NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 February 2021 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms F Doney	Ms A Davie	
Dr L Elliot	Dr M Metcalfe	
Dr J Fitton	Mr R Sivewright	
Ms M Galvin		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Mrs K Neave		
Mr M Paterson		
Dr A Sun (from item 6.2)		

IN ATTENDANCE
Ms Caitlin Wilkinson, Formulary Team administrator
Ms Christine Hay, Formulary and Medicines Management Pharmacist

ITEM	SUBJECT	ACTION
	The Chairman 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 19 JANUARY 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 - NONE**	
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.	**FG1SMC 2288 - SODIUM ZIRCONIUM CYCLOSILICATE (HYPERKALAEMIA)**	
	Mr Paterson and Dr Fitton declared personal non-specific interests in AstraZeneca UK Limited and took part in decision-making.	
	It was confirmed that: • sodium zirconium cyclosilicate is a potassium binder that was accepted for restricted use in NHS Scotland following a resubmission reviewed by the SMC executive • the SMC did not consider the use of sodium zirconium cyclosilicate in the acute setting (correction phase). The correction phase dose is 10g three times a day given for up to 72 hours. • at the December 2020 meeting the Group was minded to support the use of sodium zirconium cyclosilicate subject to clarification of the requested indications, potential patient numbers, proposed prescribing and monitoring arrangements and the service area(s) that would prescribe sodium zirconium cyclosilicate	
	The Group considered the content of the email sent on behalf of the Renal department by Dr Simon Sawhney, Clinical Nephrologist.	

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The Group noted:

- the Renal Service is requesting use of sodium zirconium cyclosilicate in two settings
  - use as emergency bridging where dialysis is unavailable - for unforeseen circumstances (loss of water supply, unable to attend dialysis due to unexpected circumstances, e.g. ferry cancelled, adverse weather) or predictable circumstances (bridging dialysis). In this scenario, use is solely as an in-patient or in the dialysis unit, and for a maximum of two to three days per patient.
    The potassium threshold may be judged on trend rather than an absolute value, but typically the level would be >6.5mmol/litre.
  - chronic use for people with recurrent hyperkalaemia and chronic kidney disease 3b to 5 with or without advanced heart failure, to enable angiotensin-converting enzyme (ACE) inhibitors/angiotensin II receptor blockers (ARBs) initiation or titration
- in the chronic setting, the Renal Service would prefer that sodium zirconium cyclosilicate was initially prescribed by the specialist service with weekly monitoring over the first month before moving to shared care with General Practice doing monthly bloods
- patient numbers are likely to be small, in both the acute and chronic settings
- many clinicians would not support therapeutic escalation, where an additional medicine is used in a way that may disguise a potentially serious adverse drug event that requires investigation, e.g. sodium zirconium cyclosilicate for a rising potassium level caused by an ACE-inhibitor in a person with bilateral renal artery stenosis

The Group considered sodium zirconium cyclosilicate a relatively specialist medicine, and discussed the potential for moving maintenance phase prescribing into Primary Care. However, concerns remain around therapeutic escalation, the arrangements for long-term monitoring and review, and the risk of patients continuing treatment when renin-angiotensin-aldosterone system (RAAS) inhibitor therapies are stopped.

The Group agreed that, at this time, prescribing and monitoring should remain within the managed service, with monitoring remaining the responsibility of the service initiating treatment.

The Group accepted the restricted local need for sodium zirconium cyclosilicate for a limited group of adults that are under the care of the Renal department.

Sodium zirconium cyclosilicate 10g powder for oral suspension (Lokelma®)▼ is routinely available in line with local guidance.
Indication under review: for the treatment of hyperkalaemia in adult patients.
Restriction: acute use [correction phase] within the Renal department as emergency bridging use 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. Treatment must be initiated and supervised by specialist physicians in the Renal department. FTEAM

SMC 2288 - Sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®)▼ is routinely available in line with local guidance.
Indication under review: for the treatment of hyperkalaemia in adult patients.
Restriction: chronic use [maintenance phase] for adults with persistent/recurrent hyperkalaemia and chronic kidney disease stage 3b to 5 with or without heart failure, if they:

- **have a confirmed serum potassium level of at least 6.0mmol/litre and**
- **are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia**

It was classified 1b - available for restricted use under specialist supervision and

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	8b – recommended for hospital use only. Treatment must be initiated and supervised by specialist physicians in the renal department.	**FTEAM**

5. FORMULARY GROUP DECISIONS JANUARY 2021 – PUBLISHED – 01/02/2021

5.1. FORMULARY GROUP DECISIONS JANUARY 2021

Members ratified the decisions of the January 2021 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. PAEDIATRIC LICENCE EXTENSIONS

The Chairman highlighted the two papers produced by the Formulary Team listing the paediatric licence extensions granted since January 2020, and a proposal for an interim local process for reviewing paediatric licence extensions.

The Group requested that the Formulary Team review the backlog of paediatric licence extensions, grouping the licence extensions by indication before providing a recommendation for the Group to consider. **FTEAM**

The Group supported the proposed interim local process to track paediatric licence extensions.

6.2. 93-DAY REPORT

The Chairman highlighted the *"NHS Grampian 93-day deadline report for Formulary Group decisions"* document. The document outlined the proposed report, and reporting timelines for medicines to be included on the formulary website. The report provides Formulary Group members with assurance that the decisions are included on the relevant section of the formulary website within a specific timeframe.

Ms Doney confirmed that previously it was agreed that decisions should be included on the formulary website within 93-days of decision-making, with compliance reported quarterly and exception reporting when the audit standard was not met (audit standard – 90%).
Reporting was expected to be implemented by the end of the 2019/20 financial year, however this was delayed due to staffing issues and COVID-19. However, the Formulary Team is now in a position to implement regular reporting.

The Group supported the proposed 93-day report and reporting schedule. **FTEAM**

The Chairman complemented the Formulary Team on the presentation of the paper and report. Ms Doney confirmed that she would pass on the Chairman's comments to Ms Dawn Bruce who did the majority of work for the report. **FD**

6.3. LEVOSERT LICENCE EXTENSION

Ms Doney confirmed that:
- the usage period for the Levosert® 20microgram/24 hours Intrauterine Delivery System has been updated from 5 to 6 years for the contraception indication
- the formulary entry has been updated, and the change highlighted to colleagues so that the current Patient Group Direction is updated
- no further action is required

7. OTHER BUSINESS

7.1. PRIADEL® 200MG AND 400MG TABLET SUPPLY DISTRIBUTION ALERT - UPDATE

The Chairman highlighted the Supply Distribution Alert Update for Priadel® 200mg and 400mg tablets.

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The Department of Health and Social Care (DHSC) has agreed a revised price for Priadel® 200mg and 400mg tablets with Essential Pharma. The revised NHS list prices agreed are:

- Priadel® MR 200mg x 100 tablets £7.50 (previously £2.76)
- Priadel® MR 400mg x 100 tablets £8.50 (previously £4.02)

Ms Doney will confirm the financial impact of these changes and bring it to the next meeting. **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2158 - BUDESONIDE (EOSINOPHILIC OESOPHAGITIS (EOE))

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

The Group considered the request for budesonide orodispersible tablets for the induction of remission of eosinophilic oesophagitis (EoE) in adults who were unsuccessfully treated with proton pump inhibitors.

The Group noted that:

- EoE is a chronic, local immune-mediated oesophageal disease, characterised clinically by symptoms related to oesophageal dysfunction (including solid food dysphagia, food impaction, and non-swallowing associated chest pain) and histologically by eosinophil-predominant inflammation
- budesonide orodispersible 1mg tablets as Jorveza®:
  - is the first medicine to be licensed in the UK for the treatment of EoE
  - was accepted for restricted use in NHS Scotland following a full submission reviewed by the SMC executive
  - has an orphan designation from the European Medicines Agency [for this indication]
- the recommended daily dose is 2mg budesonide, taken as one 1mg tablet in the morning and one 1mg tablet in the evening
- the usual duration of induction treatment is 6 weeks, however for patients who are not appropriately responding treatment can be extended up to 12 weeks. In the clinical trial 58% responded to a 6-week course.
- the service has indicated that some individuals may receive multiple courses, possibly within the year
- a 90 tablet pack of budesonide 1mg orodispersible tablets (equivalent to a 6-week treatment course) costs £323.00 [£387.60 including VAT], a 12-week course costs £646.00 [£775.20 including VAT]
- to achieve maximum efficacy patients will need to be counselled appropriately as the dosing instructions are quite complex
- current off-label treatment options for EoE include proton pump inhibitors and swallowed topical corticosteroids, e.g. swallowed puffs from inhalers, viscous slurry
- minimal cost offset will be available as budesonide orodispersible tablets will replace off-label use of swallowed topical corticosteroids
- the service would prefer that prescribing is managed in Primary Care, with prescribing only on the advice of specialists
- due to the number of budesonide preparations/formulations listed in the prescribing system drug dictionaries it would be quite easy to select the wrong budesonide preparation

It was confirmed that the licence for Jorveza® has been extended to include maintenance of remission, and the maintenance dose includes the use of a 500microgram tablet that will be marketed later this year. As the SMC will not review the maintenance licence (outwith remit) the Formulary Team will keep a watching brief on the marketing of the 500microgram tablet, and review the maintenance indication when the lower strength preparation comes to market. **FTEAM**

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The Group supported prescribing in Primary Care following advice from the specialist, and highlighted the potential to prescribe the wrong budesonide preparation, and requested that options to mitigate this are investigated, e.g. ScriptSwitch, branded prescribing, information for prescribers etc. **FTEAM**

The Group accepted the restricted local need for budesonide orodispersible tablets for the induction of remission of EoE in adults who were unsuccessfully treated with proton pump inhibitors.

SMC 2158 – Budesonide 1mg orodispersible tablets (Jorveza®) is routinely available in line with local guidance.
Indication under review: for the induction of remission of eosinophilic oesophagitis in adults patients unsuccessfully treated with proton pump inhibitors.
One randomised, double-blind phase III study, demonstrated superiority of budesonide over placebo in inducing clinic-histologic remission in adult patients with eosinophilic oesophagitis, refractory to treatment with a proton pump inhibitor.
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. Treatment with this medicinal product should be initiated by a physician experienced in the diagnosis and treatment of eosinophilic esophagitis. **FTEAM**

8.2. FG1SMC 1093/15 - BUDESONIDE 9MG PROLONGED-RELEASE TABLETS (CORTIMENT®) (MILD TO MODERATE ACTIVE ULCERATIVE COLITIS)

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

The Group considered the request for budesonide 9mg prolonged-release tablets for the induction of remission of mild to moderate ulcerative colitis (UC) in adult patients.

The Group noted:

- that the Marketing Authorisation Holder (MAH) requested SMC look specifically at *"active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone and aminosalicylate treatment is not sufficient"*
- the service has confirmed that local use may be outwith the restriction proposed by the MAH
- prednisolone/methylprednisolone are fully absorbed and have a systemic effect, whereas budesonide when given by mouth is designed to release in the large bowel and there is limited re-absorption from the large bowel so the likelihood of steroid-induced side-effects are reduced
- budesonide as Cortiment®:
  - is the first oral formulation of budesonide to be licensed for ulcerative colitis
  - was accepted for restricted use in NHS Scotland following a resubmission reviewed by the SMC
  - [for this indication] has an eight-week treatment course with gradual reduction over the final two to four weeks
  - provides a licensed treatment option, and treatment will replace off-label use of other budesonide oral preparations, e.g. Budenofalk® and Entocort®
- as with the previous budesonide submission, there is a potential for prescribing error when selecting a preparation from the prescribing systems in Primary Care

The Group accepted the restricted local need for budesonide 9mg prolonged-release tablets, as Cortiment®, for the induction of remission of mild to moderate ulcerative colitis in adult patients where aminosalicylate treatment is not sufficient, as an alternative to budesonide rectal formulations or off-label oral budesonide.

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SMC 1093/15 - Budesonide 9mg prolonged release tablets (Cortiment®) is routinely available in line with local guidance.
Indication under review: for the induction of remission of mild to moderate ulcerative colitis in adult patients where aminosalicylate treatment is not sufficient.
Restriction: as an alternative to budesonide rectal formulations or off-label oral budesonide.
It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in Primary Care on the recommendation of a consultant/specialist. **FTEAM**

8.3. FG1 430/20 - INFLIXIMAB INTRAVENOUS INFUSION (IMMUNOTHERAPY INDUCED COLITIS)

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

The Group considered the request for the off-label use of infliximab intravenous (IV) infusion for immunotherapy-induced colitis in adults who are steroid-refractory or who require early steroid-sparing management.

The Group noted:

- infliximab IV infusion:
  - is not licensed for the management of immune checkpoint inhibitor-induced enterocolitis, but is licensed for a number of other conditions including rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis
  - for the management of toxicities from immunotherapy is included in British and European guidance, e.g. the British Society of Gastroenterology (BSG) and European Society for Medical Oncology
- biosimilar products are available for infliximab IV. The current NHS Grampian preferred product is Remsima®, although a new contract is due in the next few weeks.
- patient numbers are expected to be small, but will increase with time as the use of immune checkpoint inhibitors increases
- the Oncology and Gastroenterology (GI) services have developed local guidance for the management of immune checkpoint inhibitor-induced enterocolitis
- the Oncology service is already using infliximab for this indication, so has experience in the use of infliximab IV, and works closely with the GI service - management decisions regarding infliximab are a collaboration between the Consultant Oncologist and GI specialist team
- the Summary of Product Characteristics (SmPC) for Remsima® (and other IV infliximab preparations) states that treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of the licensed indications. This will not be the case for this indication but the service has experience in the use of infliximab IV, and patients will be referred to GI specialists where appropriate. Additionally, the infusion will be administered by nurses that are trained to detect infusion-related reactions.

The Group accepted the restricted local need for the off-label use of infliximab IV infusion for the treatment of immunotherapy-induced colitis in adults who are steroid refractory or who require early steroid-sparing management.

Infliximab 100mg powder for concentrate for solution for infusion (Remsima®) is routinely available in line with local guidance.
Indication under review: [off-label use] for the treatment of immunotherapy-induced colitis in adults who are steroid refractory or who require early steroid-sparing management.
It was classified 3b - licensed product available for restricted off-label use and 8b - recommended for hospital use only. Treatment should be administered intravenously and by qualified healthcare professionals trained to detect any

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infusion-related issues. Patients should be given the package leaflet and the patient reminder card. **FTEAM**

8.4. FG1SMC 2289 - LENALIDOMIDE (NEWLY DIAGNOSED MULTIPLE MYELOMA)

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

The Group considered the request for lenalidomide as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT).

The Group noted:

- lenalidomide:
  - is already included on the formulary for the treatment of multiple myeloma, and other indications - myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma
  - [for this indication] was accepted for use in NHS Scotland following a full submission under the orphan medicine process, subject to the output from the PACE process and application of the appropriate SMC modifiers
  - is due to come off patent in June 2022
  - [for this indication] patient numbers are expected to be small
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of lenalidomide
- treatment aims to prolong survival and maintain quality of life
- the service has significant experience of using lenalidomide for the treatment of multiple myeloma and of maintenance treatment through the Myeloma XI clinical trial and PACS Tier 2 requests
- after a median follow-up of 96.7 months, the primary outcome of median progression-free survival was 44.4 months and 23.8 months for lenalidomide and placebo groups respectively
- there will be no new costs as the service is currently using lenalidomide maintenance treatment through the individual patient request processes

The Group accepted the restricted local need for lenalidomide as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone ASCT, as outlined in SMC 2289.

SMC 2289 - Lenalidomide 5mg, 10mg, 15mg hard capsules (Revlimid®) ▼ is routinely available in line with national guidance (SMC 2289).
Indication under review: as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT).
In phase III, randomised studies, lenalidomide maintenance treatment improved progression-free survival in patients with newly diagnosed multiple myeloma who had undergone ASCT compared with placebo or observation. Median overall survival data were supportive of lenalidomide maintenance treatment.
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 views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Treatment should be supervised by a physician experienced in the use of anti-cancer therapies. **FTEAM**

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8.5. FG1SMC 2290 - CARFILZOMIB (MULTIPLE MYELOMA)

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

The Group considered the request for carfilzomib, in combination with lenalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received only one prior therapy.

The Group noted:

- carfilzomib:
  - [for this indication] was accepted for restricted use in NHS Scotland following a second resubmission under the orphan medicine process, subject to the output from the PACE process and application of the appropriate SMC modifiers
  - is currently included on the formulary, used in combination with dexamethasone (SMC 1241/17), and the service plans to continue use of dual-therapy for patients who have progressed on lenalidomide maintenance treatment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of carfilzomib
- the service has experience using carfilzomib in combination with lenalidomide and dexamethasone through the Myeloma XI trial and through the PACS Tier 2 process
- in ASPIRE, the median length of treatment was 88 weeks (22 cycles) but treatment with carfilzomib was stopped after 18 cycles and patients continued on lenalidomide plus dexamethasone
- patient numbers are expected to be small
- additional costs expected include aseptic preparation, chair and nursing time and blood monitoring
- cost off-set will be available
- the SmPC states treatment beyond 18 cycles has very limited tolerability and toxicity data. The service plans to stop at 18 cycles for the majority of patients but will continue for those where there is progressive improvement ongoing at 18 cycles/months, or if there is loss of response on stopping carfilzomib.

The Group accepted the restricted local need for carfilzomib in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy, as outlined in SMC 2290.

SMC 2290 - Carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) is routinely available in line with national guidance (SMC 2290).
Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received only one prior therapy.
Carfilzomib in combination with lenalidomide and dexamethasone improved progression free survival and overall survival compared to lenalidomide and dexamethasone in adults with relapsed and / refractory multiple myeloma who had received one to three prior therapies.
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 should be supervised by a physician experienced in the use of anti-cancer therapy. FTEAM

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - FEBRUARY 2021

The Group noted the SMC provisional advice issued February 2021.

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SMC 2311 - ONASEMNOGENE ABEPARVOVEC (ZOLGENSMA®) (SPINAL MUSCULAR ATROPHY)

The Group noted the provisional advice for onasemnogene abeparvovec, for the treatment of patients with 5q spinal muscular atrophy (SMA) with a biallelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a biallelic mutation in the SMN1 gene and up to three copies of the SMN2 gene.

Ms Doney confirmed:
- SMA is a rare condition
- patient numbers are expected to be very small
- onasemnogene abeparvovec is an ultra-orphan validated medicine and will be an expensive treatment
- is administered as a single intravenous infusion and treatment would be provided by a specialist centre in another Health Board

The Group felt there was little benefit requesting a full submission from the local specialities, and requested that the Formulary Team prepare a summary for the March meeting. **FTEAM**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - FEBRUARY 2021

The Group noted the SMC advice published February 2021.

Following publication of the non-submission statements, for alpelisib (Piqray®)▼ SMC 2339, apremilast (Otezla®) SMC 2340, glasdegib (Daurismo®)▼ SMC 2341, Recarbrio® (imipenem/cilastatin/relabactam)▼ SMC 2342, mercaptamine (Cystadrops®) SMC 2343 and omalizumab (Xolair®) SMC 2344, 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 2315 upadacitinib (Rinvoq®)▼(submission expected)
- SMC 2309 ozanimod (Zeposia®)▼ (submission expected)
- SMC 2321 Trixeo® Aerosphere (formoterol fumarate dihydrate/glycopyrronium bromide/budesonide)
- SMC 2319 leuprorelin acetate (Prostap®)
- SMC 2320 leuprorelin acetate (Prostap®)
- SMC 2316 Suboxone® (buprenorphine/naloxone)

Local advice for these medicines and indications will be included in the February 2021 decisions as 'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.' **FTEAM**

SMC 1251/17 - AFAMELANOTIDE (SCENESSE®) (PHOTOTOXICITY IN PATIENTS WITH ERYTHROPOIETIC PROTOPORPHYRIA)

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

Afamelanotide (Scenesse®) has been validated as meeting the new SMC ultra-orphan criteria. Afamelanotide is a 'legacy' ultra-orphan medicine, it was assessed by SMC in July 2017 where it was not recommended for use in NHS Scotland but the advice was not issued to Boards until January 2021.

Communication from the Scottish Government, confirmed that from 8 February 2021, afamelanotide (Scenesse) 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.

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Medicines accessed via the Scottish Government ultra-orphan pathway are considered outwith remit for the Formulary Group, are classified as 'non-formulary' and recorded as 'Not routinely available in NHS Grampian however if local need is identified, treatment is available through the National Services Scotland: Ultra-Orphan Medicines Risk Share Scheme.'

SMC 1251/17 - Afamelanotide 16mg implant (Scenesse®) is not recommended for use within NHS Scotland.
Indication under review: prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).
In a phase III study, afamelanotide increased the duration of time, over a six-month period, that patients with EPP spent in direct sunlight on pain-free days compared with placebo.
The submitting company's justification of the treatment's cost in relation to its benefits was not sufficient and in addition the company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
Not routinely available as not recommended for use in NHS Scotland. If local need identified, treatment is available through the National Services Scotland Ultra-orphan medicines Risk Share Scheme. **FTEAM**

SMC 2305 RAVULIZUMAB (ULTOMIRIS®) (PAROXYSMAL NOCTURNAL HAEMOGLOBINURIA (PNH))

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

The Group discussed the SBAR submitted regarding the use of ravulizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH).

Ms Doney confirmed that:
- PNH is a very rare, life-limiting condition
- ravulizumab:
  - is the second medicine licensed for PNH
  - [for this indication] meets SMC orphan equivalent criteria
  - [February 2021] was accepted by SMC following a full submission under the orphan equivalent medicine process
  - [for this indication] was accepted for use in NHS Scotland following the output from the PACE process, an application of the appropriate SMC modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ravulizumab
- patient numbers are expected to be very small, and use is restricted to prescribing under the advice of the national PNH service
- eculizumab was the first medicine licensed for the treatment of PNH but it was not accepted for use in NHS Scotland (SMC 1130/16)
- costs are already in the system as patients' requiring eculizumab have accessed treatment via the individual treatment processes (i.e. previous IPTR process, and the PACS process)
- the patent for eculizumab expires in 2023

The Group accepted the restricted local need for ravulizumab for the treatment of adults with PNH under the advice of the national PNH service, without the need for a full submission.

SMC 2305 - Ravulizumab 300mg concentrate for solution for infusion (Ultomiris®) ▼ is routinely available in line with national guidance (SMC 2305).
Indication under review: for the treatment of adult patients with paroxysmal

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nocturnal haemoglobinuria (PNH):

- **in patients with haemolysis with clinical symptom(s) indicative of high disease activity**
- **in patients who are clinically stable after having been treated with eculizumab for at least the past 6 months.**

Restriction: under the advice of the national PNH service.
In two open-label, randomised, phase III studies, ravulizumab was non-inferior to another complement inhibitor across a range of relevant outcomes assessing the control of haemolysis.
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**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – FEBRUARY 2021

FURTHER UPDATE ON SMC REMOBILISATION

The first phase of recovery is complete; SMC has processed all medicines that were in the system at the time meetings were suspended [March 2020]. The approach to expediting some decisions has been working as intended, minimising delay and reducing demand on committee members. SMC will continue with these interim processes, with some modifications, and will review the processes in Autumn 2021.

12. DOCUMENTS FOR INFORMATION

ITEM 12.1 (SCOTTISH HEALTH TECHNOLOGIES GROUP QUARTERLY BULLETING JANUARY 2021)

The Chairman highlighted the Scottish Health Technologies Group Quarterly Bulletin, noting that there may be demand for some of the products.

Ms Doney confirmed that devices are outwith remit for the Formulary Group and NHS Grampian does not have a committee for reviewing medical devices/technologies.

The Group agreed that the bulletin should be forwarded to the Grampian Area Drug and Therapeutics Committee (GADTC) for consideration, and Ms Doney will contact the Risk Management Adviser to confirm if there is a plan to bring together a committee to review medical devices. **FD** **FD**

Item 12.2 (Grampian Primary Care Prescribing Group (PCPG) minute November 2020) was noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 16 March 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE **DATE 16 MARCH 2021**