

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 18 February 2025 at 14:30 via Microsoft Teams**

**PRESENT**

Dr V Chieng  
Ms A Davie  
Ms F Doney (Chair)  
Mrs E Milne  
Dr L Elliot (left at item 6.1)  
Mrs G McKerron  
Mrs S O'Beirne (from item 5.3)  
Mr M Paterson  
Dr K Simpson (from item 2.3)  
Mr R Sivewright (from item 5.3)

**APOLOGIES**

Ms L Cameron  
Mrs M Galvin (and deputy Mrs S Howlett)

**APPROVED**

**IN ATTENDANCE**

Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.

Note some items were taken outwith agenda order.

**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**

Members accepted the draft note of the meeting subject to minor typographical changes.

The corrected final approved minute will be in the public domain within 21 days of final approval.

**FD**

**2.2.   DRAFT MINUTE OF THE MEETING HELD 21 JANUARY 2025**

Members accepted the draft note of the meeting subject to minor typographical changes.

The corrected final approved minute will be in the public domain within 21 days of final approval.

**FD**

**2.3.   FORMULARY GROUP DECISIONS JANUARY 2025 - PUBLISHED 03/02/2025**

Members ratified the decisions of the January 2025 meeting as published.

**3.    MATTERS ARISING**

**3.1.   Action Log**

The Action log was noted.

ITEM	SUBJECT	ACTION
4.	<b>PRESENTATION/DISCUSSION</b>	
	None.	
5.	<b>NEW PRODUCT REQUESTS</b>	
	Item 5.3 was taken first.	

### 5.3. SMC 2611 - DARIDOREXANT (INSOMNIA)

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

The Group considered the request for daridorexant film-coated tablets (Quviviq®) for the treatment of adults with insomnia characterised by symptoms present for at least three months and considerable impact on daytime functioning.

The Group noted that:

- daridorexant:
  - was accepted for restricted use in NHS Scotland following a full submission. Treatment was restricted to patients who have failed cognitive behavioural therapy for insomnia (CBT-I) or for whom CBT-I is unsuitable or unavailable.
  - is a new agent, a dual orexin receptor antagonist (DORA). It works by blocking the action of orexin, a substance produced by the brain that promotes wakefulness.
- evidence comes from two main studies, phase III data (Studies 301 and 302 plus the extension to these, Study 303). In Study 301, n=930, those given 50mg over 3 months were able to reduce the time they spent awake each night by 29 minutes, on average, compared with a reduction of 11 minutes for those given placebo. Also, after 3 months of treatment, patients who took 50mg fell asleep around 35 minutes faster than before treatment, while those taking placebo fell asleep 23 minutes faster.
- limitations of the evidence were:
  - licensing is based on short-term data (efficacy data - 3 months; extension study for safety 3 months + 40 weeks)
  - long-term efficacy and safety data are limited
  - the study exclusion criteria provided a highly selected population, so the data may not be representative of the people seen in practice. The studies excluded patients with insomnia that could be explained by co-existing physical or mental health conditions or substance abuse, and there is no data for those aged over 75 years.
  - there are minimal data in patients who have failed CBT-I, i.e., the proposed positioning
- daridorexant costs significantly more than alternative hypnotics, e.g., approximately £510 (regardless of daridorexant dose) versus ~ £30 per annum (Z-drugs)
- the request did not include an estimate of patient numbers, and members considered that the manufacturer's budget impact template underestimated the potential patient numbers
- NICE's clinical experts highlighted that if daridorexant were recommended support and training for general practitioners (GPs) would be needed

Members:

- discussed the lack of data for adverse effects, the effects on peoples' sleep with prolonged use, the impact on quality of sleep when stopped and data on physiological and psychological tolerance
- considered that the populations most likely to benefit from treatment were excluded from the trial(s) [over 75 years of age]
- noted that one of the important potential risks of treatment is suicidal behaviour in

ITEM	SUBJECT	ACTION
	<p>high-risk patients, i.e., those with a medical history of depression or other psychiatric disorders, and there is no data in this patient group [study exclusion criterion]</p> <ul style="list-style-type: none"> <li>noted that a half-dose [25mg] should be given if a person has abnormal liver function tests (LFTs), and queried if patients' require a LFT check before initiating treatment</li> <li>noted the range of costs for hypnotics and that daridorexant costs significantly more than alternative agents</li> <li>accepted that digital CBT-I, in the form of Sleepio, is available in NHS Scotland and queried the availability of in-person CBT-I services locally</li> <li>considered that there is a need for an insomnia treatment pathway to support promotion of CBT-I as the first-line treatment option and, if required, subsequent prescribing of hypnotics</li> <li>queried if melatonin should be considered for formulary inclusion</li> </ul> <p>Following a long discussion the Group considered that the benefits of treatment appeared small, and concerns remained about the lack of data (long-term efficacy and safety data, and no data in certain patient groups).</p> <p>The Group agreed that there was not enough information to support prescribing, and that there was a need for more information including a local treatment pathway for insomnia.</p> <p>The Group deferred decision-making to a future meeting.</p>	
	<p><b>SMC 2611 - Daridorexant 25mg, 50mg film-coated tablets (Quviviq®)▼ decision deferred to future meeting.</b></p> <p><b>Indication under review: for the treatment of adults with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning who have failed cognitive behavioural therapy for insomnia (CBT-I) or for whom CBT-I is unsuitable or unavailable.</b></p> <p><b>Daridorexant, compared with placebo, improved time to fall asleep and waking after sleep onset in adults with insomnia.</b></p> <p><b>Decision deferred to future meeting.</b></p>	FTEAM
5.1.	<p><b>SMC 2660 - PEMBROLIZUMAB (HER2-NEGATIVE GASTRIC OR GASTRO-OESOPHAGEAL JUNCTION ADENOCARCINOMA)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the request for pembrolizumab used in combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS) <math>\geq 1</math>.</p> <p>The Group noted that:</p> <ul style="list-style-type: none"> <li>pembrolizumab [for this indication] was accepted for use in NHS Scotland following a full submission</li> <li>the recommended dose of pembrolizumab in adults is either 200mg every 3 weeks or 400mg every 6 weeks administered as an intravenous infusion</li> <li>evidence comes from KEYNOTE-859: <ul style="list-style-type: none"> <li>the primary outcome was overall survival (OS) with secondary outcomes of progression-free survival (PFS) and objective response rate (ORR)</li> <li>treatment continued until disease progression, unacceptable toxicity or a maximum of 24 months (35 cycles of pembrolizumab every three weeks)</li> <li>in the pembrolizumab plus chemotherapy group, pembrolizumab monotherapy was</li> </ul> </li> </ul>	

ITEM	SUBJECT	ACTION
	<p>permitted if chemotherapy was discontinued or capped at 6 cycles</p> <ul style="list-style-type: none"> <li>October 2022, at the interim analysis, pembrolizumab plus chemotherapy resulted in statistically significant improvements in the primary and hierarchically tested secondary outcomes. Since the primary and secondary outcomes were all met at the interim analysis, no further formal analysis was performed.</li> <li>evidence for the CPS population comes from a subgroup of KEYNOTE-859; patients with CPS <math>\geq 1</math> (78% [1235/1579] of the intention to treat (ITT) population</li> <li>exploratory post-hoc subgroup analyses in patients with CPS <math>\geq 5</math> and CPS <math>\geq 1</math> to <math>&lt; 5</math> (data cut-off 03 October 2022). For the CPS <math>\geq 5</math> subpopulation (49% [767/1579] of the ITT population), a greater treatment effect was observed in the pembrolizumab plus chemotherapy group compared with placebo plus chemotherapy group for OS (HR 0.70 [95% CI: 0.60 to 0.82]) and PFS (HR 0.69 [95% CI: 0.58 to 0.81]). For the CPS <math>\geq 1</math> to <math>&lt; 5</math> subpopulation (30% [468/1579] of the ITT population), a similarly positive treatment benefit was observed in the pembrolizumab plus chemotherapy group compared with placebo plus chemotherapy for OS (HR 0.78 [95% CI: 0.64 to 0.95]) and PFS (HR 0.78 [95% CI: 0.64 to 0.96]).</li> <li>limitations: <ul style="list-style-type: none"> <li>no evidence against nivolumab plus doublet chemotherapy</li> <li>some uncertainties in the generalisability of KEYNOTE-859</li> <li>the treatment benefit appears to be driven by patients with a higher CPS level</li> </ul> </li> <li>no new or unexpected safety issues, and the Service has significant experience using immunotherapies like pembrolizumab</li> <li>patient numbers are expected to be small</li> <li>this will be a new additional cost for people with a CPS <math>\geq 1</math> to <math>&lt; 5</math> as pembrolizumab is used alongside chemotherapy</li> <li>nivolumab plus doublet chemotherapy is already available for CPS <math>\geq 5</math>, and pembrolizumab plus doublet chemotherapy for CPS <math>\geq 10</math></li> <li>in line with KEYNOTE 859, treatment will be limited to people with an ECOG-PS of 0 or 1</li> <li>the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab</li> </ul>	

The Group accepted the restricted local need for pembrolizumab as outlined in SMC 2660, in combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS  $\geq 1$ . In line with previous advice formulary acceptance is subject to inclusion of a two-year stopping rule.

**SMC 2660 - Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2660). Indication under review: in combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS)  $\geq 1$ .**

**Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.**

**In a phase III study, the addition of pembrolizumab to a fluoropyrimidine and platinum-containing chemotherapy regimen was associated with a significant improvement in overall survival in adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma whose tumours express PD-L1 with a CPS  $\geq 1$ .**

**This advice applies only in the context of approved NHS Scotland Patient Access**

ITEM	SUBJECT	ACTION
	<p><b>Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.</b></p> <p><b>This advice replaces advice in SMC 2420 only relating to patients with HER2-negative gastro-oesophageal junction adenocarcinoma expressing PD-L1.</b></p> <p><b>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.</b></p>	FTEAM

## 5.2. SMC 2535 - TEPOTINIB (ADVANCED NON-SMALL CELL LUNG CANCER)

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

The Group considered the request for tepotinib for the treatment of adults with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations.

The Group noted that:

- tepotinib:
  - [for this indication] has a conditional marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) and meets SMC end of life criteria
  - [for this indication] was accepted for use in NHS Scotland following a resubmission assessed under the end of life process and the output from the PACE process
- in NSCLC patients with 'METex14 skipping', an abnormal form of the MET protein is produced that causes cancer cells to divide and grow in an uncontrolled fashion. Tepotinib, is a receptor tyrosine kinase inhibitor (TKI) that attaches to this abnormal MET protein inside cancer cells. This stops the effect of MET, helping to slow down the growth and spread of the cancer.
- the efficacy of tepotinib was evaluated in one cohort of a single-arm, open-label, multicentre study (VISION) in adults with locally advanced or metastatic NSCLC harbouring METex14 skipping alterations
  - the primary objective was to evaluate the activity of tepotinib by determining objective response rate (ORR). Secondary outcomes include duration of response, progression-free survival, overall survival (OS) and health-related quality of life.
  - at the 20 February 2022 data cut-off, with 9 months follow-up, Cohorts A+C (n= 313) of the phase II VISION study reported an ORR of 51% in patients with advanced NSCLC with METex14 skipping alterations. The median duration of response was 18.0 months and median OS was 19.3 months (15.8 to 22.3).
  - longer-term follow-up is now available, for Cohorts A (>3 years) and C, that confirms the response rates and durability of response
- limitations:
  - evidence is based on one non-randomised cohort of a phase II study – uncertainty in the data, and immature data
  - single-arm study, no comparative arm limits the interpretation of efficacy and safety
  - small patient numbers
  - there are no safety or efficacy data in less fit patients [those with a ECOG-PS ≥2]
- tepotinib is the first targeted treatment licensed for METex14 skipping alterations in advanced NSCLC, and it is included in the national treatment pathway
- patient numbers are expected to be very small
- treatment should continue until disease progression or unacceptable toxicity. Dose interruption or reduction, or discontinuation of treatment may be required based on adverse reactions (36% of patients required a dose reduction due to a treatment-emergent adverse event).
- the median treatment duration was 8.02 months (range: 0.03 to 43.33, ref SmPC)
- cost offset would be available from displacement of immunotherapy monotherapy or chemo-immunotherapy or chemotherapy

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none"> <li>the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of tepotinib</li> <li>the requestor confirmed that METex14 skipping alteration is tested locally at diagnosis [for all adenocarcinomas]</li> </ul> <p>Noting that tepotinib is the first targeted treatment licensed for METex14 skipping alterations in advanced NSCLC, the Group accepted the restricted local need for tepotinib for the treatment of adults with advanced NSCLC harbouring METex14 skipping alterations.</p> <p><b>SMC 2535 - Tepotinib 225mg film-coated tablets (Tepmetko®)▼ is routinely available in line with national guidance (SMC 2535).</b></p> <p><b>Indication under review: for the treatment of adults with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations.</b></p> <p><b>In a phase II single-arm study in adults with advanced NSCLC with METex14 skipping mutations, tepotinib was associated with an objective response rate of 51%.</b></p> <p><b>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.</b></p> <p><b>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.</b></p> <p><b>Treatment must be initiated and supervised by a physician experienced in the use of anticancer therapies.</b></p> <p><b>Prior to initiation of treatment with tepotinib the presence of METex14 skipping alterations should be confirmed by a validated test method using nucleic acids isolated from either tumour or plasma specimens. Testing for the presence of METex14 skipping alterations in tissue specimens is recommended because of higher sensitivity. However, plasma specimens may be used in patients for whom a tumour biopsy cannot be obtained. If an alteration is not detected in a plasma specimen, the feasibility of biopsy for tumour tissue testing should be evaluated.</b></p>	
	<p><b>5.4. NCMAG 116 - DASATINIB ((OFF-LABEL USE) NEWLY DIAGNOSED PH+ ACUTE LYMPHOBLASTIC LEUKAEMIA)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the request for the off-label use of dasatinib for the treatment of adults with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) integrated with chemotherapy, as outlined in the National Cancer Medicines Advisory Group (NCMAG) advice document NCMAG 116.</p> <p>The Group noted that:</p> <ul style="list-style-type: none"> <li>ALL is a blood cancer that develops rapidly with the overproduction of immature B-cells or T-cells. Historically, Ph+ ALL was characterised as having the worst prognosis; however, with the introduction of TKIs, survival rates have improved. In the UK, the estimated 5-year overall survival for Ph+ ALL patients range from 27% (40 year or over) to 57% (15 to 39 years).</li> <li>common symptoms of ALL include spontaneous bleeding, fatigue, infections, fever, weight loss, and swollen lymph nodes. Due to the aggressive nature of ALL patients require urgent treatment and supportive therapy on diagnosis which usually requires an admission to hospital.</li> </ul>	FTEAM

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none"> <li>the primary goal of therapy in newly diagnosed Ph+ ALL is to achieve cure, if possible, which may depend on patient's fitness to tolerate treatment</li> <li>the treatment of newly diagnosed Ph+ ALL currently involves induction therapy with imatinib (a first generation TKI), steroids, multi-agent chemotherapy and monoclonal antibodies. After induction, the treatment response is assessed to inform the decision to proceed with an allogeneic stem cell transplant (SCT).</li> <li>if a transplant is not performed after the first complete remission, patients who can tolerate it will typically receive intensified chemotherapy aimed at preventing central nervous system (CNS) relapse and consolidating remission, followed by maintenance treatment. Older patients have high relapse rates despite maintenance treatment and may not be able to tolerate intense chemotherapy treatment.</li> <li>due to the effectiveness of TKIs, the benefit of stem cell transplants at first complete remission is more uncertain. Patients responding well to TKIs may experience long-term durable remission without a transplant.</li> <li>dasatinib is currently included on the formulary [for the treatment of chronic myelogenous leukaemia]</li> <li>dasatinib is subject to confidential contract pricing</li> <li>patient numbers are expected to be small</li> <li>dasatinib will replace imatinib for this indication</li> <li>the service has experience prescribing dasatinib and managing its adverse effects</li> <li>dasatinib provides the potential for better response, plus with better CNS penetration/reduced CNS relapse rates, and better gastrointestinal tolerability</li> </ul> <p>The Group accepted the restricted local need for the off-label use of dasatinib for the treatment of adults with newly diagnosed Ph+ ALL integrated with chemotherapy, as outlined in NCMAG 116.</p> <p><b>NCMAG 116 – Dasatinib 20mg, 50mg, 100mg film-coated tablets is routinely available in line with national guidance (NCMAG 116).</b>  <b>Indication under review: [off-label use] for the treatment of adults with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) integrated with chemotherapy.</b>  <b>This advice applies only in the context of the confidential pricing agreements in NHS Scotland, upon which the decision was based, or confidential pricing agreements or list prices that are equivalent or lower.</b>  <b>It was classified 3b - licensed product available for restricted off-label use and 8b - recommended for hospital use only.</b>  <b>Therapy should be initiated by a physician experienced in the diagnosis and treatment of patients with leukaemia.</b></p>	
		FTEAM

## 6. FORMULARY REVIEW

### 6.1. FORMULARY UPDATES – DISCONTINUED MEDICINES

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

The Chair reported that:

- Noden Pharma DAC has discontinued aliskiren tablets. Aliskiren is a non-formulary medicine that is not recommended for use in NHS Scotland.
- Britannia Pharmaceuticals Limited is discontinuing apomorphine hydrochloride 5mg/mL solution for infusion in 10mL pre-filled syringes (APO-go®). Once stock of the 10mL pre-filled syringes are depleted, patients will be switched to apomorphine hydrochloride 5mg/mL in 20mL solution for infusion cartridges (APO-go® POD). The change is cost neutral but a different pump is used to administer the medication.
- Orion Pharma (UK) Ltd has discontinued Tridestra® tablets (estradiol 2mg, estradiol

ITEM	SUBJECT	ACTION
	<p>2mg/medroxyprogesterone 20mg and placebo), alternative Hormone Replacement Therapy (HRT) preparations are available.</p> <p>The Chair confirmed that the discontinuations are considered low impact withdrawals.</p>	
	<p><b>Members supported update of the formulary entries to note the discontinuations.</b></p>	FTEAM
	<p>SMC 2624 - FOSDENOPTERIN 9.5MG POWDER FOR SOLUTION FOR INJECTION (NULIBRY®)</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group noted that:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• January 2025, using the ultra-orphan framework, the SMC completed its initial assessment of the evidence for fosdenopterin (Nulibry®) for the treatment of patients with molybdenum cofactor deficiency (MoCD) Type A.</li> <li>• January 2025 fosdenopterin was added to the formulary as '<i>Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).</i>'</li> <li>• The Scottish Government confirmed that from 12 February 2025, fosdenopterin (Nulibry®) can be prescribed within the ultra-orphan pathway while further evidence on its effectiveness is generated. After 3 years the company will provide an updated submission for reassessment to allow a decision on its routine use in NHS Scotland.</li> </ul> <p>In line with local processes, the Group supported updating the formulary decision to '<i>Not routinely available in NHS Grampian. If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme.</i>'</p> <p><b>SMC 2624 - Fosdenopterin 9.5mg powder for solution for injection (Nulibry®)▼ is not routinely available in NHS Grampian.</b></p> <p><b>Indication under review: for the treatment of patients with molybdenum cofactor deficiency (MoCD) Type A.</b></p> <p><b>Not routinely available in NHS Grampian. If local need identified, treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme.</b></p>	FTEAM
	<p><b>6.2. POMALIDOMIDE NOW AVAILABLE GENERICALLY (UPDATE FORMULARY ENTRY; LINKS WITH CONFIDENTIAL NCMAG ADVICE ITEM 8.2)</b></p> <p>The Chair reported that as pomalidomide is now off-patent and available as generic products the Formulary Team will update the current formulary entry to remove the brand name.</p>	FTEAM
	<p><b>6.3. GALCANEZUMAB (ANTI-CGRP FOR MIGRAINE - REQUEST TO INCLUDE ON FORMULARY AGAIN FOR SOME PATIENTS, E.G., COMING TO NHS GRAMPIAN ALREADY ESTABLISHED ON TREATMENT)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the request for re-inclusion of galcanezumab on the formulary for the prophylaxis of migraine.</p>	



ITEM	SUBJECT	ACTION
	<p>The Group noted that:</p> <ul style="list-style-type: none"> <li>the service is requesting galcanezumab is (re-)included on the formulary primarily to allow continuation of therapy for patients moving to NHS Grampian already established on treatment. Formulary inclusion will reduce the potential for delays in treatment and allow treatment continuation whilst follow-up in the Headache Service is arranged.</li> <li>there are four calcitonin gene-related peptide (CGRP) antagonists licensed in the UK for the prophylaxis of migraine, erenumab, fremanezumab, galcanezumab and eptinezumab (the only IV preparation)</li> <li>if failure of the first agent, patients are generally offered a second CGRP antagonist, and previously the service confirmed that a third CGRP antagonist would not be sequenced</li> <li>currently erenumab will remain first-line for chronic migraine</li> </ul> <p>Noting that formulary inclusion would reduce delays in access to treatment for patients moving into NHS Grampian already established on treatment the Group accepted the restricted local need for galcanezumab. Acceptance was in line with the previous approval. <b>Galcanezumab 120mg solution for injection in prefilled pen (Emgality®) is routinely available in line with local guidance.</b></p> <p><b>Indication under review: for prophylaxis of migraine in adults with:</b></p> <p><b>1) chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine)</b></p> <p><b>2) high frequency episodic migraine (headaches on 10 to 15 days per month)</b></p> <p><b>Restriction: adults whose condition has failed to respond to at least three prior oral prophylactic treatments.</b></p> <p><b>Selection of appropriate patients and provision of galcanezumab is restricted to the NHS Grampian Headache Service.</b></p> <p><b>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.</b></p> <p><b>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.</b></p> <p><b>Treatment should be initiated by physicians experienced in the diagnosis and treatment of migraine.</b></p>	FTEAM

## 7. PUBLISHED ADVICE

### 7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED FEBRUARY 2025

The Group noted the SMC advice published February 2025.

Following publication of the negative SMC recommendation for lecanemab (Leqembi®) ▼ SMC 2700, this medicine will not be included on the Grampian Joint Formulary for the indication in question.

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

- SMC 2718 cabotegravir (Apretude®) ▼ (submission expected)
- SMC 2719 cemiplimab (Libtayo®) ▼ (submission expected)
- SMC 2734 durvalumab (Imfinzi®) ▼
- SMC 2723 fenfluramine (Fintepla®) ▼ (submission expected)
- SMC 2737 olaparib (Lynparza®) (submission expected)
- SMC 2720 Roclanda® ▼ (netarsudil/latanoprost)

Local advice for these medicines and indications will be included in the February 2025

ITEM	SUBJECT	ACTION
	decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.	FTEAM
8.	<b>PROVISIONAL ADVICE</b>	
8.1.	<b>SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED FEBRUARY 2025</b>	
	The Group noted the SMC provisional advice issued February 2025.	
	If the negative SMC recommendations and non-submission statements are published next month, these medicines will not be included on the formulary for the indications in question.	
8.2.	<b>NATIONAL CANCER MEDICINES ADVISORY GROUP (NCMAG) ADVICE ISSUED FEBRUARY 2025</b>	
	The Group noted the NCMAG provisional advice issued February 2025.	
9.	<b>OTHER BUSINESS</b>	
9.1.	<b>MEDICINES - ACHIEVING VALUE AND SUSTAINABILITY IN PRESCRIBING: GUIDANCE</b>	
	The Chair confirmed that the Scottish Government guidance achieving value and sustainability in prescribing will be taken forward by the local Medicines Management Team.	
10.	<b>DOCUMENTS FOR INFORMATION</b>	
	Items 10.1 (Drug Safety Update January 2025), 10.2 (Medicines Guidelines and Policies Group meeting minute October 2024), 10.3 (Antimicrobial Management Team meeting minute November 2024), and 10.4 (Grampian Area Drug and Therapeutics Committee meeting minute November 2024) were noted.	
	ITEM 10.5 (THE FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE STATEMENT: ULIPRISTAL ACETATE AND BREASTFEEDING)	
	A member asked if this information had been sent to Community Pharmacists. The Formulary Team will highlight the information with colleagues in the Pharmaceutical Care Services Team for consideration for inclusion in a future newsletter.	FTEAM
11.	<b>AOCB</b>	
	NATIONAL REVIEW PANEL FOR PACS TIER 2 – REQUEST FOR ADTC MEMBER	
	The Chair will forward on an email from the national PACS panel looking for panel members.	FTEAM
	FSRH STATEMENT: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONISTS AND ORAL CONTRACEPTION	
	The Chair reported that the FSRH statement regarding glucagon-like peptide-1 (GLP-1) agonists and oral contraception was linked to the formulary and would be emailed to members after the meeting.	FTEAM
	<b>DATE OF NEXT MEETING</b>	
	Tuesday 18 March 2025 starting at 14.30 via Microsoft Teams	

ITEM	SUBJECT	ACTION
------	---------	--------

Signature on file

CHAIR'S SIGNATURE	<u>Fiona Doney</u>	DATE 18 MARCH 2025
-------------------	--------------------	--------------------