NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 May 2021 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms A Davie (from item 6.3)	Mrs L Montgomery	
Ms F Doney	Mr R Sivewright	
Dr L Elliot	Dr A Sun	
Dr J Fitton		
Ms M Galvin		
Professor J McLay (Chairman)		
Dr M Metcalfe		
Mrs K Neave		
Mrs S O'Beirne		
Mr M Paterson		

IN ATTENDANCE
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Asimina Chairetaki, Rotational Pharmacist Aberdeen Royal Infirmary

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

The Chairman welcomed Mrs O'Beirne as a Group member, and confirmed that Mrs Asimina Chairetaki, a rotational pharmacist in Aberdeen Royal Infirmary, is observing the meeting.

1. APOLOGIES

Apologies for absence were requested and noted.

Ms Doney confirmed that Dr Sun is taking a career break so is stepping off the Group meantime.

2. DRAFT MINUTE OF THE MEETING HELD 20 APRIL 2021

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 approval. **FD**

3. PRESENTATION

Ms Doney confirmed that there are no presentations until July, when a discussion about sodium-glucose co-transporter-2 (SGLT-2) inhibitors is planned. Item 12.2 is included as background reading for the July meeting.

4. MATTERS ARISING

4.1. ACTION LOG

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

4.2. ACTIONS CLOSED FROM MARCH AND APRIL MEETINGS

The Chairman confirmed the following actions were now closed:
- trimetazidine 20mg tablet (unlicensed product), is available to prescribe on both EMIS and Vision prescribing systems
- the ScriptSwitch profile has been updated for fostamatinib
- an interaction warning triggers when prescribing cariprazine on EMIS or Vision. For diltiazem, erythromycin and clarithromycin, Vision notes concomitant use with

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cariprazine is contraindicated, whereas EMIS notes 'Manufacturer advises avoid.'

CARIPRAZINE INTERACTION WARNINGS

The Chairman highlighted the difference in tone between the warning messages in Vision and EMIS.

Ms Hay confirmed that concomitant administration of strong or moderate CYP3A4 inhibitors or inducers are contraindications in the cariprazine Summary of Product Characteristics (SmPC).

Mrs Neave will send a change request to EMIS asking that the 'warnings' reflect the contraindications in the cariprazine SmPC. **KN**

5. FORMULARY GROUP DECISIONS APRIL 2021 - PUBLISHED 03/05/2021

Members ratified the decisions of the April 2021 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. PAEDIATRIC LICENCE EXTENSIONS HEPATITIS B, HEPATITIS C, HIV

Dr Fitton declared a personal, non-specific interest in Gilead Sciences Ltd and ViiV Healthcare UK Ltd, and took part in decision-making.

The Group considered the Formulary Team's recommendations for some paediatric licence extensions for medicines indicated for the treatment of Human Immunodeficiency Virus (HIV-1), chronic hepatitis C (CHC) and chronic hepatitis B (CHB).

The Group noted that, when used for the treatment of children and adolescents:

- prescribing will only be on the advice of specialists in paediatric infectious diseases or paediatric gastroenterology, with advice from specialists in other Health Boards where appropriate
- costs will be subject to current pricing arrangements (including patient access schemes (PAS))
- patient numbers will be very small or none, but local approval will bring use in line with the adult service and/or prevent delay in access should a local need be identified

Ms Doney confirmed that the classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

The Group supported:

- dolutegravir for HIV-1:
  - extending formulary acceptance to infants and children from 4 weeks to <6 years and weighing at least 3kilograms (kg) by including the new 5mg dispersible tablet on the formulary. Inclusion also provides an option for children, adolescents and adults with swallowing difficulties, although the dispersible and standard formulation tablets are not bioequivalent.
  - a minor change to the current formulary acceptance for 10mg, 25mg and 50mg tablets - noting the minimum weight and clarification of age - for children 6 years and older and weighing at least 14kg
- Genvoya® for HIV-1 - extending formulary acceptance [in line with licensing] to include children from 6 to <12 years
- Epclusa® for CHC:
  - extending formulary acceptance of the 400/100mg film-coated tablet to include children and adolescents aged 6 to <18 years and weighing at least 30kg
  - include the new lower strength 200mg/50mg film-coated tablet on the formulary for children and adolescents aged 6 to <18 years and weighing between 17kg and less than 30kg

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	• Harvoni® for CHC: ▪ extending formulary acceptance of the 90mg/400mg film-coated tablet to include children aged 3 years and older who weigh at least 35kg ▪ include the new lower strength 45mg/200mg film-coated tablet on the formulary for children aged 3 years and older who weigh between 17kg and less than 35kg • sofosbuvir for CHC [used in combination with other treatments for CHC]: ▪ extending formulary acceptance of the 400mg film-coated tablets to include children and adolescents aged 3 to <18 years who weigh at least 35kg • tenofovir disoproxil, as the brand Viread®, for CHB: ▪ including the lower strength 123mg, 163mg and 204mg tablets on the formulary for CHB in line with current licensing to include children aged 6 to <12 years and weighing between 17kg and less than 35kg ▪ extending formulary acceptance of the 33mg/g granules in line with current licensing for CHB to include children aged 2 to <12 years who weigh at least 10kg	
	Dolutegravir 5mg dispersible tablets (Tivicay®) is routinely available in line with local guidance. **Indication under review: in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children of at least 4 weeks of age or older and weighing at least 3kg.** **Restriction: to be prescribed under the supervision of specialists in HIV/paediatric HIV.** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.**	**FTEAM**
	Dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) is routinely available in line with local guidance. **Indication under review: in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children of at least 6 years of age or older and weighing at least 14kg.** **Restriction: to be prescribed under the supervision of specialists in HIV/paediatric HIV.** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.**	**FTEAM**
	Genvoya® 150mg/150mg/200mg/10mg film-coated tablets (elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide) is routinely available in line with local guidance. **Indication under review: for the treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in children aged from 6 to <12 years and with body weight at least 25kg for whom alternative regimens are unsuitable due to toxicities.** **Restriction: to be prescribed under the supervision of specialists in paediatric HIV.** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.**	**FTEAM**
	Epclusa® 200mg/50mg film-coated tablets (sofosbuvir/velpatasvir) is routinely available in line with local guidance. **Indication under review: for the treatment of chronic hepatitis C virus (HCV) infection in adolescents and children aged 6 years and older and weighing 17kg to less than 30kg.** **Restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology.**	

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	It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Epclusa® 400mg/100mg film-coated tablets (sofosbuvir/velpatasvir) is routinely available in line with local guidance. Indication under review: for the treatment of chronic hepatitis C virus (HCV) infection in adults, adolescents and children aged 6 years and older and weighing at least 30kg. Restriction: prescribing by specialist in (paediatric) infectious disease or (paediatric) gastroenterology. It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Harvoni® 45mg/200mg film-coated tablets (ledipasvir/sofosbuvir) is routinely available in line with local guidance. Indication under review: for the treatment of chronic hepatitis C virus (HCV) infection in adults, adolescents and children aged 3 years and above and weighing 17kg to <35kg. Restriction: prescribing by specialist in (paediatric) infectious disease or (paediatric) gastroenterology. It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Harvoni® 90mg/400mg film-coated tablets (ledipasvir/sofosbuvir) is routinely available in line with local guidance. Indication under review: for the treatment of chronic hepatitis C virus (HCV) infection in adults, adolescents and children aged 3 years and above and weighing at least 35kg. Restriction: prescribing by specialist in (paediatric) infectious disease or (paediatric) gastroenterology. It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Sofosbuvir 400mg film-coated tablets (Sovaldi®) is routinely available in line with local guidance. Indication under review: in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in children and adolescents aged 3 to <18 years who weigh at least 35kg. Restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology. It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg tablets (Viread®) is routinely available in line with local guidance. Indication under review: for the treatment of chronic hepatitis B in paediatric patients aged 6 to <12 years and weighing 17kg to less than 35kg with: - compensated liver disease and evidence of immune active disease, i.e. active viral replication, and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. Restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology. It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTEAM**
	Tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®) is routinely available in line with local guidance.	

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Indication under review: for the treatment of chronic hepatitis B in paediatric patients 2 to <12 years who weigh at least 10kg and for whom a solid dosage form is not appropriate with:
- compensated liver disease and evidence of immune active disease, i.e. active viral replication, and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis.
Restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTEAM**

6.2. SBAR LINACLOTIDE

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

The Group reviewed the SBAR requesting a minor change to extend the current prescribing recommendation to include general surgeons.

Members accepted that:
- the current formulary recommendation is not in line with practice
- patients with chronic/refractory constipation are managed by a gastroenterologist and/or a general surgeon with a specialist interest in pelvic floor/bowel dysfunction
- treatment should only be initiated in Primary Care following prescribing recommendation by the Departments of Digestive Disorders or General Surgery

The Group supported the request to extend the prescribing recommendation to include general surgeons, bringing use in line with the recommendation for prucalopride.

Linaclotide 290micrograms hard capsules (Constella®) is routinely available in line with local guidance.
Indication under review: for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults who have not responded adequately to or cannot tolerate all other suitable treatment options.
Restriction: treatment should only be initiated in Primary Care following prescribing recommendation by the Departments of Digestive Disorders or General Surgery.
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**

6.3. CHLORAMPHENICOL EYE DROPS

The Chairman highlighted information from the Scottish Antimicrobial Prescribing Group (SAPG) regarding chloramphenicol eye drops.

The European Medicines Agency (EMA) has recommended that chloramphenicol 0.5% eye drops containing boric acid as an excipient are contraindicated for use in children under 2 years of age. The recommendation is due to an associated future risk of impaired fertility.
There is lack of clarity regarding this contraindication, and the Medicines and Healthcare products Regulatory Agency (MHRA) is considering the available evidence in collaboration with specialists and plans to issue a statement in due course.

SAPG suggests that chloramphenicol 1% ointment may be used as a suitable alternative.

Mrs O'Beirne, confirmed that the Marketing Authorisation Holders (MAHs) have recently updated their SmPCs to include the contraindication, and she will investigate if there are other eye drops that include boron. **SO**

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	The Group supported linking information to the formulary entry.	FTEAM

7. OTHER BUSINESS

7.1. PHARMACY FIRST

Ms Doney briefly described the 'NHS Pharmacy First Scotland' service, and highlighted the request for area drugs and therapeutics committees (ADTCs) to review the 'Approved List' that underpins the service.

Members were asked to review the 'Approved List' and proposed amendments, and send feedback to the Formulary Team for collation and discussion at the June meeting. **ALL/ FTEAM**

7.2. NCMAG (UPDATE)

Ms Galvin provided members with an update on the status of the COVID-19 National Cancer Medicines Advisory Group (NCMAG), its advice and proposed review process.

Ms Galvin reported that:

- the Scottish Government [has confirmed that it] will continue to support the work of COVID-19 NCMAG, and ongoing COVID-19 cancer medicines cost pressures will be supported until the end of the 2021-2022 financial year
- initially COVID-19 NCMAG advice was given a nominal one-year timeline, however where published advice remains relevant it will be extended until March 2022
- communication is via the cancer networks and the NCMAG advice is hosted on the West of Scotland Cancer Network website - https://www.intranet.woscan.scot.nhs.uk/covid-19-guidance/covid-19-national-cancer-medicines-advisory-group/
- review of the first advice documents has started. NCMAG00l (Abiraterone in low risk metastatic hormone sensitive prostate cancer) is extended until March 2022 and review of NCMAG002 (G-CSF (granulocyte-colony stimulating factor)) is underway.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2310 - BRENTUXIMAB (UNTREATED SYSTEMIC ANAPLASTIC LARGE CELL LYMPHOMA)

Dr Fitton declared a personal, non-specific interest in Takeda UK Ltd and took part in decision-making.

The Group considered the request for brentuximab vedotin in combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).

The Group noted:

- brentuximab vedotin:
  - is used in combination with CHP for previously untreated sALCL
  - is also licensed for relapsed or refractory sALCL but this indication is not accepted for use within NHS Scotland
  - [for untreated sALCL] was accepted for use within NHS Scotland following a full submission and review by the SMC executive
  - [for untreated sALCL] meets SMC orphan criteria and has a conditional marketing authorisation from the European Medicines Agency (EMA).
  - will replace vincristine (O) in the CHOP chemotherapy regimen, so minimal cost offset will be available
  - [for untreated sALCL] is administered as an intravenous infusion over 30 minutes every three weeks for six to eight cycles, and the service anticipates use will not extend beyond six cycles
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of brentuximab vedotin

- patient numbers are expected to be small
- the ECHELON-2 study did not include sALCL patients who were ALK-positive with an International Prognostic Index (IPI) score less than 2. However as ALK-positive ALCL is very rare the service plans to treat all patients with brentuximab regardless of their IPI score [as it is likely to increase the chance of cure].

The Group accepted the restricted local need for brentuximab in combination with CHP for adults with previously untreated sALCL, as outlined in SMC 2310.

SMC 2310 - Brentuximab 50mg powder for concentrate for solution for infusion (Adcetris®)▼ is routinely available in line with national guidance (SMC 2310).
Indication under review: in combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL).
In a phase III study, brentuximab vedotin in combination with CHP was associated with a significant improvement in progression-free survival compared with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) 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.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.
Brentuximab should be administered under the supervision of a physician experienced in the use of anti-cancer agents. **FTEAM**

8.2. FG1SMC 2309 - OZANIMOD (RELAPSING REMITTING MULTIPLE SCLEROSIS)

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

The Group considered the request for ozanimod for the treatment of adults with relapsing remitting multiple sclerosis (RRMS).

The Group noted:
- ozanimod:
  - is a disease modifying therapy (DMT) licensed for the treatment of adults with RRMS with active disease as defined by clinical or imaging features
  - is an oral treatment option that following initial dose escalation is taken once daily at a dose of 0.92mg
  - was accepted for restricted use within NHS Scotland following a full submission reviewed by the SMC executive. The submitting company requested that the SMC considered ozanimod for adults suitable for or requesting an oral treatment.
  - offers an alternative oral DMT to other oral agents e.g., dimethyl fumarate, teriflunomide
  - patient numbers will be cumulative as treatment will continue until a patient develops non-relapsing secondary progressive disease and/or is unable to walk 20metres with bilateral aids without stopping i.e., has an Expanded Disability Status Scale (EDSS) score greater than 6.5
- the service confirmed that treatment would be discontinued in favour of an alternative DMT if the patient shows evidence of continued disease activity despite this treatment, or no change in relapses
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ozanimod
- cost offset is available as ozanimod will replace the use of other [oral or injectable] DMTs

The Group accepted the restricted local need for ozanimod for the treatment of adults with RRMS with active disease, as outlined in SMC 2309.

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SMC 2309 - Ozanimod 0.23mg, 0.46mg, 0.92mg hard capsules (Zeposia®)▼ is routinely available in line with national guidance (SMC 2309).
Indication under review: treatment of adults with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features who are suitable for or requesting an oral treatment.
In two phase III studies, ozanimod demonstrated a significantly greater reduction in annualised relapse rate compared with another disease-modifying treatment in patients with relapsing forms of multiple sclerosis.
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 should be initiated under the supervision of a physician experienced in the management of multiple sclerosis. **FTEAM**

8.3. FG1SMC 2260 - FLUOCINOLONE ACETONIDE IMPLANT (NON-INFECTIOUS UVEITIS)

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

The Group considered the request for fluocinolone acetonide 190micrograms intravitreal implant for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

The Group noted that:

- fluocinolone acetonide intravitreal implant:
  - is already included on the formulary for the treatment of vision impairment associated with chronic diabetic macular oedema, SMC 864/13
  - will reduce the use of dexamethasone intravitreal implant
  - requires less frequent intravitreal injections leading to a reduction in the potential risks of intraocular surgery, less time spent in theatre and will be more convenient for patients
- each implant releases fluocinolone acetonide for up to 36 months, however, the submission states that the sustained release of steroids in uveitic eyes is shorter in duration in comparison with other conditions causing retinal swelling. The service expects a shorter duration of steroid release for this indication.
- it is possible that re-injection will be considered if a person has a further flare up and there are no other suitable alternative treatments
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of fluocinolone acetonide implant

The Group accepted the restricted local need for fluocinolone acetonide intravitreal implant for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye, as outlined in SMC 2260.

SMC 2260 - Fluocinolone acetonide 190micrograms intravitreal implant (Iluvien®) is routinely available in line with national guidance (SMC 2260).
Indication under review: in adults for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.
In a double-blind, phase III study in patients with recurrent non-infectious uveitis affecting the posterior segment of the eye, fluocinolone acetonide intravitreal implant reduced the number of recurrences of uveitis compared with sham injection.
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

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8b – recommended for hospital use only.
Treatment with Iluvien® is for intravitreal use only and should be administered by an ophthalmologist experienced in intravitreal injections. The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anaesthesia and a broad-spectrum microbicide should be given prior to the injection. **FTEAM**

8.4. FG1 434/20 - ENOXAPARIN (ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION)

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

The Group considered the request from the Emergency Department in Dr Gray's hospital for the use of enoxaparin as part of ST-segment elevation myocardial infarction (STEMI) thrombolysis for patients not going directly for primary PCI.

Dr Metcalfe reported that:

- more than 17 years ago, the ESSENCE* trial was published that showed that low-molecular-weight heparin (LMWH) was superior to unfractionated heparin as part of the treatment for acute myocardial infarction. The LMWH used in the ESSENCE trial was enoxaparin.
- at the time, dalteparin was considerably cheaper than enoxaparin, and on cost grounds the local consultant Haematologists looked at dalteparin versus enoxaparin, and they concluded that dalteparin and enoxaparin were identical in terms of their action
- the Cardiology departments' [in NHS Grampian] agreed with the Haematologists' assessment and considered there would not be a difference between using the two LMWHs, and dalteparin was accepted as the preferred LMWH
- dalteparin is not licensed for acute STEMI, but other hospitals/centres use dalteparin for this indication
- there will never be a comparative study of the two LMWHs, and it is unlikely that licensing will change, most centres will use their traditional LMWH
- the interventional Cardiologist in Dr Gray's was not aware of the formulary request and supports the continued use of dalteparin

The Group accepted that antithrombotic therapy optimises outcomes, and that the use of dalteparin for this indication is off-label however, the dalteparin regimen has been established practice for many years. The Group requested that the Emergency Department consultant(s) liaise with the interventional Cardiologist in Dr Gray's to discuss the use of dalteparin in the treatment of acute STEMI.

The Group backed the position of the Cardiology departments in ARI and Dr Gray's, and did not support the request for Dr Gray's Emergency Department to include enoxaparin on the formulary for the treatment of acute STEMI for patients that are not going directly for primary percutaneous cardiovascular intervention.

Enoxaparin solution for injection is not routinely available as there is a local preference for alternative medicines.
Indication under review: for use in Dr Gray's Emergency Department for the treatment of acute ST-segment elevation myocardial infarction (STEMI) for patients that are not going directly for primary percutaneous cardiovascular intervention (PCI).
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

* Efficacy and Safety of Subcutaneous Enoxaparin in Non–Q-Wave Coronary Events (ESSENCE) trial. Antithrombotic therapy reduces the risk of recurrent ischemic events in patients with unstable angina. The primary aim of the ESSENCE trial was to evaluate the efficacy of enoxaparin (low molecular weight heparin) versus unfractionated heparin, plus aspirin, in patients with rest angina or non-Q-wave infarction.

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9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - MAY 2021

The Group noted the SMC provisional advice issued May 2021.

If the SMC non-submission statement is published next month, this medicine will not be included on the formulary for the indication in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - MAY 2021

The Group noted the SMC advice published May 2021.

Following publication of the non-submission statement for Bevespi Aerosphere® (SMC 2377), this medicine will not be included on the Grampian Joint Formulary for the indication in question. **FTEAM**

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

- SMC 2361 upadacitinib (Rinvoq®) ▼ (submission expected)
- SMC 2318 chlormethine gel (Ledaga®) (submission received)
- SMC 2312 encorafenib (Braftovi®) ▼ (submission expected)
- SMC 2338 niraparib (Zejula®) ▼ (submission expected)

Local advice for these medicines and indications will be included in the May 2021 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2330 - RAVULIZUMAB (ULTOMIRIS®) ▼ (ATYPICAL HAEMOLYTIC UREMIC SYNDROME)

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

The Group considered the SBAR submitted regarding the use of ravulizumab for the treatment of patients with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least three months and have evidence of response to eculizumab.

The Group noted that:

- ravulizumab:
  - is a very expensive medicine licensed for a very rare disease
  - is the second medicine licensed for aHUS
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for restricted use in NHS Scotland following a full submission under the orphan equivalent medicine process, the output from the PACE process, and application of the appropriate SMC modifiers
  - [for this indication] is an alternative to/would replace the use of eculizumab
  - is restricted to prescribing on the advice of the national renal complement therapeutics service (SMC 2330, May 2021)
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ravulizumab
- eculizumab was the first medicine licensed for the treatment of aHUS. Following a full submission assessed under the ultra-orphan process (SMC 767/16) it was not accepted for use in NHS Scotland - *the submitting company did not present a sufficiently robust economic analysis and their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC*.
- patients' requiring eculizumab have accessed treatment via local individual treatment processes

The Group accepted the restricted local need for ravulizumab for the treatment of aHUS

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as outlined in SMC 2330, without the need for a full submission.

SMC 2330 - Ravulizumab 300mg/3mL, 300mg/30mL, 1,100mg/11mL concentrate for solution for infusion (Ultomiris®) ▼ is routinely available in line with national guidance (SMC 2330).
Indication under review: for the treatment of patients with a body weight of 10kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.
Restriction: under the advice of the national renal complement therapeutics service.
Two single-arm, phase III studies demonstrated the beneficial treatment effect of ravulizumab on complete thrombotic microangiopathy (TMA) response, defined as normalisation of haematological parameters and improvement in renal function.
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 must be administered by a healthcare professional and under the supervision of a physician experienced in the management of patients with haematological or renal disorders. **FTEAM**

BREEZHALER® DEVICE

Ms Doney confirmed that as the Breezhaler® device is not a pre-loaded device it would not be a preferred product on formulary.

SMC 2356 - Atectura Breezhaler® 125micrograms/62.5micrograms, 125micrograms/127.5micrograms, 125 micrograms/260micrograms (indacaterol/mometasone furoate) is not routinely available as there is a local preference for alternative medicines.
Indication under review: as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta$_2$-agonists.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

SMC 2355 - Enerzair Breezhaler® 114micrograms/46micrograms/136micrograms (indacaterol/glycopyrronium/mometasone furoate) is not routinely available as there is a local preference for alternative medicines.
Indication under review: as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta$_2$-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - MAY 2021

The Chairman highlighted that a pilot of new health technology evaluation process for antimicrobials is currently underway.
National Institute for Health and Care Excellence (NICE) is working with NHS England and NHS Improvement (NHSE&I) to pilot a new health technology evaluation process for antimicrobials. SMC along with several other organisations (NSS National Procurement, SAPG and Scottish Government) have been invited as observers to the pilot process.
Two antimicrobial products have been selected for the pilot – ceftazidime/avibactam (Zavicefta®, Pfizer) launched in 2017 and cefiderocol (Fetcroja®, Shionogi) launched in 2020.

ITEM	SUBJECT	ACTION

A joint statement between SMC and SAPG makes boards aware that SMC will not be issuing any further advice for these products and advises NHS Boards that during the pilot the selected medicines can be accessed for individual patients where required through local Health Board processes based on appropriate specialist advice; https://www.scottishmedicines.org.uk/about-us/latest-updates/pilot-of-new-health-technology-evaluation-process-for-antimicrobials/.

12. DOCUMENTS FOR INFORMATION

The Group noted items 12.1 (Drug Safety Update April 2021) and 12.2 (All Wales Advice on SGLT-2 Inhibitors in Type 2 Diabetes and Cardiovascular Disease).

13. AOCB

SUBOXONE SUBLINGUAL FILMS

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

Ms Doney reported that colleagues in the Substance Misuse Service have confirmed that, following review, the new sublingual film formulation of Suboxone® will not be included on the formulary. The existing sublingual and supralingual buprenorphine tablets are available and preferred, information is provided in the local guidance: https://www.nhsgrampian.org/globalassets/foidocument/foi-public-documents1---all-documents/Guide_Buprenorphine.pdf.

The Group supported recording the new sublingual film formulation as 'not routinely available as there is a local preference for alternative medicines'.

SMC 2316 – Suboxone® 12mg/3mg, 8mg/2mg, 4mg/1mg, 2mg/0.5mg sublingual film 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. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.
Restriction: to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.
Buprenorphine/naloxone sublingual film (Suboxone®) and buprenorphine/naloxone sublingual tablets (Suboxone®) deliver similar plasma concentrations of buprenorphine but are not bioequivalent. Please refer to the relevant Summary of Product Characteristics for further detail, including guidance on switching between formulations.
Generic buprenorphine sublingual tablets are available at lower cost.
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.
Not routinely available as there is a local preference for alternative medicines. FTEAM

DATE OF NEXT MEETING

Tuesday 15 June 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE DATE 15 JUNE 2021