock indefinitely due to issues in sourcing the raw materials to make the ointment.
- Johnson & Johnson Ltd confirmed that Neutrogena® T/Gel® therapeutic shampoo is being discontinued from February 2025 with stocks expected to be depleted by March 2025. The decision is due to commercial reasons.
- Pfizer Ltd confirmed that Norinyl-1® 1mg/50microgram tablets (norethisterone/mestranol) is discontinued. The discontinuation is not due to a safety concern and stocks are now depleted. Alternatives are available - Brevinor® 35microgram/500microgram tablets (norethisterone/ethinylestradiol) and Norimin® 35microgram/1mg tablets (norethisterone/ethinylestradiol).
- Aristo Pharma Limited has discontinued Strontium ranelate Aristo® 2g granules for oral suspension. The MAH has confirmed that the product has been out of stock since October 2023 (due to a manufacturing issue affecting the active pharmaceutical

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ingredient) and the MAH has discontinued it on prescribing systems.

Ms Doney confirmed that the discontinuations are considered low impact withdrawals, and after meetings information about the decisions is routinely shared with the Medicines Management Team.

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

6.2. DARA-VRD

Ms Doney confirmed that:

- the licence for daratumumab subcutaneous injection has been extended to include use in combination with bortezomib, lenalidomide and dexamethasone (Dara-VRD), for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant
- SMC will not review this minor change to the indication
- August 2024 the Group accepted the off-label use of both the intravenous and subcutaneous formulations of daratumumab as the four drug regimen Dara-VRD [for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant]
- December 2024 the Formulary Team updated the current formulary entry for daratumumab subcutaneous injection noting that this regimen is now licensed
- the Haematology Service confirmed that daratumumab infusion is no longer used in NHS Grampian

The Group accepted the licence extension for daratumumab subcutaneous injection without the need for a full submissions.

Daratumumab 1,800mg solution for subcutaneous injection (Darzalex®) is routinely available in line with local guidance.
Indication under review: in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
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. **FTEAM**

Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) is not routinely available as there is a local preference for alternative medicines.
Indication under review: as licensed.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

6.3. SBAR BOWEL CLEANSING PREPARATIONS

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

The Group considered the SBAR from the Gastroenterology and Surgical departments requesting a change of bowel cleansing preparation from Picolax® to Plenvu®.

The Group noted that:

- Klean-prep® was discontinued last year, leaving Moviprep® and Picolax® as the remaining formulary options in NHS Grampian
- the consensus from the Gastroenterologists and Colorectal surgeons is that NHS Grampian should change its bowel preparation treatment from Picolax® to Plenvu®
- recent analysis of bowel preparation data showed better bowel preparation satisfaction scores with Plenvu® than was achieved with Picolax®

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- Plenvu® is a polyethylene glycol (PEG) based laxative
- other health boards in NHS Scotland have moved to PEG-based solutions
- by improving the quality of bowel preparation at the index procedure, the need for repeat procedures due to poor preparation will be reduced
- Picolax® is the only bowel cleansing product that is licensed for children and adolescents, so will remain on the formulary

The Group accepted that Plenvu® offered advantages for the services (potential for less failures) and patients (lower volume of fluid) and supported the request to include Plenvu® on the formulary as a preferred bowel cleansing preparation.

SBAR – Plenvu® powder for oral solution is routinely available in line with local guidance.
Indication under review: in adults for bowel cleansing prior to any procedure requiring a clean bowel.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

6.4. SBAR BUPRENORPHINE

The Group discussed the SBAR requesting changes to the current formulary choices for opioid substitution.

Members deferred decision-making and requested additional information:
- costings to include the comparative cost of individual agents and the potential impact on costs from the suggested changes
- breakdown of use of methadone versus buprenorphine formulations
- if product switch is being considered how will this be implemented and what support is planned for prescribers **FTEAM**

6.5. NEW FORMULATION OF DESMOPRESSIN

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

Ms Doney reported that the Paediatric Service and local Medicines Management Team have requested that a new formulation of desmopressin is considered for inclusion on the formulary.

The Group noted that:
- other formulations of desmopressin are currently included on the formulary (nasal spray, tablet (including oral lypophilisate) and injection)
- the Paediatric Service is requesting addition of desmopressin liquid, as a 360micrograms/mL oral solution (Demovo®)
- there is currently a small use of other strengths of desmopressin liquid, and desmopressin acetate 360micrograms/mL oral solution provides a cost-effective choice with more flexible dosing
- the 360micrograms/mL oral solution has shown bioequivalence to desmopressin acetate tablets (0.5mL 180micrograms = 200micrograms desmopressin tablets = 120microgrmas DesmoMelt®)

The Group accepted the restricted local need for an additional formulation of desmopressin acetate, oral solution, with the preferred preparation currently being the 360micrograms/mL oral solution.

Desmopressin acetate 360micrograms/mL oral solution (Demovo®) is routinely available in line with local guidance.
Indication under review: in adults, adolescents and children over 5 years for the treatment of:

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- **central diabetes insipidus**
- **primary nocturnal enuresis in patients with normal capacity to concentrate urine**

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. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED DECEMBER 2024

The Group noted the SMC advice published December 2024.

Following publication of the negative SMC recommendations, for durvalumab (Imfinzi®) SMC 2677 and Lecigon® (levodopa/carbidopa monohydrate/entacapone) SMC 2507, 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 2696 vibegron (Obgemsa®)▼ (request expected)
- SMC 2684 zanubrutinib (Brukinsa®) (submission received)

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

Members discussed the abbreviated advice for vibegron, a beta-3 adrenergic agonist, licensed for the symptomatic treatment of adults with overactive bladder syndrome. Vibegron costs marginally less than mirabegron (~ £30 less per annum), and the Service has confirmed it would be beneficial to have a second beta-3 adrenergic agonist on the formulary.

The Medicines Information representative confirmed that vibegron can be crushed so may be beneficial for people with swallowing difficulties.

Members requested further information, including a comparison versus mirabegron (to include review of cautions, side-effects, etc.). **FTEAM/ MI**

The Service will be contacted to request a review of the current pathways for lower urinary tract symptoms. **FTEAM**

7.2. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED JANUARY 2025

The Group noted the SMC advice published January 2025.

Following publication of the non-submission statements, for Biktarvy®▼ (bictegravir/emtricitabine/ tenofovir alafenamide) SMC 2760 and rozanolixizumab (Rystiggo®)▼ SMC 2761, 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 2739 ciclosporin (Cequa®) (submission expected)
- SMC 2728 crovalimab (Piasky®)▼
- SMC 2675 danicopan (Voydeya®)▼
- SMC 2676 iptacopan (Fabhalta®)▼
- SMC 2686 risankizumab (Skyrizi®) (submission received)
- SMC 2666 Ryeqo®▼ (relugolix/estradiol/norethisterone acetate) (submission

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expected)
- SMC 2710 sirolimus (Hyftor®) (submission expected)
- SMC 2731 ublituximab (Briumvi®)▼
- SMC 2721 vamorolone (Agamree®)▼ (submission received)

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

7.3. ULTRA-ORPHAN MEDICINES ASSESSMENT REPORT (UMAR)

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

The Group noted that:
- SMC 2624, fosdenopterin, is an ultra-orphan medicines assessment report (UMAR). Medicines undergoing an initial assessment of evidence by the SMC are considered outwith remit for the Formulary Group; these medicines will ultimately be accessed via the Scottish Government ultra-orphan pathway.
- Scottish Government Medicines Policy Branch will notify Health Boards when this medicine is available for prescribing within the ultra-orphan pathway. Meantime any requests to access treatment should be considered through local non-formulary processes.
- in NHS Grampian there are currently no paediatric patients affected with this condition or needing this treatment. If a case was identified, they would be assessed by the inherited metabolic diseases service and treatment recommendations would be made by one of the specialist consultants.

In line with local processes, the Group supported recording the decision as 'Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).'

SMC 2624 - fosdenopterin 9.5mg powder for solution for injection (Nulibry®)▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of patients with molybdenum cofactor deficiency (MoCD) Type A.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED JANUARY 2025

The Group noted the SMC provisional advice issued January 2025.

If the negative SMC advice is published next month, this medicine will not be included on the formulary for the indication in question.

8.2. NATIONAL CANCER MEDICINES ADVISORY GROUP (NCMAG) ADVICE

8.2.1. NCMAG119 POMALIDOMIDE IN COMBINATION WITH DEXAMETHASONE. FOR TREATMENT OF ADULTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR TREATMENT REGIMEN INCLUDING LENALIDOMIDE (OFF-LABEL USE, OFF-PATENT).

8.2.2. NCMAG120 POMALIDOMIDE IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE. FOR TREATMENT OF ADULTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR TREATMENT REGIMEN INCLUDING LENALIDOMIDE (OFF-PATENT).

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Ms Doney confirmed that advanced notification and publication of the decisions for NCMAG 119 and 120 has been delayed while National framework contract pricing for generic pomalidomide is finalised.

9. OTHER BUSINESS

9.1. ASTHMA: DIAGNOSIS, MONITORING AND CHRONIC ASTHMA MANAGEMENT (SIGN 245) – ADVICE PUBLISHED NOVEMBER 2024

The Chair confirmed that the Respiratory Managed Clinical Network (MCN) will review the updated SIGN asthma guidance and take forward any necessary changes.

9.2. ALL WALES MEDICINE STRATEGY GROUP – PRESCRIBING DILEMMAS A GUIDE FOR PRESCRIBERS UPDATED NOVEMBER 2024

The Chair confirmed that the All Wales document was shared with the local Medicines Management Team for consideration.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update November 2024), 10.2 (Drug Safety Update December 2024), 10.3 (Primary Care Prescribing Group meeting minute July 2024), 10.4 (Primary Care Prescribing Group meeting minute September 2024), 10.5 (Antimicrobial management team meeting minute October 2024), 10.6 (Acute and Mental Health Medicines Safety Group meeting minute Oct 2024), 10.7 (MedWatch newsletter December 2024) and 10.8 (Advice to health professionals from UK Chief Medical Officers, UK Chief Nursing Officers and UK Chief Midwifery Officers - Folic acid supplementation - continued advice for those who are planning a pregnancy or newly pregnant) were noted.

11. AOCB

TRIAL CANCELLATION OF THE DECEMBER MEETING

Members discussed the trial cancellation of the December meeting, and agreed that it was a success without overloading the January meeting.
Members approved reducing the meeting schedule to 10 meetings a year. **FTEAM**

DATE OF NEXT MEETING

Tuesday 18 February 2025 starting at 14.30 via Microsoft Teams

Signature on file

CHAIR'S SIGNATURE **Fiona Doney** **DATE 18 FEBRUARY 2025**