NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 15 November 2022 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Dr D Culligan	Ms L Cameron	
Ms F Doney (Vice-Chair)	Dr V Chieng	
Dr L Elliot (Chair)	Ms A Davie	
Mrs G McKerron	Dr E Elias	
Dr M Metcalfe (Vice-Chair)	Ms M Galvin	
Mrs K Neave		
Dr J Newmark		
Mrs S O'Beirne		
Mr M Paterson		
Mr R Sivewright		

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. DRAFT MINUTE OF THE MEETING HELD 18 OCTOBER 2022

As the draft minute was issued late, members were given an extra week to return comments to Ms Doney (by 23 November). **ALL**

If significant changes are required, these will be highlighted with members and the minute agreed via email, otherwise if minor typographical changes are required these will be accepted and processed by the Formulary Team. **FD**

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

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. Action Log

The action log was noted.
No additional items were identified that should have been included on the agenda.

5. FORMULARY GROUP DECISIONS OCTOBER 2022 - PUBLISHED 31/10/2022

Members ratified the decisions of the October 2022 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. Discontinuation of prochlorperazine 5mg/5mL syrup (Stemetil®)

Ms Doney reported that:

- all batches of Stemetil® 5mg/5mL Syrup have been recalled as a precautionary measure due to the identification of N-nitrosomethylphenylamine (NMPA) above the acceptable limit
- this is in effect a product discontinuation as there will be no further production of Stemetil® 5mg/5mL Syrup, and supplies are no longer available

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- prochlorperazine tablets and buccal tablets remain available, and alternative antiemetics are available to support a full uplift in demand

Ms Doney confirmed the formulary entry will be updated to note the discontinuation. **FTEAM**

7. OTHER BUSINESS

7.1. EMA recommends measures to minimise risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders

Ms Doney reported that on 28 October 2022 the European Medicines Agency (EMA) recommended measures to minimise the risk of serious side-effects associated with Janus kinase (JAK) inhibitors used to treat several chronic inflammatory disorders. The side-effects include cardiovascular conditions, blood clots, cancer and serious infections.

The Group noted that:

- the EMA's committee responsible for assessing and monitoring the safety of human medicines recommended that JAK inhibitors should be used in the following patients only if no suitable treatment alternatives are available:
  - those aged 65 years or above,
  - those at increased risk of major cardiovascular problems (such as heart attack or stroke),
  - those who smoke or have done so for a long time in the past and
  - those at increased risk of cancer
- the committee also recommended using JAK inhibitors with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism (VTE)) other than those listed above. Further, the doses should be reduced in some patient groups who may be at risk of VTE, cancer or major cardiovascular problems.

The Medicines and Healthcare products Regulatory Agency (MHRA), is considering the new EMA safety recommendations and these will be shared when available. Meantime the EMA recommendations have been shared with the relevant services. **FTEAM**

8. NEW PRODUCT REQUESTS

8.1. SMC 2368 - Olaparib in combination with bevacizumab (epithelial ovarian, fallopian tube or primary peritoneal cancer)

Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and took part in decision-making.

The Group considered the request for the use of olaparib, in combination with bevacizumab, for the maintenance treatment of adults with newly diagnosed advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in response following completion of first-line platinum-based chemotherapy in combination with bevacizumab, and whose cancer is associated with homologous recombination deficiency (HRD) positive status.

The Group noted that:

- olaparib is a poly ADP-ribose polymerase inhibitor (PARP inhibitor), it is taken orally twice daily (total daily dose of 600mg)
- bevacizumab, is an antiangiogenic agent that binds to vascular endothelial growth factor, it is given as an intravenous infusion (15mg/kg once every 3 weeks)
- both medicines are already included on the formulary for use in epithelial ovarian, fallopian tube or primary peritoneal cancer
- the addition of bevacizumab to carboplatin plus paclitaxel, followed by bevacizumab maintenance, is a standard treatment option in patients with newly diagnosed

advanced cancer, FIGO stage IV disease only

- [for this indication] olaparib plus bevacizumab as maintenance therapy was accepted for use in NHS Scotland following a full submission assessed under the 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
- HRD is an important biomarker for advanced ovarian cancer
- evidence comes from PAOLA-1:
  - a randomised, double-blind, phase III trial that examined the efficacy and safety of maintenance olaparib plus bevacizumab vs placebo plus bevacizumab in patients with newly diagnosed advanced ovarian cancer (FIGO stage III and IV disease) who had received first-line standard of care treatment including bevacizumab
  - patients were in response after first-line platinum-taxane chemotherapy plus bevacizumab. Patients were eligible regardless of surgical outcome or BRCA* mutation status. [806 patients 2:1 randomisation: 537 olaparib/bevacizumab: 269 placebo/bevacizumab].
  - olaparib was continued until radiological disease progression, unacceptable toxicity or for up to 2 years if there is no radiological evidence of disease after 2 years of treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating physician can derive further benefit from continuous treatment, can be treated beyond 2 years.
  - bevacizumab treatment was given for a total of up to 15 months/22 cycles, including the period given with chemotherapy and given as maintenance
  - in the primary analysis (data cut-off March 2019), the primary outcome, progression-free survival (PFS) was met (37.2 months versus 17.8 months; hazard ratio 0.33 (0.25 to 0.45)). The duration of treatment in the olaparib group was 17.3 months (bevacizumab 11 months).
  - 5-year data is now available (March 2022), median follow-up 62 months:
    - the 5-year overall survival (OS) rates were better with olaparib plus bevacizumab in the subset of patients with a BRCA mutation (73.2% with olaparib plus bevacizumab vs 53.8% with placebo/bevacizumab)
    - the 5-year OS rates for HRD-positive patients (excluding BRCA-positive patients) were 54.7% with olaparib plus bevacizumab vs 44.2% with placebo/bevacizumab; 55% of patients in the control arm received a PARP inhibitor in the subsequent lines of treatments after relapse
    - in the HRD-negative subgroup no benefit of maintenance olaparib plus bevacizumab was observed
    - the 5-year progression-free survival rates were 46.1% and 19.2% respectively. In the olaparib plus bevacizumab arm 46% of patients had not relapsed after 5 years compared to 19% in the placebo arm.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of olaparib
- there are some costs in the system as bevacizumab maintenance is used in FIGO stage IV disease, and PARP inhibitors are used in the relapsed setting
- introduction will have service implications - staffing, aseptic preparation, chair time, monitoring/imaging, and additional costs related to managing adverse events
- HRD-positive status is defined by either a BRCA1/2 mutation and/or genomic instability, and it is not known if genomic instability testing is available locally
- the Summary of Product Characteristics (SmPC) states that before olaparib with bevacizumab treatment is initiated for the first-line maintenance treatment, patients must have confirmation of either deleterious or suspected deleterious BRCA1/2 mutation and/or genomic instability determined using a validated test

* A BRCA mutation is a mutation in either of the BRCA1 (BReast CAncer gene 1) and BRCA2 (BReast CAncer gene 2) genes

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Members noted the lack of benefit in HRD-negative patients, and considered that treatment outcomes would be optimised if treatment was guided by biomarker testing.

The Group was minded to accept the combination to formulary for HRD-positive patients. However, mindful of the lack of benefit in HRD-negative patients, members requested confirmation that a validated genomic instability test is available locally. **FTEAM**

SMC 2368 - Olaparib 100mg, 150mg film-coated tablets (Lynparza®) is routinely available in line with local guidance.
Indication under review: in combination with bevacizumab for the maintenance treatment of adults with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability.
Restriction: patients with BRCA1 and/or BRCA2 mutation.
In a phase III study, maintenance treatment with olaparib plus bevacizumab significantly prolonged progression-free survival (PFS) compared with placebo plus bevacizumab in patients with advanced ovarian cancer who responded to first-line standard therapy including bevacizumab.
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 with olaparib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

8.2. SMC 2446 - Sacituzumab govitecan (metastatic triple-negative breast cancer (mTNBC))

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

The Group considered the request for sacituzumab govitecan for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease (SMC 2446).

The Group noted that:

- sacituzumab govitecan:
  - is the first antibody-drug conjugate, combining a Trop-2 directed antibody and a topoisomerase I inhibitor, licensed in the UK for mTNBC
  - is administered once weekly, as an intravenous infusion at a dose of 10mg/kg on days 1 and 8 of 21-day treatment cycles, and treatment is continued until disease progression or unacceptable toxicity
  - can only be administered in Aberdeen Royal Infirmary, as after reconstitution the infusion bag can only be stored in a refrigerator for up to 4 hours
  - was accepted for use within NHS Scotland, following a full submission assessed under the end of life and orphan equivalent process, the output from the PACE process, and application of the appropriate SMC modifiers that can be applied when encountering high cost-effectiveness ratios
- evidence for efficacy and safety comes from ASCENT a phase III study of sacituzumab govitecan versus single-agent treatment of physician's choice, in participants with and without previously treated and stable brain metastases, with locally advanced or mTNBC who relapsed after two or more prior chemotherapies

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- the primary outcome was PFS, the primary analysis population was patients without brain metastases
- at the data cut-off, 11 March 2020:
  - sacituzumab govitecan prolonged the median PFS and median OS in comparison with physician's choice [5.6 vs 1.7 months; P<0.001 and 12.1 vs 6.7 months; P<0.001, respectively]
  - the clinical benefits in the total population (including those with brain metastases) were PFS 4.8 vs 1.7 months; P<0.001, and OS 11.8 vs 6.9 months; P<0.001, respectively
- the most common side-effects are diarrhoea, nausea, neutropenia, tiredness, alopecia, anaemia, vomiting, constipation, decreased appetite, cough, and abdominal pain
- at the data cut-off March 2020, the median duration of treatment in ASCENT was 4.4 months, but the estimated local duration of treatment is higher, although this may be related to the scanning interval (12 weeks locally versus 6 weeks in ASCENT)
- costs are already in the system from individual patient requests
- introduction will incur additional costs/pressure on services (aseptic preparation, chair time (note the initial infusion time is three hours)), staffing, premedication needed, and management of adverse events/reactions (including potential for infusion-related reactions/hypersensitivity reactions))
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of sacituzumab govitecan
- locally advanced or mTNBC is an incurable, aggressive disease with a poor prognosis

Members had a long discussion, and queried what patients would value at the end stages of the disease, taking account of the short PFS, the need to travel to Aberdeen for treatment and other considerations in terms of quality of life for patients.
Dr Culligan reported that in his experience with young people with incurable malignancy, adverse effects from treatment were potentially less important than to older patients.

Members were unclear of the current treatment options for TNBC, but noted that this is an area of expanding choices. Members accepted that these are challenging situations, and were unclear of the clinical practice guideline for patients with TNBC.

Members wished to understand the treatment options available for TNBC, and considered that for a pathway with expensive medicines there should be a clinical practice guideline available.

The Group was minded to accept sacituzumab govitecan to formulary, but considered that additional information related to the treatment options and pathway/clinical practice guideline for mTNBC was needed to support decision-making. **FTEAM**

The Group deferred decision-making for sacituzumab govitecan to a future meeting.

SMC 2446 - Sacituzumab govitecan 180mg powder for concentrate for solution for infusion (Trodelvy®) ▼ decision deferred to future meeting.
Indication under review: treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease.
Sacituzumab govitecan, compared with a range of single-agent chemotherapies, significantly improved progression free survival and overall survival in adults with mTNBC, without brain metastases, who had received at least two prior chemotherapy regimens including a taxane.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon

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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.
Sacituzumab govitecan must only be prescribed and administered to patients by healthcare professionals experienced in the use of anti-cancer therapies and should be administered in an environment where resuscitation facilities are available.
Decision deferred to future meeting. **FTEAM**

8.3. SMC 2385 - Nivolumab in combination with ipilimumab (malignant pleural mesothelioma (MPM))

Dr Culligan declared a personal, non-specific interest in Bristol-Myers Squibb Pharmaceuticals Ltd and took part in decision-making.

The Group considered the request for nivolumab in combination with ipilimumab for the first-line treatment of adults with unresectable malignant pleural mesothelioma (MPM).

The Group noted that:

- nivolumab and ipilimumab are immunotherapy cancer treatments, they are monoclonal antibodies that stimulate the body's immune system to target and destroy tumours
- [for this indication] nivolumab [plus ipilimumab] meets SMC end of life criteria and was accepted for use in NHS Scotland following a full submission assessed under the end of life process, the output from the PACE process, and application of the appropriate SMC modifiers that can be applied when encountering high cost-effectiveness ratios
- evidence comes from CheckMate 743 (n = 605), a randomised, open-label, phase III study. Eligible adults had histologically confirmed unresectable MPM that was not amenable to curative therapy, had not received prior systemic therapy, and had an Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0 or 1.
- the relevant comparator is standard of care chemotherapy
- treatment is continued until disease progression, unacceptable toxicity, or for up to 24 months
- in CheckMate 743:
  - treatment with nivolumab plus ipilimumab was permitted to continue beyond disease progression if the patient had investigator-assessed clinical benefit and was tolerating treatment
  - patients who discontinued combination therapy because of an adverse reaction attributed to ipilimumab were permitted to continue nivolumab monotherapy
- at the interim analysis (data cut-off 3 April 2020), after a median follow-up of 29.7 months, the study was stopped for superiority of OS and this was considered the final primary analysis (additional 4 months OS (17.4 versus 13.3 months (HR 0.74 p=0.002)))
- three year data is now available (May 2021), and this supports the primary analysis, i.e., data with patients off therapy for 1 year. Median follow-up of 43.1 months, nivolumab plus ipilimumab continued to prolong OS versus chemotherapy. Median OS was 18.1 (16.8 – 21.0) versus 14.1 months (12.4 – 16.3) [hazard ratio (95% confidence interval), 0.73 (0.61 - 0.87)].
- the service confirmed that inclusion criteria for CheckMate 743 would be used to direct treatment
- this is a new line of therapy and represents a new cost to the service, however some costs will be in the system from individual patient requests
- introduction will have service implications – aseptic preparation, staffing (chair, clinic and nursing time for ongoing infusions), management of adverse events

The Group accepted the restricted local need for nivolumab in combination with ipilimumab for the first-line treatment of adults with unresectable MPM, as outlined in SMC 2385.

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SMC 2385 - Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) is routinely available in line with national guidance (SMC 2385).
Indication under review: in combination with ipilimumab for the first-line treatment of adults with unresectable malignant pleural mesothelioma (MPM).
In a phase III study of patients with previously untreated, unresectable MPM, overall survival was significantly longer in the nivolumab plus ipilimumab group compared with standard chemotherapy.
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. Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. **FTEAM**

8.4. SBAR - Ceftazidime/avibactam and cefiderocol (for treating severe drug-resistant infections caused by Gram-negative bacteria)

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

The Group considered the request from the Antimicrobial Management Team (AMT) to include two new antibacterial agents on the formulary, ceftazidime/avibactam and cefiderocol.

The Group noted that:

- National Institute for Health and Care Excellence (NICE) is currently undertaking a new health technology evaluation process and payment model for these agents
- under the payment model, the payments made to companies are based on the value to the NHS and not linked to the volumes sold
- the pilot was launched in England in July 2022. The Scottish Government, SMC, Scottish Antimicrobial Prescribing Group (SAPG) and National Services Scotland National Procurement are involved as observers in the pilot.
- while the pilot is ongoing no further SMC advice will be issued [for these products]
- SAPG and the SMC have published the following statement: "*SMC and SAPG advise that during the pilot these medicines can be accessed for individual patients where required through local Health Board processes based on appropriate specialist advice*"
- both agents are given by intravenous infusion, and are currently noted as non-formulary
- NICE has issued guidance for the use of ceftazidime/avibactam and cefiderocol, and recommends that they are considered an option for treating severe drug-resistant infections caused by Gram-negative bacteria
- the AMT considers these agents to be useful additional, last resort treatment options, for infections caused by resistant Gram-negative bacteria
- inclusion on formulary would reduce the potential for delays accessing treatment
- if accepted to formulary treatment would be restricted, and approval subject to:
  - inclusion in the alert antibiotic policy, and only
  - available after authorisation by a medical microbiologist or infection specialist, and only
  - if the infection is susceptible to ceftazidime/avibactam or cefiderocol, and not susceptible to other suitable antibiotics; or if susceptibility results are not available but the infection needs urgent treatment and is expected to be susceptible to ceftazidime/avibactam or cefiderocol but not to other suitable antibiotics
- ceftazidime/avibactam (Zavicefta®) is licensed for children and adolescents from three months. The AMT requested use in children and adolescents, although usage is expected to be very low.

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The Group accepted the restricted local need for ceftazidime/avibactam and cefiderocol as licensed as last-line treatment options for treating severe drug-resistant infections without the need for full submissions.
Formulary acceptance is subject to inclusion in the 'NHS Grampian staff guidance for optimising use of alert (restricted) antimicrobials', with both agents only available in the managed service after authorisation by a medical microbiologist or infection specialist and only if there are no suitable alternative treatment options.

SBAR - Zavicefta® 2g/0.5g powder for concentrate for solution for infusion (ceftazidime/avibactam) is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment.
Indication under review: adults, adolescents and children aged 3 months and older for the treatment of the following infections:

- **complicated intra-abdominal infection (cIAI)**
- **complicated urinary tract infection (cUTI), including pyelonephritis**
- **hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)**
- **infections due to aerobic Gram-negative organisms in patients with limited treatment options**

Restriction: for the treatment of severe drug-resistant infections caused by gram-negative bacteria, including, but not limited to, infections caused by OXA-48 carbapenemase-producing Enterobacterales

- **only on the advice of a Consultant/Specialist Microbiologist or infectious disease specialist and,**
- **only if the infection is susceptible to ceftazidime/avibactam and not susceptible to other suitable antibiotics; or if susceptibility results are not available but the infection needs urgent treatment and is expected to be susceptible to ceftazidime/avibactam but not to other suitable antibiotics.**

It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTEAM**

SBAR - Cefiderocol sulfate tosylate 1g powder for concentrate for solution for infusion (Fetcroja®) ▼ is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment.
Indication under review: for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment option.
Restriction: for the treatment of severe drug-resistant infections caused by gram-negative bacteria, including, but not limited to, infections caused by OXA-48 carbapenemase-producing Enterobacterales

- **only on the advice of a Consultant/Specialist Microbiologist or infectious disease specialist and,**
- **only if the infection is susceptible to cefiderocol sulfate tosylate and not susceptible to other suitable antibiotics; or if susceptibility results are not available but the infection needs urgent treatment and is expected to be susceptible to cefiderocol sulfate tosylate but not to other suitable antibiotics.**

It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTEAM**

8.5. FG1 449/22 - ESOMEPRAZOLE (TABLETS/CAPSULES)

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

The Group considered the request to include esomeprazole oral solid dosage formulations on the formulary when omeprazole and lansoprazole have failed.

ITEM **SUBJECT** **ACTION**

The Group noted that:

- esomeprazole is available generically as capsule and tablet formulations, and both formulations are included in the Scottish Drug Tariff (SDT)
- at current SDT prices (October 2022), the capsule formulation costs less than the tablet formulation, and the tablet is a not a dispersible preparation
- the Gastroenterology Service currently requests that Primary care colleagues prescribe esomeprazole for patients that have failed other proton pump inhibitors (PPIs)
- review of primary care prescribing data shows esomeprazole represents a small percentage of prescriptions ~5% but ~16% of costs
- esomeprazole is available over-the counter from Community Pharmacies
- other Health Board formularies in Scotland restrict esomeprazole to use on the recommendation of a Gastroenterology Consultant/specialist
- the most cost-effective formulation should be utilised as PPI prescription volumes are significant, and although available generically esomeprazole costs more than the capsule formulations of omeprazole and lansoprazole

The Group accepted the restricted local need for esomeprazole tablets/capsules to be included on the formulary where alternative PPIs, omeprazole and lansoprazole, have failed. In view of the cost differential, the most cost-effective formulation should be highlighted on the formulary, at current costs the hard-capsule formulation will be the preferred formulation.

FG1 449/22 - Esomeprazole 20mg, 40mg hard capsules, gastro-resistant tablets is routinely available in line with local guidance.
Indication under review: where maximum doses of omeprazole and lansoprazole have been tried and failed, for adults with the following:

- **gastro-oesophageal Reflux Disease (GORD)**
- **patients requiring continued NSAID therapy**
- **prolonged treatment after I/V induced prevention of re-bleeding of peptic ulcers**
- **treatment of Zollinger Ellison Syndrome**

Restriction: only on the advice of a Gastroenterology Consultant/specialist.
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**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED NOVEMBER 2022

The Group noted the SMC provisional advice issued November 2022.

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

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS PUBLISHED NOVEMBER 2022

The Group noted the SMC advice published November 2022.

Following publication of the non-submission statements, for esketamine (Spravato®) ▼ SMC 2539 and venetoclax (Venclyxto®) ▼ SMC 2509 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 2482 asciminib (Scemblix®) ▼ (submission expected)
- SMC 2477 belimumab (Benlysta®) ▼ (submission expected)
- SMC 2530 belimumab (Benlysta®) ▼ (submission expected)
- SMC 2499 faricimab (Vabysmo®) ▼ (submission received)
- SMC 2486 finerenone (Kerendia®) ▼ (clinicians not responded)

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- SMC 2480 upadacitinib (Rinvoq®) ▼ (submission expected)
- SMC 2528 zanubrutinib (Brukinsa®) ▼ (submission received)

Local advice for these medicines and indications will be included in the November 2022 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2123 - ZUBSOLV® SUBLINGUAL TABLETS (BUPRENORPHINE/NALOXONE)

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

Ms Doney reported that, at this time, colleagues in the Substances Misuse Service do not wish to include Zubsolv® on the formulary, as there is a local preference for alternative medicines.

The Group supported the position proposed by the Substances Misuse Service.

SMC 2123 - Zubsolv® 1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg sublingual tablets (buprenorphine/naloxone) is not routinely available as there is a local preference for alternative medicines.
Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction.
Restriction: for use in patients for whom methadone is not suitable.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

SMC 2515 - SODIUM ZIRCONIUM CYCLOSILICATE

Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and took part in decision-making.

Ms Doney reported that:

- the SMC has previously issued advice for sodium zirconium cyclosilicate, for the treatment of hyperkalaemia in adults with chronic kidney disease stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor therapy to maintain a clinically acceptable serum potassium level [SMC 2288, accepted to formulary February 2021]
- sodium zirconium cyclosilicate is also included on the formulary for restricted emergency use correction phase use. Use in limited to acute use [correction phase use] within the Renal department as emergency bridging where dialysis is unavailable but urgently needed and potassium is dangerously elevated [accepted to formulary February 2021]
- this new SMC advice [SMC 2515] would allow correction phase use [of sodium zirconium cyclosilicate] in other settings, and a new submission is awaited

Mrs O'Beirne requested clarification of the current formulary wording because renal physicians might request that other departments initiate emergency bridging treatment.

Pending a new submission, the Group ratified the current formulary position for the correction phase use of sodium zirconium cyclosilicate, subject to a minor clarification that current use includes 'at the request of renal physicians'.

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	SMC 2515 - Sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®) ▼ is routinely available in line with local guidance. Indication under review: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia in adults alongside standard care. Restriction: correction phase use, within the renal department/at the request of renal physicians, as emergency bridging use for adults where dialysis is unavailable but urgently needed and potassium is dangerously elevated. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.	**FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - NOVEMBER 2022

None.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update October 2022), 12.2 Notes of the Antimicrobial Management Team Meeting 25 August 2022 and 12.3 Grampian Primary Care Prescribing Group minute 20 July 2022 were noted.

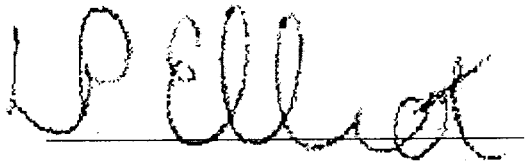
13. AOCB

MEETING DATES FOR 2023

Ms Doney confirmed that Outlook event invites have been issued for the 2023 meetings and the dates will be sent via email before Christmas. **FD**

DATE OF NEXT MEETING

Tuesday 20 December 2022 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 20 DECEMBER 2022**