NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 March 2024 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Dr V Chieng	Ms L Cameron	
Ms F Doney (Vice-Chair)	Dr D Culligan	
Dr L Elliot (Chair)	Ms A Davie	
Mrs G McKerron (from item 4)	Mrs S Howlett	
Dr M Metcalfe (Vice-Chair) (until item 5.2)	Mrs S O'Beirne	
Mrs E Milne	Dr K Simpson	
Mr M Paterson	Mr R Sivewright	
Mrs B Tiesmann		

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

OBSERVER
Mr Nick Murray, Principal Pharmacist – New Medicines, National Procurement, NHS National Services Scotland

ITEM	SUBJECT	ACTION

WELCOME

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

THANK YOU AND GOODBYE

The Chair confirmed that Dr Metcalfe is retiring and this was his last meeting. The Chair thanked Dr Metcalfe for all of his contributions to the Group and NHS Grampian. He was a very valuable member, and his knowledge and experience will be greatly missed.

Members wished Dr Metcalfe all the best for his retirement.

OBSERVER

The Chair welcomed Mr Nick Murray, Principal Pharmacist – New Medicines, National Procurement, to the meeting. Mr Murray was attending the meeting as an observer, and to present item 4.

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 20 FEBRUARY 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. FORMULARY GROUP DECISIONS FEBRUARY 2024 - PUBLISHED 29/01/2024

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

ITEM	SUBJECT	ACTION

3. MATTERS ARISING

3.1. ACTION LOG

The action log was noted.

Mrs Standen provided members with a summary of the survey results regarding reducing the number of meetings from 11 to 10 per year.
Mrs Standen confirmed that of the eight responses, five (62.5%) were in favour of cancelling a meeting (with 25% not in favour), with the majority (six; 75%) in favour of cancelling the December meeting.

Based on the survey, members agreed to cancel the December meeting. **FTEAM**
Workload will be monitored and if it is not manageable the decision can be revisited in the future.

3.2. DECLARATIONS OF INTEREST FOR CALENDAR YEAR 2023

The Chair reminded members to return their conflicts of interest for calendar year 2023 before the end of March and that null responses are required.

3.3. SCRIPTSWITCH

The Chair confirmed that a meeting is planned to discuss if ScriptSwitch can be utilised to direct treatment away from single agent topical clindamycin.

3.4. *H.PYLORI* TREATMENT REGIMEN

At the February 2024 meeting, pending information from the service, members agreed to update the current *H.Pylori* guidance in line with the request but withhold publication of the new second-line penicillin allergy treatment regimen.

Ms Doney shared the email from Dr Phull confirming he believed that the suggestions are in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance. The discussions around the *H.Pylori* treatment regimens took place at the end of last year, before the updated MHRA guidance was issued, however, the reviewers were cognisant of the adverse effects of fluoroquinolones and had agreed a review date at one year post-implementation.

Members noted the Scottish Antimicrobial Prescribing Group (SAPG) response to the updated MHRA fluoroquinolone prescribing advice, and that feedback is awaited from the Antimicrobial Management Team (AMT).

Members deferred decision-making pending a response from the AMT. **FTEAM**

3.5. IVERMECTIN TABLETS [UNLICENSED TABLETS]

The Chair confirmed that a new licensed 3mg tablet is now available, and a submission for the licensed product is expected from the AMT.

Item closed. **FTEAM**

4. PRESENTATIONS

Mr Nick Murray Principal Pharmacist, New Medicines, National Procurement, provided the Group with a comprehensive update on the variety of pricing arrangements for medicines, and the financial governance systems and safeguards that are in place to support Health Technology Assessments.

ITEM	SUBJECT	ACTION

5. NEW PRODUCT REQUESTS

5.1. FG1 460/23 - BUDESONIDE (REMISSION OF EOSINOPHILIC ESOPHAGITIS)

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

The Group considered the request for budesonide orodispersible tablets, as the brand Jorveza®, for the maintenance of remission of eosinophilic esophagitis (EoE) in adults.

The Group noted that:

- in 2021, Jorveza® 1mg tablets was added to formulary for the induction of remission of EoE in adults who were unsuccessfully treated with proton pump inhibitors, in line with SMC 2158
- the licence for Jorveza® has been extended to include the maintenance of remission of EoE, and a new 0.5mg tablet is now licensed and marketed in the UK. The licence extension and new strength are considered outwith remit for the SMC.
- for the maintenance of remission the recommended dose is 0.5mg in the morning and 0.5mg in the evening or 1mg in the morning and 1mg in the evening, depending on individual clinical requirement
- the British Medical Journal (BMJ) Best Practice recommends budesonide orodispersible tablets for the acute and maintenance treatment of EoE
- evidence for maintenance of remission comes from a 48-week trial which compared the efficacy of budesonide vs placebo. The number of patients in remission after 48 weeks maintenance treatment was 73.5% (n=50), 75% (n=51) and 4.4% (n=3) for budesonide orodispersible 0.5mg tablets, budesonide orodispersible 1mg tablets and placebo respectively.
- Jorveza® has complex dosing instructions which are important to achieve maximum efficacy
- budesonide is available in other oral and inhaled formulations but the licensing and cost of these treatments differs to Jorveza®. Care should be taken to ensure the correct preparation is prescribed.
- the service states that patients will receive Jorveza® maintenance treatment for 6 months and then reassess with endoscopy or biopsy
- treatment for six months would cost £1,288.80 [£1,546.56 inc VAT] or £1,292.00 [£1,550.40 including VAT] for budesonide orodispersible 0.5mg tablets and budesonide orodispersible 1mg tablets respectively
- minimal cost offset will be available as Jorveza® will be used instead of inhaled corticosteroids, e.g., fluticasone inhaler, which are available generically

Members discussed the potential for mis-selection of generic budesonide preparations in prescribing systems and supported branded prescribing for budesonide orodispersible tablets. **FTEAM**

The Group accepted the restricted local need for Jorveza® orodispersible tablets for the maintenance of remission of EoE in adults who have been unsuccessfully treated with proton pump inhibitors.

FG1 460/23 - Jorveza® 0.5mg, 1mg orodispersible tablets (budesonide) is routinely available in line with local guidance.
Indication under review: for the maintenance of remission of eosinophilic esophagitis (EoE) in adults who have been unsuccessfully treated with proton pump inhibitors.
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**

ITEM	SUBJECT	ACTION

5.2. SMC 2562 - REGORAFENIB (METASTATIC COLORECTAL CANCER)

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

The Group considered the request for regorafenib as monotherapy for the treatment of adults with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for other available therapies.

The Group noted that:

- regorafenib:
  - [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for 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 taken orally at a dose of 160mg once daily for 3 weeks followed by one week off therapy. This 4-week period is considered a treatment cycle and treatment should continue as long as benefit is observed or until unacceptable toxicity occurs.
  - tablets should be swallowed whole with water after a light meal that contains less than 30% fat
  - is already included on the formulary for hepatocellular carcinoma and gastrointestinal stromal tumours
  - is an oral treatment, that can be taken at home which is an important consideration for late-stage cancer (ref SMC)
- evidence comes from two studies, CORRECT and CONCUR, and the primary outcome was overall survival
- in CORRECT the median overall survival was 6.4 months for regorafenib versus 5 months for placebo
- in CONCUR the median overall survival was 8.8 months for regorafenib versus 6.3 months for placebo
- patient numbers will be relatively small
- in the CORRECT study, the median duration of treatment in the regorafenib group was 7.27 weeks
- the SMC DAD includes that regorafenib would either displace trifluridine plus tipiracil in the third-line or be used fourth line where patients would receive best supportive care. However, the service anticipates that regorafenib will be used fourth-line where there is currently no formulary treatment options available, so this would be a new cost to the service.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of regorafenib

Members had a lengthy discussion about quality of life and use of chemotherapy in the end-of-life setting, particularly as latter lines of therapy where the potential toxicity of treatment needs to be balanced against a small gain in progression-free or overall survival.

Members agreed that these are difficult situations and are also personal discussions between the patient and the consultant that is dealing with their care.
There was general acceptance that in the current financial climate it is challenging to keep accepting medicines to formulary when affordability is not part of decision-making and monies do not necessarily follow SMC acceptance.

Recognising that the discussion was treading into the moral and ethical discussion around entitlement to access medicines, the Group agreed that there needs to be a wider discussion to understand the financial impact and implications for the organisation, and it is not for this group alone to discuss.

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Ms Doney was tasked with presenting the Group's concerns, about the tension between marginal gains and affordability, for a wider debate with colleagues in the organisation. **FD**

The Group accepted the restricted local need for regorafenib as monotherapy for the treatment of adults with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies, as outlined in SMC 2562.

SMC 2562 – Regorafenib 40mg film-coated tablets (Stivarga®) is routinely available in line with national guidance (SMC 2562).
Indication under review: as monotherapy for the treatment of adults with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.
In two phase III studies, regorafenib was associated with statistically significant benefits in overall survival versus placebo.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
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. Regorafenib should be prescribed by physicians experienced in the administration of anticancer therapy. **FTEAM**

5.3. FG1 462/23 - DIENOGEST (ENDOMETRIOSIS)

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

The Group considered the request for dienogest for the treatment of pain caused by endometriosis and prevention of recurrence of endometriosis following surgery.

The Group noted that:

- dienogest:
  - is licensed for the treatment of endometriosis
  - will not be reviewed by SMC as it is considered outwith remit
  - is taken orally as one tablet daily without any break, and any hormonal contraception needs to be stopped prior to initiation
  - is included as a first-line progestogen choice in the BMJ Best Practice Endometriosis guidance
  - is one of the few progestogens that is licensed for the treatment of endometriosis
- treatment will be given from diagnosis of endometriosis until menopause
- the service anticipates prescribing will be in primary care on the recommendation of secondary care, but review in secondary care would be available
- if patients have a diagnosis of endometriosis, prior to the referral to secondary care for consideration of dienogest the service would expect patients to have been trialled on the combined pill or other progestogen treatment
- evidence comes from various trials:
  - when compared to placebo in a 12-week trial the reduction of endometriosis-associated pelvic pain by 50% or more was achieved in 37.4% on dienogest patients compared to 19.8% on placebo
  - in a 24-week study, the absolute reductions in visual analog scale score were 47.5mm with dienogest and 46.0mm with leuprolide acetate, demonstrating non-inferiority
  - a meta-analysis including 10 studies found that the incidence rate of endometriosis recurrence after surgery was 2 per 100 women for dienogest and 29 per 100 women for the expectant population
- patient numbers are moderate and may increase with time

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- cost offset will be available as treatment with dienogest will displace an alternative progestogen

The BMJ Best Practice Endometriosis guidance provided a useful treatment algorithm but members queried how patients would be monitored and what monitoring patients' need, because treatment from 18 years to 55 years is a long time to potentially be on this drug.

Members queried if patients would remain under the supervision of the specialist service or would be discharged, and how would patients' [that had previously been initiated on dienogest] access review in secondary care without re-referral and joining the end of the waiting list?

Members noted the Summary of Product Characteristic advises that dienogest '*must not be administered to pregnant women because there is no need to treat endometriosis during pregnancy'*, and queried if treatment should or should not be re-started in primary care, or if patients should be seen in the specialist service after giving birth.

The Group accepted the restricted local need for dienogest for the treatment of endometriosis. However, there is a need for information for prescribers regarding:
1) the monitoring/ongoing monitoring requirements when prescribing progestogens,
2) the use of dienogest after pregnancy, and
3) the referral pathway back into the specialist service if patients previously established on dienogest need to see a gynaecologist.

FG1 462/23 - Dienogest 2mg tablets is routinely available in line with local guidance.
Indication under review: for the treatment of endometriosis.
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**

5.4. SMC 2589 - PEMBROLIZUMAB (MSI-H OR DMMR TUMOURS IN COLORECTAL, ENDOMETRIAL, GASTRIC, SMALL INTESTINE OR BILIARY CANCER)

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

The Group considered the request for SMC 2589 for pembrolizumab for four advanced solid tumour sites; colorectal, gastric, small intestine and biliary, all with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR).

The Group noted that:
- the SMC advice also includes endometrial carcinoma but this indication was not included in this request
- pembrolizumab:
  - is administered as an intravenous infusion over 30 minutes at a dose of 200mg every 3 weeks or 400mg every 6 weeks
  - is already included on formulary for multiple other indications, including first-line treatment of metastatic MSI-H or dMMR colorectal cancer (SMC 2375)
- MSI-H/dMMR tumour status should be confirmed by a validated test. This is routinely carried out at the time of diagnosis for the colorectal cohort. It is not yet carried out for upper GI cohorts but will be performed if requested in specific cases.
- NICE has accepted pembrolizumab for these indications, but restricts treatment with pembrolizumab to 2 years of uninterrupted treatment
- the service acknowledge that for the majority of immunotherapy studies in the metastatic setting an arbitrary cut off of up to two years therapy has been applied, this would also be reasonable for this patient group

- evidence for use in colorectal cancer comes from KEYNOTE-164 (n=124). The objective response rate (ORR) (the proportion of patients with a complete response (CR) or partial response (PR)) was 34% (CR: 9.7%, PR: 24%, stable disease: 19%)
- evidence for MSI-H positive advanced solid tumours (except colorectal) comes from KEYNOTE-158. The ORR for:
  - gastric was 37% (CR: 14%, PR: 24%, stable disease: 14%)
  - small intestine was 56% (CR: 15%, PR: 41%, stable disease 22%)
  - cholangiocarcinoma was 41% (CR: 14%, PR: 27%, stable disease: 14%)
- an indirect treatment comparisons suggest that
  - in colorectal cancer, pembrolizumab was superior to FOLFOX/FOLFIRI and trifluridine/tipiracil
  - in gastric carcinoma pembrolizumab was superior to FOLFIRI and there was no difference between pembrolizumab and paclitaxel
  - in small intestine carcinoma pembrolizumab was superior to nab-paclitaxel
  - in biliary carcinoma pembrolizumab was superior to mFOLFOX and mFOLFIRI
- patient numbers for all indications will be very small each year
- in the trials, patients who achieved a complete response could stop treatment after receiving at least eight administrations of pembrolizumab 200mg every 3 weeks
- the service has stated that:
  - this will provide access to immunotherapy for MSI-H patients with unresectable or metastatic gastric, small intestine or biliary cancer in this setting instead of chemotherapy. Therefore, minimal offset will be available.
  - in patients with MSI-H colorectal cancer, the majority of patients would receive immunotherapy first-line, so use in this setting is unlikely as there is a definite advantage to use immunotherapy first-line

The Group accepted the restricted local need for pembrolizumab monotherapy as outlined in SMC 2589 for the four advanced solid tumour sites; colorectal, gastric, small intestine and biliary, all with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR). Acceptance was subject to including a 2-year stopping rule.

SMC 2589 - Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) is routinely available in line with local guidance.
Indication under review: as monotherapy for the treatment of the following microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) tumours in adults with:

- **unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy**
- **unresectable or metastatic gastric, small intestine or biliary cancer, who have disease progression on or following at least one prior therapy**

Restriction: pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if the cancer progresses.
In two phase II, single-arm studies, pembrolizumab demonstrated objective response rates from 34% to 56% in patients with MSI-H or dMMR tumours.
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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. Patient selection for treatment with pembrolizumab based on MSI-H/dMMR tumour status should be confirmed by a validated test. **FTEAM**

5.5. SBAR - HYDROGEN PEROXIDE 1% CREAM (IMPETIGO)

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

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The Group reviewed the SBAR request for hydrogen peroxide 1% cream to be added to the formulary.

The Group noted that:

- hydrogen peroxide 1% cream (Crystacide®):
  - is licensed for topical application for the treatment of primary and secondary superficial skin infections caused by organisms sensitive to hydrogen peroxide
  - is available as 25g and 40g tubes with an in-use shelf-life of 28 days
  - is a P (Pharmacy) medicine so can be sold to the public under the supervision of a pharmacist (including via online pharmacies), and currently only the 40g pack is included in the NHS Scotland Pharmacy First Approved List
- the local request for use is in line with NICE guideline [NG153] Impetigo: antimicrobial prescribing - for the initial treatment of localised non-bullous impetigo in patients who are not systemically unwell or at high risk of complications
- NICE advises that for localised non-bullous impetigo:
  - *consider prescribing hydrogen peroxide 1% cream (apply two or three times daily for 5 days) for people who are not systemically unwell or at a high risk of complications*
  - *if this is unsuitable, prescribe a short course (5 days) of a topical antibiotic, offer:*
    - *fusidic acid 2% (apply three times a day for 5 days), or*
    - *mupirocin 2% (apply three times a day for 5 days) if fusidic acid resistance is suspected or confirmed*
  - *the length of course can be increased to 7 days if required based on clinical judgment, depending on the severity and number of lesions*
  - *if meticillin resistant Staphylococcus aureus (MRSA) is suspected, consult local microbiologist. For more information, see the CKS topic on MRSA in primary care.*
  - *advise people with impetigo, and their parents or carers if appropriate, to seek medical help if symptoms worsen rapidly or significantly at any time, or have not improved after completing a course of treatment*
- a PRESQuipp Hot topic article from 2020 provides information on hydrogen peroxide 1% cream and its use in impetigo to support implementation of NG153 - https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f4701%2fhydrogen-peroxide-1-cream-for-impetigo-21.pdf
- the development of bacterial resistance is an increasing problem and is a known problem when using topical antibiotics
- the small number prescriptions issued locally for hydrogen peroxide 1% cream

Primary Care members reported that they do not see impetigo as much as previously, and suspect that cases are dealt with in Community Pharmacy.
Members discussed the lack of awareness of hydrogen peroxide 1% cream and the need to advise healthcare professionals of the change in practice and provide information about hydrogen peroxide 1% cream.

The Group agreed that inclusion will support the aims of antimicrobial stewardship to educate and support health care professionals to follow evidence-based guidelines for prescribing and administering antimicrobials, and as hydrogen peroxide 1% cream does not give rise to resistant bacteria it is a valuable alternative to topical antibiotics.

The Group accepted the restricted local need for hydrogen peroxide 1% Cream (Crystacide®) without the need for a full submission. Acceptance should be supported with information regarding hydrogen peroxide 1% cream as healthcare professionals may not be familiar with it, or its use in impetigo. **AMT**

SBAR - Hydrogen Peroxide 1% Cream (Crystacide®) is routinely available in line with national guidance (NG153).
Indication under review: for initial treatment of localised non-bullous impetigo in

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patients who are not systemically unwell or at high risk of complications.
It was classified 1a - available for general use, 8f – treatment may be initiated in either Primary or Secondary Care, including Community Pharmacies for minor illnesses included in the NHS Pharmacy First Scotland Approved List. **FTEAM**

Note: The medicines listed in the NHS Pharmacy First Scotland Approved List should be used within their GSL or P licensed indication, and the PoM products listed should only be used under the terms of the relevant Patient Group Directions (PGDs).

5.6. SBAR - AFLIBERCEPT 114.3 MG/ML SOLUTION FOR INJECTION (NAMD AND DMO) (NEW FORMULATION OF EXISTING FORMULARY PRODUCT)

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

The Group reviewed the SBAR request for a new higher strength, less frequent, aflibercept intravitreal injection to be added to the formulary.

The Group noted that:
- this new formulation higher dose aflibercept (8mg) for intravitreal use is considered outwith remit by the SMC, and the 2mg preparation is included on the formulary
- aflibercept 8mg dose is requested, in line with the SMC advice for the 2mg preparation, in adults for the treatment of:
  - neovascular (wet) age-related macular degeneration (nAMD)
  - visual impairment due to diabetic macular oedema (DMO)
- nAMD is a common cause of acute and significant visual loss, and its prevalence in the UK is expected to increase with an ageing population
- a significant proportion of people with diabetes have some evidence of DMO, and its prevalence is expected to rise with the increasing prevalence of diabetes
- aflibercept 8mg:
  - was shown to be non-inferiority to the 2mg preparation, with no safety signals
  - has the same treatment initiation [one injection per month for three consecutive doses] for nAMD and DMO, whereas the 2mg preparation treatment initiation is one injection per month for three consecutive doses for nAMD and five consecutive doses for DMO
  - injection intervals may be extended up to every four months based on the physician's judgement of visual and/or anatomic outcomes. Subsequently, the treatment intervals may be further extended up to five months, such as with a treat-and-extend dosing regimen, while maintaining stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly based on the physician's discretion. The shortest interval between two injections is two months in the maintenance phase.
  - at monthly doses has not been studied for more than three consecutive doses
- the frequency of monitoring visits should be based on the patient's status and at the physician's discretion

It was confirmed that:
- aflibercept as Eylea® is subject to a PAS and confidential contract price
- there is uncertainty that there will be an 8mg biosimilar available, but there is certainty that the 2mg biosimilar will be marketed

Members queried if faricimab with its dual-action might be more efficacious than higher dose aflibercept, and if introducing the 8mg strength will negatively affect the opportunity to benefit from the availability of the 2mg biosimilar.

Members acknowledged that this new formulation of aflibercept is wanted for capacity reasons, but requested more information to support decision-making, including clarity on the treatment pathway for the different indications and when a step-up in aflibercept dose

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would be preferred to a change to faricimab, and if introduction will also affect the number of monitoring visits needed. **FTEAM**

Decision deferred to a future meeting. **FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

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

The Group reviewed the Formulary Team's summary document highlighting a minor update to the classification for an 'ultra-orphan' medicine and some discontinued medicines.

OLIPUDASE ALFA (XENPOZYME®)

Ms Doney confirmed that:

- SMC 2560 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.
- September 2023, using the ultra-orphan framework, the SMC completed its initial assessment of the evidence for olipudase alfa as an enzyme replacement therapy for the treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients with type A/B or type B.
- September 2023 olipudase alfa was added to the formulary as 'Not routinely available in NHS Grampian. *If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).*'
- The Scottish Government has confirmed that from 23 February 2024, olipudase alfa (Xenpozyme®) can be prescribed within the ultra-orphan pathway while further evidence on its effectiveness is generated. After three years the company will provide an updated submission for reassessment to allow a decision on its routine use in NHS Scotland.

In line with local formulary processes the Group updated the decision to ''Not routinely available in NHS Grampian. *If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme'*.

SMC 2560 - Olipudase alfa 20mg powder for concentrate for solution for infusion (Xenpozyme®)▼ is not routinely available in NHS Grampian.
Indication under review: as an enzyme replacement therapy for the treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients with type A/B or type 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. **FTEAM**

DISCONTINUATIONS

The Group noted that the following medicines have been withdrawn/discontinued:

- ocriplasmin 0.5mg/0.2mL intravitreal injection (Jetrea®). Voluntarily withdrawn on 31 December 2023 and will no longer be available on the market after this date.
- Maalox® 175mg/200mg oral suspension and Maalox® Plus 175mg/200mg/25mg oral suspension. Both products have been discontinued and the marketing authorisations have not been divested.

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Ms Doney confirmed that these products are low-impact, non-formulary discontinuations. Ocriplasmin was not requested locally, and Mucogel® is the preferred antacid. Maalox® oral suspension is included in the local hypomagnesaemia guidance (fourth-line after Mucogel®) and will remain in the guidance until its next scheduled update.

The Group supported update of the formulary noting the withdrawal/discontinuation of the three medicines. **FTEAM**

6.2. PREFERRED BRANDS/PRODUCTS WITHIN THE MANAGED SERVICE

Ms Doney reported that there are several managed service contract reviews underway. Where there is a preferred product in the managed service and prescribing may transfer to Primary Care the Formulary Team is linking with colleagues to try and ensure that the preferred choice will not be a loss leader for Primary Care.

The outcomes of these contract changes will come to the Group for information.

6.3. SBAR - CARBON FOOTPRINT FOR INHALERS (PAPER FOR DISCUSSION)

Mrs Standen confirmed that there is a need to add the carbon footprint of inhalers to the formulary to highlight the environmental impact that different inhalers can have. This was a recommendation in the Quality Prescribing for respiratory illness 2024 to 2027.

Mrs Standen summarised several options for including the carbon footprint for inhalers, all options used data from PresQuipp.

There was general support for using an indicative carbon footprint per inhaler, with some support for creating a 'carbon footprint key'. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED MARCH 2024

The Group noted the SMC advice published March 2024.

Following publication of the negative SMC recommendation, for axicabtagene ciloleucel (Yescarta®)▼ SMC 2628, and the non-submission statements, for pitolisant (Wakix®)▼ SMC 2662 and satralizumab (Enspryng®)▼ SMC 2663, 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 2615 ivosidenib (Tibsovo®)▼ (submission expected)
- SMC 2617 olaparib (Lynparza®)
- SMC 2574 Produodopa®▼ foslevodopa/foscarbidopa (submission expected)
- SMC 2607 talazoparib (Talzenna®)▼ (submission expected)

Local advice for these medicines and indications will be included in the March 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

TABLED ITEM - SMC COLLABORATION WITH NICE ON MTA TA878

Ms Doney reported that updated advice was published on the SMC website the day after the SMC papers were sent to members.

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	Following collaboration with NICE on TA878, the SMC has accepted nirmatrelvir and ritonavir (Paxlovid®) for the treatment of COVID in patients with any of the following: increased risk for progression to severe COVID-19 (as defined in section 5 of NICE final guidance), age ≥70 years, BMI ≥35 kg/m^2, diabetes, and/or heart failure.	
	The current formulary entry and local protocols will need to be updated in line with the updated criteria, information is awaited from the AMT and Mr David Pfleger.	**AMT/DP**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED MARCH 2024

The Group noted the SMC provisional advice issued March 2024.

9. OTHER BUSINESS

9.1. SCOTTISH ANTIMICROBIAL PRESCRIBING GROUP (SAPG) RESPONSE TO THE UPDATED MHRA FLUOROQUINOLONE PRESCRIBING ADVICE

This item was noted under item 3.4.

10. DOCUMENTS FOR INFORMATION

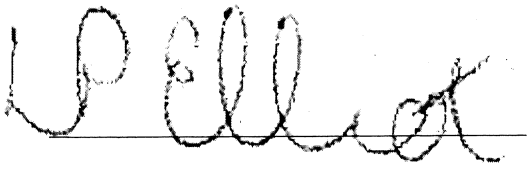
Items 10.1 (Drug Safety Update February 2024) and 10.2 (AMT minute December 2023) were noted.

11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 16 April 2024 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 16 APRIL 2024**