NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 June 2023 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Miss R Anderson	Dr D Culligan	
Ms L Cameron (from item 4)	Mrs S Howlett	
Dr V Chieng		
Ms A Davie		
Ms F Doney (Vice-Chair)		
Dr E Elias		
Dr L Elliot (Chair)		
Mrs G McKerron		
Dr M Metcalfe (Vice-Chair)		
Mrs E Milne		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Dr Callum Duncan, Consultant Neurologist, and Dr David Watson, GP with Extended Role (GPwER), for item 3.
Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

OBSERVER
Mrs Mary Macfarlane, Principal Pharmacist, NHS Shetland for item 3.

Note some items were taken outwith agenda order.

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WELCOME

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

The Chair welcomed Mrs Emma Milne to the Group as a Primary Care Lead Pharmacist representative.

1. APOLOGIES

Apologies for absence were requested and noted.

3. PRESENTATION – RIMEGEPANT AND EPTINEZUMAB IN MIGRAINE

The Chair welcomed Dr Callum Duncan, Consultant Neurologist, and Dr David Watson, GPwER, to the meeting to discuss the formulary submissions for two new medicines for migraine, rimegepant and eptinezumab.

Dr Duncan provided the Group with an overview of the burden of migraine, the classification and treatment of migraine, barriers to care including underutilisation of acute and preventative treatment, and the development of a national headache pathway for the acute treatment of migraine. He then moved on to discuss the possible use of the calcitonin gene-related peptide (CGRP) antagonists, rimegepant for the acute treatment of migraine and eptinezumab for the prophylaxis of migraine.

Dr Duncan and Dr Watson felt strongly that rimegepant, as an acute treatment, should be prescribed in Primary Care. Treatment would be restricted to adults that had inadequate relief to a trial of two or more triptans, or where triptans are contraindicated, and it should have the same guidance as other acute treatments, e.g., limit acute treatment up to 10 days per month/~two per week to prevent development of medication overuse headache.

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The proposed national treatment protocol for the acute treatment of migraine in Primary Care provides guidance on the proposed placement of rimegepant.

The national headache pathway should be available by the end of Summer and Dr Duncan and Dr Watson plan to provide education sessions about the acute treatment of migraine in Primary Care, including how to use triptans correctly.

Dr Duncan and Dr Watson proposed replacing galcanezumab with eptinezumab, and restricting the use to the 100mg dose, with treatment only available from the Headache Service.

The Chair thanked Dr Duncan and Dr Watson for the informative presentation and discussion. Dr Duncan and Dr Watson left before decision-making.

8.1. FG1SMC 2547 - EPTINEZUMAB (PROPHYLAXIS OF MIGRAINE) AND

8.2. FG1SMC 2521 - RIMEGEPANT (ACUTE TREATMENT OF MIGRAINE)

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

The Group considered the request to include eptinezumab on the formulary for the prophylaxis of chronic and episodic migraine in adults who have at least four migraine days per month and who have had prior failure on three or more migraine preventive treatments.

The Group noted that:

- eptinezumab:
  - is a monoclonal antibody designed to attach to CGRP and prevent it from binding to its target
  - is given as 100mg intravenous infusion every 12 weeks. Some patients may benefit from a dosage of 300mg every 12 weeks.
- the other CGRP antagonists already on formulary include erenumab, fremanezumab and galcanezumab. These are all available as subcutaneous injections which patients can self-administer.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of eptinezumab
- the Headache Service considers that the advantages of eptinezumab [compared to the other CGRP antagonists] is that it has a rapid onset of action making it attractive for patients who are very severely affected, and it is available as an intravenous preparation making it attractive for patients who are unable to self-inject
- the Headache Service plans to use eptinezumab in the following groups:
  - for chronic migraine it may be given in preference to:
    1) Botox® in some patients severely affected. Botox® will be given first in the majority of patients.
    2) erenumab as the first-line CGRP antagonist in some severely affected patients. Erenumab will be given after Botox® in the majority as per current protocol.
  - for high frequency episodic migraine and chronic migraine it will displace some fremanezumab, careful consideration will be given to fremanezumab vs eptinezumab. It will replace galcanezumab.
- the Headache Service considers that if eptinezumab is included on the formulary then galcanezumab can be removed from formulary
- patients will be assessed for response at 3 and 6 months. Each patient will complete a headache diary ahead of treatment and continue to keep a headache diary thereafter. If patients do not achieve >30% response with chronic migraine or >50% response with high frequency episodic migraine, treatment will be stopped.
  The need for ongoing treatment will be reviewed at 12 months and yearly thereafter.
- costs are already in the system and the cost of eptinezumab will generally be offset

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from displacement of alternative treatment options.

The Group accepted the restricted local need for eptinezumab infusion for the prophylaxis of chronic migraine and high frequency episodic migraine in line with local guidance.

SMC 2547 - Eptinezumab 100mg concentrate for solution for infusion (Vyepti®) ▼ is routinely available in line with local guidance.
Indication under review: for the prophylaxis of migraine in adults with:
1) chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine) whose condition has failed to respond to ≥3 prior oral prophylactic treatments
2) high frequency episodic migraine (headaches on 10 - 14 days per month) whose condition has failed to respond to ≥3 prior oral prophylactic treatments
Eptinezumab provides an additional treatment choice in the therapeutic class of calcitonin gene-related peptide (CGRP) inhibitors.
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.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. The treatment should be initiated by a healthcare professional experienced in the diagnosis and treatment of migraine. **FTEAM**

The Group supported the Headache Service's position to remove galcanezumab from the formulary, as there is now a local preference for other medicines.

SMC 2313 - Galcanezumab 120mg solution for injection in pre-filled pen (Emgality®) ▼ is not routinely available as there is a local preference for alternative medicines.
Indication: prophylaxis of migraine in adults who have at least 4 migraine days per month.
Restriction: for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

The Group considered the request to include rimegepant on the formulary for the acute treatment of migraine with or without aura.

The Group noted that:

- the submitting company requested that the SMC consider rimegepant restricted for use in the acute treatment of migraine for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol
- 8 May 2023, SMC published a full submission for rimegepant for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month, but it was not recommended for use in NHS Scotland (SMC 2567). After publication the list price was reduced, and the company may resubmit.
- rimegepant:
  - is the first oral CGRP antagonist, and is the first of this therapeutic class to be licensed for the acute treatment of migraine as well as preventive treatment
  - [for acute treatment] the recommended dose is 75mg, as needed, once daily
- the Headache Service:
  - supports prescribing rimegepant in Primary Care
  - proposes to limit treatment in line with the other acute treatments for migraine, limited to 8-10 days per month (on average 2 days per week) to prevent the development of medication overuse headache

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The Group accepted the restricted local need for rimegepant for the acute treatment of migraine, limited to a maximum of 8 to 10 days treatment per month (approximately two per week), in line with the recommendations of the national headache pathway, and the provision of education for prescribers. **CD/DW**

SMC 2521 - Rimegepant 75mg oral lyophilisate (Vydura®) ▼ is routinely available in line with local guidance.
Indication under review: for the acute treatment of migraine with or without aura in adults who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated, and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.
Restriction: for moderate to severe headache, and acute treatment should be limited to 10 days per month (on average 2 days per week).
In three double-blind, randomised, phase III studies, significantly more patients who received acute treatment with rimegepant compared with placebo for a single migraine attack were free from pain and most bothersome symptom of migraine after 2 hours.
It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. **FTEAM**

2. DRAFT MINUTE OF THE MEETING HELD 16 MAY 2023

The Group 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**

4. MATTERS ARISING

4.1. ACTION LOG

The action log was noted.

No additional items were identified for discussion at the meeting.

4.2. SMC 2368 OLAPARIB [IN COMBINATION WITH BEVACIZUMAB]

Previously the Group noted the lack of benefit in homologous recombination deficiency (HRD)-negative patients when olaparib [in combination with bevacizumab] was used for the maintenance treatment of ovarian cancer (SMC 2368).
The Service confirmed that testing is now available for the HRD status and the Service will now start using this combination.

4.3. RESPIRATORY PRESCRIBING ADVICE (UPDATE)

It was confirmed that the Respiratory Managed Clinical Network (MCN) management and prescribing guidance for chronic obstructive pulmonary disease (COPD) and asthma are published and linked to the formulary.

4.4. CRIZANLIZUMAB – FOR INFORMATION

It was confirmed that the European Medicines Agency's (EMA) human medicines committee (CHMP) has recommended revoking the marketing authorisation for crizanlizumab (Adakveo®), a medicine for preventing painful crises in patients aged 16 years and older with sickle cell disease. The decision is awaiting the European Commission to issue a legally binding decision.

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Crizanlizumab has a Conditional Marketing Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) and was accepted for use in NHS Scotland on an interim basis.
The MHRA is the relevant regulatory body, and the Group will have to wait for a decision from the MHRA. Meantime the EMA recommendation has been shared with the relevant service.

5. FORMULARY GROUP DECISIONS MAY 2023 - PUBLISHED 26/05/2023

Members ratified the decisions of the May 2023 meeting as published.

6. netFORMULARY/FORMULARY REVIEW

6.1. CENOBAMATE (FOCAL ONSET SEIZURES)

The Group reviewed the information provided by Dr MacKay requesting review of the current formulary classification for cenobamate.

Members discussed the points raised and supported the request to reclassify cenobamate from AMBER 2 to AMBER 1, to allow initiation of prescribing in Primary Care on the advice of specialists.
A treatment initiation pack (containing 12.5mg tablets and 25mg film-coated tablets) is available for prescribers.

Members supported the request to reclassify cenobamate film-coated tablets to allow initiation in Primary Care.

SMC 2408 - Cenobamate 12.5mg, 25mg, 50mg, 100mg, 150mg, 200mg film-coated tablets (Ontozry®) ▼ is routinely available in line with national guidance (SMC 2408).
Indication under review: as a second-line adjunctive treatment of focal-onset seizures with or without secondary generalisation in adults with drug-resistant epilepsy who have not been adequately controlled despite previous treatment.
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. OTHER BUSINESS

7.1. PHARMACY FIRST REVIEW

Members discussed the proposed changes to the Pharmacy First Approved List.
Ms Doney will collate the Group's feedback and submit for the end of June deadline. **FD**

7.2. DRAFT FORMULARY GROUP ANNUAL REPORT 2022/23

Members noted the content of the draft Formulary Group annual report for 2022/23.

The Chair supported the need to highlight the pressures experienced, in terms of Group membership, the need for workload linked to membership being recognised within work plans, and the financial pressures created from the access to medicines agenda.

The Chair thanked members and the Formulary Team for supporting the work of the Formulary Group.

No additional points were highlighted for inclusion in the report, and subject to inclusion of the relevant reports, the annual report was ratified for release to the Grampian Area Drug and Therapeutics Committee (GADTC). **FD**

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8. NEW PRODUCT REQUESTS

8.3. SMC 2501 - PEMBROLIZUMAB (CERVICAL CANCER)

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

The Group considered the request for pembrolizumab in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1.

The Group noted that:

- pembrolizumab:
  - was accepted for restricted use in NHS Scotland following a full submission assessed under the end-of-life and orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is administered as an intravenous infusion over 30 minutes at a dose of either 200mg every 3 weeks or 400mg every 6 weeks
  - is the first immunotherapy to be licensed for this indication
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab
- PD-L1 testing is now available to identify the appropriate cohort of patients
- evidence comes from KEYNOTE-826 [the addition of pembrolizumab to standard first-line treatment]:
  - only recruited patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
  - demonstrated a 2.2 month improvement in median progression-free survival in patients with PD-L1 CPS≥1
  - the median duration of treatment with pembrolizumab was 10 months, equivalent to 7 cycles and 14 cycles for 400mg every 6 weeks and 200mg every 3 weeks respectively
- licensing allows treatment with or without bevacizumab. The Service has stated that ideally patients will be treated with bevacizumab and pembrolizumab in combination with chemotherapy but bevacizumab will be omitted if patients have a high risk of fistulation or other contraindications, and pembrolizumab will be omitted if PDL1-CPS <1% or if significant underlying autoimmune/inflammatory conditions.
- patient numbers are expected to be small, but this will be a new cost to the system as pembrolizumab is added to the current first-line treatment for this patient group

The Group accepted the restricted local need for pembrolizumab, in combination with chemotherapy with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS≥1, as outlined in SMC 2501.

SMC 2501 - Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2501).
Indication under review: in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1.
Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
In a phase III study, the addition of pembrolizumab to chemotherapy with or without bevacizumab was associated with a significant improvement in progression-free survival and overall survival in patients with persistent, recurrent or metastatic cervical cancer with PD-L1 CPS≥1.

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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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTEAM**

8.4. SMC 2520 - BULEVIRTIDE (CHRONIC HEPATITIS DELTA VIRUS (HDV))

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

The Group considered the request for bulevirtide injection, for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adults with compensated liver disease and evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based therapy or who are ineligible to receive interferon-based therapy due to intolerance or contra-indication.

The Group noted that:

- bulevirtide:
  - was accepted for use in NHS Scotland following a full submission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is the first medicine licensed for the treatment of hepatitis D
  - should be administered by subcutaneous injection at a dose of 2mg once daily (every 24 hours ± 4 hours), as monotherapy or in co-administration with a nucleoside/nucleotide analogue for treatment of underlying hepatitis B virus (HBV) infection
  - can be self-administered and patients should receive training for reconstitution and self-administration
  - has a Conditional Marketing Authorisation from the MHRA. Longer term data on sustained virological response and disease progression to clinically important disease specific events, including cirrhosis and liver transplant, are not available. Further data will be available in 2025 when the final study results are available.
- treatment should be continued as long as associated with clinical benefit. The Service plans to use the same stopping criteria as polyethylene glycol (PEG) interferon, and also plans to consider discontinuation in case of sustained (6 months) HBsAg (Hepatitis B surface antigen) seroconversion.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of bulevirtide
- this is a new cost to the system, and costs will be cumulative as treatment is taken long-term
- the service plans to supply bulevirtide from secondary care but homecare supply may be considered in the future

The Group accepted the restricted local need for bulevirtide injection for the treatment of a group of adults with chronic HDV, as outlined in SMC 2520.

SMC 2520 - Bulevirtide 2mg powder for solution for injection (Hepcludex®) ▼ is routinely available in line with national guidance (SMC 2520).
Indication under review: for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adults with compensated liver disease and evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based therapy or

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who are ineligible to receive interferon-based therapy due to intolerance or contra-indication.
In an open-label, phase III study, combined virological and biochemical response at week 48 was significantly improved with bulevirtide compared with observation in patients with HDV infection.
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 only by a physician experienced in the treatment of patients with HDV infection. **FTEAM**

8.5. SMC 2523 - EMPAGLIFLOZIN (SYMPTOMATIC CHRONIC HEART FAILURE WITH PRESERVED EJECTION FRACTION)

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

The Group considered the request to include empagliflozin on the formulary for the treatment of adults with symptomatic chronic heart failure with preserved ejection fraction.

The Group noted that:
- empagliflozin and dapagliflozin are included on the formulary for the treatment of symptomatic chronic heart failure with reduced ejection fraction as per SMC 2396 and SMC 2322 respectively. A local restriction was included for treatment to be started on the advice of a heart failure specialist.
- in December 2022, dapagliflozin was also licensed for use in patients with chronic heart failure with preserved ejection fraction, however this indication is awaiting review by SMC
- evidence for empagliflozin for this indication comes from EMPEROR-preserved and at randomisation, 81.5% of patients were NYHA class II, 18.1% were class III and 0.3% were class IV
- the median follow-up in EMPEROR-preserved was 26.2 months which is short-term data for a potentially long-term treatment
- empagliflozin did not significantly reduce the incidence of cardiovascular death alone. The benefit shown in the primary composite outcome was driven by a decrease in hospitalisations for heart failure.
- the requestor estimates that patient numbers will ultimate reach 1500 after several years
- the service anticipates that empagliflozin will be prescribed in primary care
- this will be a new cost to the system, and costs will be cumulative as this is potentially a long-term treatment

Members noted the high cost associated with treatment, and that the absolute difference is very small.
Members asked that the requestor be invited to the August meeting to discuss the request and which patients they feel will benefit most from treatment. Decision-making was deferred to a future meeting. **FTEAM**

SMC 2523 - Empagliflozin 10mg film-coated tablet (Jardiance®) decision deferred to future meeting.
Indication under review: in adults for the treatment of symptomatic chronic heart failure with preserved ejection fraction (left ventricular ejection fraction [LVEF] >40%).
In a phase III study of adults with symptomatic chronic heart failure and LVEF >40%, the addition of empagliflozin to standard of care significantly improved time

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	to first hospitalisation for heart failure or cardiovascular death. **Decision deferred to future meeting.**	**FTEAM**

8.6. FG1SMC 2575 - UPADACITINIB (MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE)

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

The Group considered the request for the Janus kinase (JAK) inhibitor upadacitinib for the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.

The Group noted that:

- upadacitinib:
  - blocks the action of JAK
  - is the first JAK inhibitor to be licensed and accepted for use in NHS Scotland for the treatment of Crohn's disease
  - is already included on formulary for multiple indications including ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and atopic dermatitis
  - [for this indication] is taken as an induction dose of 45mg once daily for 12 weeks, followed by a maintenance dose of 15mg or 30mg once daily based on individual patient presentation
  - offers a different mode of action to the alternative treatment options
  - is an oral tablet rather than an injection, and does not require refrigeration
  - is expected to be supplied via a homecare arrangement
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of upadacitinib
- cost offset will be available from the displacement of alternative treatment options, and costs will be cumulative as this is a potentially long-term treatment option

The Group accepted the restricted local need for upadacitinib for the treatment of adults with moderately to severely active Crohn's disease, as outlined in SMC 2575.

SMC 2575 - Upadacitinib 15mg, 30mg, 45mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2575).
Indication under review: for the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.
Upadacitinib offers an additional treatment choice in the therapeutic class of selective immunosuppressants in this setting.
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 with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated. **FTEAM**

8.7. NICE/SMC COLLABORATION - COVID 19 MEDICINES

SMC 2555 sotrovimab, SMC 2552 tocilizumab, SMC 2557 Paxlovid®

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

The Group considered the SBAR prepared by the Antimicrobial Management Team (AMT) in relation to the NICE/SMC Collaborative Advice Documents published 29 March.

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The Group noted that:

- the AMT and Infectious Diseases colleagues have assessed the recommendations and considered the evidence for use, and:
  - do not wish to add sotrovimab to the formulary at this time, due to the uncertain benefit of sotrovimab in current variants and in line with recent local practice
  - agree that nirmatrelvir plus ritonavir (Paxlovid®), and tocilizumab will continue to be used in line with current practice and as per the NICE and SMC recommendations and request both agents are included on the formulary

The Group accepted the recommendations of the AMT and accepted the restricted local need for nirmatrelvir plus ritonavir (Paxlovid®) and tocilizumab for the treatment of COVID-19 infection, in line with the recommendations of the relevant NICE/SMC Collaborative Advice Documents.

SMC 2555 - Sotrovimab 500mg concentrate for solution for infusion (Xevudy®) is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication under review: treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection.
Restriction: patients with increased risk for progression to severe COVID-19, as defined in the independent advisory group report commissioned by the Department of Health and nirmatrelvir and ritonavir is contraindicated or unsuitable.
Not recommended for use in NHS Grampian. **FTEAM**

SMC 2557 - Nirmatrelvir 150mg plus ritonavir 100mg film coated tablets (Paxlovid®) ▼ is routinely available in line with national guidance (NICE TA878).
Indication under review: treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.
Restriction: patients with increased risk for progression to severe COVID-19, as defined in the independent advisory group report commissioned by the Department of Health.
It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community.
Nirmatrelvir must be coadministered with ritonavir. Failure to correctly coadminister nirmatrelvir with ritonavir will result in plasma concentrations of nirmatrelvir that will be insufficient to achieve the desired therapeutic effect. **FTEAM**

SMC 2552 - Tocilizumab 20mg/mL concentrate for solution for infusion (RoActemra®) is routinely available in line with national guidance (NICE TA878).
Indication under review: treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of COVID-19. **FTEAM**

SMC 2580 - TIXAGEVIMAB 150MG/ML PLUS CILGAVIMAB 150MG/ML SOLUTION FOR INJECTION (EVUSHELD®) ▼

Mr Paterson declared a personal non-specific interest in relation to AstraZeneca UK Limited.

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The Group considered the additional NICE/SMC Collaborative Advice Document, SMC 2580, which was published 14 June 2023.

The Group noted that tixagevimab and cilgavimab (Evusheld®) ▼ is not recommended for use in NHS Scotland, SMC 2580, and agreed that this medicine would not be included on the Grampian Joint Formulary for the indication in question.

SMC 2580 - Tixagevimab 150mg/mL plus cilgavimab 150mg/mL solution for injection (Evusheld®) ▼ is not recommended for use in NHS Scotland.
Indication under review: pre-exposure prophylaxis of COVID-19 in adults who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and:
- who are unlikely to mount an adequate immune response to COVID-19 vaccination or
- for whom COVID-19 vaccination is not recommended
Not routinely available as not recommended for use in NHS Scotland. **FTEAM**

9. SMC PROVISIONAL ADVICE ISSUED - JUNE 2023

The Group noted the SMC provisional advice issued June 2023.

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

10. PUBLISHED ADVICE - JUNE 2023

10.1. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - JUNE 2023

The Group noted the SMC advice published June 2023.

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

- SMC 2519 – nivolumab (Opdivo®) (submission expected)
- SMC 2538 – pembrolizumab (Keytruda®) (submission received)
- SMC 2525 – polatuzumab vedotin (Polivy®)▼ (submission received)

Local advice for these medicines and indications will be included in the June 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2527 - TREOSULFAN 1G, 5G POWDER FOR SOLUTION FOR INFUSION (TRECONDI®) ▼

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

The Haematology Service confirmed that there is not a local need for this medicine as allogeneic stem cell transplant is not performed in NHS Grampian.

This medicine will not be included on the Grampian Joint Formulary for this indication.

SMC 2527 - Treosulfan 1g, 5g powder for solution for infusion (Trecondi®) ▼ is routinely available from a specialist centre in another health board.
Indication under review: in combination with fludarabine as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in paediatric patients older than one month with malignant diseases.
SMC restriction: in patients with malignant disease for whom a reduced intensity

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conditioning regimen is required.
Treosulfan plus fludarabine was non-inferior to another reduced intensity conditioning regimen for event-free survival (EFS) in adults undergoing alloHSCT for acute myeloid leukaemia (AML) or myelodysplatic syndrome (MDS) who were at increased risk with standard conditioning regimens.
Not routinely available in NHS Grampian. If local need identified treatment is available from a specialist centre in another health board. **FTEAM**

UMAR SMC 2559 - METRELEPTIN 3MG, 5.8MG, 11.3MG POWDER FOR SOLUTION FOR INJECTION

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

Members noted that the Scottish Government Medicines Policy Branch will notify Health Boards when this medicine is available for prescribing within the ultra-orphan pathway, i.e., when Amryt Pharmaceuticals DAC has met all the conditions of the ultra-orphan pathway, including providing a data collection plan and a Patient Access Scheme. Meantime any requests to access treatment should be considered through local non-formulary processes.

In line with local processes, and pending confirmation that this medicine is available for prescribing within the ultra-orphan pathway, the Group recorded metreleptin (Myalepta®) ▼ as 'not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI)'.

UMAR SMC 2559 - Metreleptin 3mg, 5.8mg, 11.3mg powder for solution for injection (Myalepta®) ▼ is not routinely available in NHS Grampian.
Indication under review: as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients with:
- **confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children 2 years of age and above**
- **confirmed familial partial LD or acquired partial LD (Barraquer-Simons syndrome), in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control**

Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - JUNE 2023

None.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update May 2023), 12.2 (Primary Care Prescribing Group minute March 2023), and 12.3 (Acute and Mental Health Medicines Safety Group minute January 2023) were noted.

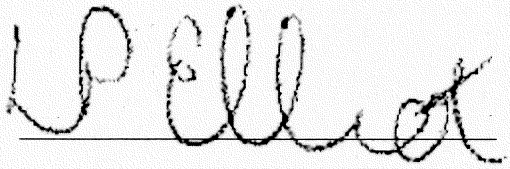
13. AOCB

The Chair reminded members that there is not a meeting scheduled for July and wished everyone a lovely summer break.

ITEM	SUBJECT	ACTION

DATE OF NEXT MEETING

Tuesday 15 August 2023 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 15 AUGUST 2023**