NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 November 2018 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Culligan	
Ms F Doney	Mrs L Harper	
Dr L Elliot	Dr A MacDonald	
Dr J Fitton	Dr W Moore	
Ms M Galvin	Dr A Sun	
Professor J McLay (Chairman)		
Mrs L Montgomery		
Mr M Paterson		
Mr C Rore (from item 4.2)		
Mr R Sivewright		

IN ATTENDANCE
Dr Jamie Cooper, Consultant in Emergency Medicine, Aberdeen Royal Infirmary, for item 4.2.

OBSERVERS
Mr Gilchrist Docherty, Rotational Pharmacist, Aberdeen Royal Infirmary.
Ms Sarah Hassall, Management Trainee, Learning and Development, Summerfield House.

Note some items were taken outwith agenda order.

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.

4. 4.2. PENTHROX® ▼ INHALER

Dr Jamie Cooper, Consultant in Emergency Medicine, attended the meeting to discuss the request for Penthrox® ▼ (methoxyflurane) inhaler.

Dr Cooper confirmed that:

- Penthrox® ▼ is licensed for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain. Use is subject to certain caveats (detailed in the administration guide for Healthcare Professionals and Summary of Product Characteristics). The European Medicines Agency licence does not include children and adolescents, however the adult Emergency Department (ED) would manage adolescents 16-18 years, and the service does not consider there to be specific concerns if it was used off-label in this age group.
- Penthrox® ▼ is used extensively in Australasia (including for children and adolescents)
- the Paediatric ED is currently taking part in a trial to establish the safety and efficacy of Penthrox® ▼ in paediatrics
- Penthrox® ▼ is a patient-controlled portable inhaler-type device that contains methoxyflurane, a volatile anaesthetic that at low doses appears to have good analgesic properties. It is available as a 3mL inhaler and the maximum dose is two 3mL inhalers. One inhaler (3mL) costs £17.89 (£21.47 including VAT).
- the adult ED feels that Penthrox® ▼ fits the analgesic ladder where Entonox® is currently used but it is not possible to say if it will replace Entonox®
- Penthrox® ▼ would not be used for visceral pain/medically unwell patients but only for people with isolated injuries, burns/limb injuries
- Penthrox® ▼ is not a panacea for acute traumatic pain but may be useful in combination with others analgesics to get control of pain quickly. The service feels that Penthrox® ▼ would be a useful addition to the current armamentarium. It may fit a gap in the current choices for patients with traumatic acute severe pain, e.g. dislocated fingers/knees, potentially allowing faster control of pain that would be beneficial for patients.
- experience from other centres showed no significant problems in use, and there are no special storage instructions

- the device is simple to assemble, and training on the preparation and correct administration of Penthrox® ▼ is provided by the Marketing Authorisation Holder (MAH)
- there are risk minimisation materials available for healthcare professionals to use to help reduce the risk associated with using this medicine and patients should be issued with a patient alert card

At the previous meeting, members were minded to support formulary inclusion but raised a few points for clarification. The points were addressed in turn.

Points for clarification:

- *Concern about abuse potential – is there count/sign out and count/sign in process under consideration?* - Penthrox® ▼ should be stored in a locked cabinet and not on an open shelf. The MHRA Public Assessment Report for Penthrox® ▼ (http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con773654.pdf) states the risk of abuse is small therefore the storage guidance of 'store in a locked cabinet' should be sufficient to minimise the abuse potential and a sign in/sign out system not required. This is consistent with other UK hospitals.
- *Disposal – we note the product will be bagged and disposed of in waste containers, we assume this is in cin-bins. Does the size of the product cause an issue for the size of bins available in the department? Or would this be an issue if the number of patients using the device increased?* The SmPC says to 'dispose responsibly'. Most hospitals are putting the used inhaler into the plastic bag provided in the Penthrox® ▼ pack and then placing this into the large yellow clinical waste bags. The predicted volumes of usage, even at the upper end of the scale, should not cause any issues with waste volumes.
- *We assume patient will not be allowed to leave the hospital with a device, but is there a potential that patients would leave the ED (to another ward or home) with a device? Or will there be a process for taking the product back from patients?*
  The inhaler lasts approximately 25 to 60 minutes, depending on the frequency and size of breaths taken through it. Most patients will be finished the dose before being ready to leave the ED however it could be transported with the patient, if needed. Patients will not be sent home with the inhaler but if one was to take it with them when leaving the ED it wouldn't last long as the dose is small and the drug will evaporate.
- *Is there a potential that patients would come into the ED using Penthrox® ▼? Will Penthrox® ▼ be used by paramedics/the ambulance service?*
  At present the Scottish Ambulance Service are not using Penthrox® ▼ but I have been informed that they are in the process of rolling it out to some staff members (e.g. motorcycle response paramedics) so we may start to see patients coming into the ED already using Penthrox® ▼.
- *Is there guidance for use being considered? – not only how it should be used and which patients it would be available for but which members of staff could access it?*
  There will be a guideline on the use of Penthrox® ▼. Only staff members trained in the use of Penthrox® ▼ will be permitted to use it.

The Chairman thanked Dr Cooper for attending the meeting to discuss the Penthrox® ▼ submission. Dr Cooper left the meeting before decision-making.

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

The Group considered that:

- the points for clarification had been addressed by the requestor
- there is a risk of occupation exposure to methoxyflurane if the device is used incorrectly
- if proven to be beneficial, the use of Penthrox® ▼ may increase
- Penthrox® ▼ could be advantageous for healthcare professionals involved in pre-hospital emergency care

The Group supported the restricted local need within the adult ED for Penthrox® ▼ inhaler for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.

ITEM	SUBJECT	ACTION
	Methoxyflurane 99.9% 3mL inhalation vapour, liquid (Penthrox®) ▼ is routinely available in line with local guidance. **Indication under review: for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.** **Penthrox® ▼ should be self-administered under supervision of a person trained in its administration, using the hand held Penthrox® ▼ Inhaler. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only; restricted to use within the Adult Emergency Department.** **Healthcare Professional administering Penthrox® ▼ must provide and explain the Product Information Leaflet to the patient.**	**FTeam**

2. DRAFT MINUTE OF THE MEETING HELD 16 OCTOBER 2018

The Group accepted the draft note of the meeting subject to the following changes:

- page 2, item 2 include a paragraph to confirm why Elmiron® was included as an agenda item
- page 7, item 10 – in the paragraph above the decision - clarification of the age range for the ipilimumab advice, change to 'aged 12 to 18 years' **FD**

Ms Doney will email the revised Elmiron® entry for authorisation by the Group, timeline for response 7 working days. **All**

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

Ms Doney confirmed the status of the items not included on the agenda.

4.1.1. MERCAPTAMINE EYE DROPS (COSTS)

At the October meeting Cystadrops® was noted as non-formulary pending review of a local submission and/or advice from the SMC, and the Chairman requested clarification of the current cost of prescribing mercaptamine eye drops.

It was reported that:

- it was not possible to identify prescriptions issued in Primary Care for unlicensed mercaptamine eye drops. However, in the 12 months July 2017 to June 2018, a small number of prescriptions were issued for the licensed product Cystadrops® 3.8mg/mL at a cost of approximately £10,000.
- Cystadrops® costs £865 (ex VAT) for 5mL and has a shelf-life of 7 days after first opening

Ms Davie reported that the unlicensed product previously cost approximately £50 for 10mL.

Ms Doney will request confirmation of the potential patient numbers and when Cystadrops® will be considered by SMC. **FD**

4.1.2. BEVACIZUMAB FOR WET AGE-RELATED MACULAR DEGENERATION (UPDATE)

Ms Doney confirmed that there is national work being undertaken following the High Court decision regarding the use of bevacizumab in the treatment of wet age-related macular degeneration.

There is no work required of the Formulary Group at the moment.

This item will be removed from the Action log. **FD**

ITEM	SUBJECT	ACTION

4.3. GLYCEROL PHENYLBUTYRATE (RAVICTI® ▼) (UREA CYCLE DISORDERS)

Ms Doney reported that there has been correspondence regarding the 'hospital only' classification given to glycerol phenylbutyrate for urea cycle disorders (UCDs). The feeling being that the classification was wrong and prescribing in Primary Care should be supported.

The points raised in the correspondence were discussed at the October meeting and considered reasons for glycerol phenylbutyrate not being appropriate for prescribing in Primary Care. Additionally the licence states that 'Ravicti® ▼ should be prescribed by a physician experienced in the management of UCDs.'

The Group noted that patient numbers would be extremely small, and that the local consultant would be working with specialists experienced in the management of UCDs to manage patients.

The Group was not minded to change the classification from 'hospital only', but would review any information if the service wished to provide a paper/proposal. Ms Doney will relay this information to the service. **FD**

5. FORMULARY GROUP DECISIONS OCTOBER 2018 - PUBLISHED 30/10/2018

5.1. FORMULARY GROUP DECISIONS OCTOBER 2018

The Group ratified the advice as published.

5.2. DRAFT NETFORMULARY UPDATE FOR OCTOBER 2018 FORMULARY GROUP DECISIONS

The draft netFormulary update was issued via email just prior to the meeting.

Ms Doney confirmed that only the sarilumab decision was not published on netFormulary prior to the meeting. The sarilumab entry remains in draft pending confirmation that the homecare arrangement will be available (advice expected towards the end of November). **FTeam**

The Group authorised the October formulary decision entries as presented, subject to a 7-day period for review and request for change if required. **All**

6. NETFORMULARY/FORMULARY REVIEW - NONE

7. OTHER BUSINESS

7.1. CMO LETTER – CANNABIS BASED PRODUCTS FOR MEDICINAL USE

7.2. DRAFT POSITION STATEMENT REGARDING CANNABIS BASED PRODUCTS FOR MEDICINAL USE (CBPM) IN NHS GRAMPIAN

Items 7.1 and 7.2 were taken together.

The Group discussed the draft position statement regarding cannabis-based products for medicinal use (CBPM).

Ms Doney reported that an additional Chief Medical Officer (CMO) letter has been released, and the consultation on the scope of the NICE guidance has just opened.

The Group supported availability of an NHS Grampian position and requested:

- clarity on where the final document(s) will be housed
- a patient-friendly version of the information, with frequently asked questions to provide clarity on, for example, which conditions will and will not be considered for the prescribing of CBPM. [Conditions that you can ask for and conditions that will not be granted].
- advice for clinicians regarding who to approach for prescribing [in terms of an adult or child services], and a request that it is highlighted to patients not to approach their GP as GPs will not be able to prescribe CBPM. Will there be specific consultants that GPs can refer patients to?
- clarity on whether cannabidiol is or is not available for prescribing

ITEM	SUBJECT	ACTION

Ms Doney will email the additional CMO letter issued 21/11/2018 and a link to the draft scope for the NICE guidance. **FD**

7.3. GLIPTINS (DIPEPTIDYL PEPTIDASE 4 INHIBITORS)

Dr Fitton and Mr Paterson declared personal specific interests in AstraZeneca UK Limited. Dr Fitton and Mr Paterson did not take part in decision-making.

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

The Group discussed the proposal to review the current dipeptidyl peptidase 4 (DPP-4) inhibitor choices.

The Group noted:
- the current DPP-4 inhibitors included on the formulary are sitagliptin and saxagliptin
- sitagliptin accounts for the majority of prescribing, and there is minimal prescribing of saxagliptin
- sitagliptin was the first DPP-4 inhibitor to come to market and its patent expires in 2022
- sitagliptin has a wider licence than alogliptin, and includes lower strength tablets for patients with renal impairment
- the Diabetes Managed Clinical Network (MCN) and the Primary Care Prescribing Group support the proposal to include alogliptin on the formulary as the first-choice DPP-4 inhibitor. Guidance and a Service Level Agreement will be available for prescribers to support review of DPP-4 inhibitors used in people with Type 2 diabetes mellitus, with continuation only where benefit is shown, and a switch to alogliptin where appropriate.
- the patent for alogliptin expires in 2028

The Group supported review of patients to ensure those receiving DDP-4 inhibitors (and other oral antidiabetic drugs) continue treatment only where benefit is shown.

The Group supported the proposal to:
- include alogliptin on the formulary as the preferred DPP-4 inhibitor
- sitagliptin to remain on the formulary as it has some benefits over alogliptin
- saxagliptin to be removed from the formulary as local prescribing is limited and it confers no additional benefits over sitagliptin and alogliptin

Alogliptin 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) is routinely available in line with local guidance.
Indication under review: adults (18 years and older) with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
- **in combination with other glucose lowering medicinal products including insulin, when these do not provide adequate glycaemic control.**

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTeam**

Saxagliptin is not routinely available in NHS Grampian.
Indication under review: adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
- **as monotherapy when metformin is inappropriate due to intolerance or contraindications**
- **in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.**

Not routinely available in NHS Grampian. **FTeam**

7.4. WORLD ANTIBIOTIC AWARENESS WEEK (W/C 12/11/2018) AND EUROPEAN ANTIBIOTIC AWARENESS DAY 18/11/2018

This item was noted.

ITEM	SUBJECT	ACTION

8. NEW PRODUCT REQUESTS

8.1. FG1 399/16 – SILDENAFIL ('OFF-LABEL' USE FOR SEVERE REFRACTORY RAYNAUD'S PHENOMENON)

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

The Group considered the updated review of the request for the 'off-label' use of sildenafil tablets for adults with severe refractory Raynaud's phenomenon.

Previously when the Group reviewed the request it was not clear which patient group(s) would be eligible for treatment and what the anticipated outcomes would be.

Ms Doney confirmed that:
- the request relates to the use of sildenafil for the symptomatic management of adults with severe refractory Raynaud's phenomenon, potentially used before or as an alternative to iloprost infusion. It is not requested as a treatment option for digital ulcers.
- the service is aware that for this indication sildenafil would have to be supplied by the hospital. Under the current regulations sildenafil is only available on a Primary Care prescription for the treatment of erectile dysfunction in men who meet the criteria listed in Part 12 of the Scottish Drug Tariff (Selected List Scheme (SLS)).

The Group noted that:
- there is some evidence, not strong evidence, for the use of sildenafil when other agents have failed. The majority of evidence relates to use in patients with progressive systemic sclerosis, however Raynaud's phenomenon is not limited to people with progressive systemic sclerosis.
- use would be off-label, but sildenafil is noted in some national and international guidance for the management of Raynaud's phenomenon
- if effective, sildenafil would be taken long-term as a multiple daily dose (unlike the dosing for erectile dysfunction)
- if effective sildenafil would be more convenient for patients than a three to five day in-patient stay required for an iloprost infusion
- there is limited use of sildenafil for Raynaud's in other Health Boards in NHS Scotland
- tadalafil is now included in the Scottish Drug Tariff (SDT), but there is less data [than sildenafil] for its use in this indication
- based on their vasodilatory effects, there is a theoretical rationale for the use of phosphodiesterase type 5 inhibitors in the symptomatic management of Raynaud's phenomenon
- use for very severe Raynaud's rather than iloprost suggests that use would be for people that are likely to have digit infarct/digital gangrene
- sildenafil for this indication is currently available only on an individual patient basis

The Group accepted that severe refractory Raynaud's is a debilitating condition and supported the restricted use of sildenafil for the symptomatic management of severe refractory Raynaud's Phenomenon on the condition that:
- a treatment algorithm/guidance is developed
- use is audited, and the audit data presented to the Group in a year

FG1 399/16 - Sildenafil 25mg, 50mg tablets is routinely available in line with local guidance.
Indication under review: off-label use for the symptomatic management of adults with severe refractory Raynaud's phenomenon.
Restriction: severe refractory Raynaud's requiring iloprost, or as an alternative to iloprost.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be prescribed by a Consultant/specialist experienced in the management of severe refractory Raynaud's phenomenon. **FTeam**

Note: 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.

ITEM	SUBJECT	ACTION

Ms Davie will investigate if ScriptSwitch can highlight sildenafil prescriptions with multiple daily dosing. **AD**

8.2. FG1SMC 2011 – DUPILUMAB (ATOPIC DERMATITIS)

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

Members considered the request from the Dermatology service for dupilumab for the treatment of moderate-to-severe atopic dermatitis in adult patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.

The Group noted:
- dupilumab:
  - is a recombinant human immunoglobulin G4 monoclonal antibody
  - is the first biologic medicine approved for use in atopic dermatitis
  - is available under a homecare arrangement
  - [for this indication] meets SMC orphan equivalent criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of dupilumab
- the lack of long-term data, so it is not clear if response will be maintained
- estimating (cumulative) patient numbers is difficult due to the lack of long-term data

The Group accepted the restricted local need for dupilumab in line with SMC 2011, for the treatment of moderate to severe atopic dermatitis in adult patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.

SMC 2011 - Dupilumab 300mg solution for injection in pre-filled syringe (Dupixent®) ▼ is routinely available in line with national guidance (SMC 2011).
Indication under review: the treatment of moderate-to-severe atopic dermatitis in adult patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.
Four phase III studies demonstrated superiority of dupilumab in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dupilumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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 initiated by healthcare professionals experienced in the diagnosis and treatment of atopic dermatitis. **FTeam**

8.3. FG1SMC 1336/18 - ATEZOLIZUMAB (NSCLC)

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

The Group considered the submission for atezolizumab as a second-line treatment option for patients with metastatic non-small cell lung carcinoma (NSCLC).

The Group noted:
- atezolizumab:
  - is the third programmed cell death 1 (PD-1)/programmed cell death ligand 1 (PD-L1) inhibitor targeted therapy licensed for patients with advanced NSCLC
  - is administered intravenously every three weeks at a dose of 1,200mg

  - (for this indication) meets SMC end of life and orphan-equivalent criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of atezolizumab
- treatment could be given for up to 2 years
- that the introduction of atezolizumab may be cost-neutral to cost saving; reduced chair time compared to the two-weekly regimen for nivolumab, and this less frequent dosage schedule would be advantageous to patients
- that a four-weekly regimen for nivolumab in NSCLC may be licensed and the choice of second-line immunotherapy would be revisited at that time
- the service feels the data [for atezolizumab] may be stronger for non-squamous and PD-L1 positive patients

Ms Galvin confirmed that the service does not intend to sequence immunotherapies, and that further licences/licence extensions are expected for immunotherapies used in NSCLC (including use in combination with chemotherapy).

The Group accepted the restricted local need for a**tezolizumab** monotherapy as a second-line option for metastatic NSCLC as outlined in SMC 1336/18.

SMC 1336/18 - Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) ▼ is routinely available in line with national guidance (SMC 1336/18). Indication under review: as monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (EGFR) activating mutations or anaplastic lymphoma kinase (ALK) positive tumour mutations should also have received targeted therapy before receiving atezolizumab.
Restriction: treatment with atezolizumab is subject to a two-year clinical stopping rule.
Atezolizumab, compared with a standard taxane monotherapy, significantly improved overall survival in adults with advanced NSCLC who had progressed after platinum-based chemotherapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of atezolizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Atezolizumab must be initiated and supervised by physicians experienced in the treatment of cancer. **FTeam**

8.4. FG1SMC 1218/17 – DESMOPRESSIN (NOCTURIA DUE TO IDIOPATHIC NOCTURNAL POLYURIA IN ADULTS)

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

Members considered the submission from Urology for the use of Noqdirna®, a low dose desmopressin product.

The Chairman requested that information is shared with the Geriatricians for comment. **FTeam**

The Group noted:
- Noqdirna®
  - is licensed for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults
  - is available as 25microgram and 50microgram tablets, and dosing is gender specific (25microgram for females and 50microgram for males)
- the submitting company requested that the SMC considered use in patients aged 65 years and over, however the licence would include adults under 65 years of age
- nocturnal polyuria is associated with decreased secretion of arginine vasopressin and is

defined as nocturnal urine output greater than 20% to 33% of 24-hour output, depending on age [SMC Detailed Advice Document, SMC 1218/17]

The Group queried:
- the estimate of patient numbers, feeling that it was high, and noting that it was based on Census data from 2011, assuming that approximately three quarters of all 65 years and over with nocturia had a diagnosis of idiopathic nocturnal polyuria
- the diagnosis of idiopathic nocturnal polyuria, as it is not a diagnosis that the Group is familiar with. Members were unclear of how many patients would have carried out a 24-hour urine collection to confirm a diagnosis of idiopathic nocturnal polyuria.

The Group noted some concerns:
- about the risk of hyponatraemia with the use of desmopressin, especially in the elderly. There is a potential that people 65 years of age and older may be taking other medicines that would contribute to the risk of hyponatraemia, and/or have reduced renal function.
- about the risk of selecting the wrong desmopressin preparation from primary care prescribing systems
- about the gender-specific dosing for Noqdirna® [for people 65 years of age and older daily doses above 25microgram for females and 50microgram for males should not be used]
- that part of the analysis presented to the SMC was based on people not getting up in the night to go to the toilet translating to a reduced risk of falls/fractures and contributing to the cost-effectiveness of treatment (due to lower costs associated with the treatment of fractures). However, no data on falls/fractures was collected in the pivotal studies and this relationship was not shown to be causative.
- the adverse effects of treatment, i.e. hyponatraemia and dizziness, would increase the risk of falls/fracture

The Group had some concerns about the use of desmopressin [oral lyophilisate (Noqdirna®)] for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults aged 65 years and over, and considered that prescribing should be led by secondary care.

The Group accepted the restricted local use of desmopressin oral lyophilisate (Noqdirna®) as outlined in SMC 1218/17 on the condition that:
- local treatment algorithm/guidance is developed
- the diagnosis of idiopathic nocturnal polyuria and initiation of prescribing is undertaken in secondary care, with monitoring and review to determine if treatment is effective and appropriate to be continued before transfer of prescribing to Primary Care

SMC 1218/17 - Desmopressin oral lyophilisate (Noqdirna®) is routinely available in line with local guidance.
Indication under review: symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults aged 65 years and over.
Restricted: diagnosis of idiopathic nocturnal polyuria and initiation of prescribing in secondary care, with monitoring and review to determine if effective before transfer to Primary Care.
It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover. **FTeam**

8.5. FG1SMC 2093 - BIKTARVY® ▼ (HIV-1)

8.6. FG1SMC 2091 - JULUCA® ▼ (HIV-1)

Items 8.5 and 8.6 were taken together.

Dr Fitton declared a personal specific interest in ViiV Healthcare UK Ltd (GlaxoSmithKline (GSK)) and Gilead, Mr Rore declared a personal specific interest in GSK.
Dr Fitton and Mr Rore did not take part in decision-making.

ITEM	SUBJECT	ACTION

The Group discussed the submissions for two new combination tablets licensed for the treatment of adults with human immunodeficiency virus 1 (HIV-1).

The Group noted that:
- treatment choice will be led by the specialist service
- neither product is licensed for use in children

The Group considered that both Biktarvy® ▼ and Juluca® ▼ would be used in line with national guidance and accepted the restricted local need for both medicines for the treatment of adults infected with HIV-1.

SMC 2093 – Biktarvy® ▼ (bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg film-coated tablet) is routinely available in line with national guidance (SMC 2093).
Indication under review: treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.
Bictegravir/emtricitabine/tenofovir alafenamide was non-inferior for control of HIV-1 infection compared with anti-retroviral regimens comprising an integrase inhibitor plus backbone of dual nucleos(t)ide reverse transcriptase inhibitors (NRTIs) in treatment-naïve adults. Bictegravir/emtricitabine/tenofovir alafenamide was non-inferior to anti-retroviral regimens containing a dual NRTI backbone plus an integrase inhibitor or a protease inhibitor in maintaining virological suppression in virologically suppressed adults.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bictegravir/emtricitabine/tenofovir alafenamide and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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 should be initiated by a physician experienced in the management of HIV infection. **FTeam**

Note: 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.

SMC 2091 - Juluca® ▼ (dolutegravir 50mg/rilpivirine 25mg film-coated tablets) is routinely available in line with national guidance (SMC 2091).
Indication under review: the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor.
Dolutegravir plus rilpivirine was shown to be non-inferior to antiretroviral regimens containing a dual nucleos(t)ide reverse transcriptase inhibitor (NRTI) backbone plus a third agent (integrase inhibitor, protease inhibitor or NNRTI) in maintaining plasma HIV-1 RNA <50 copies/mL in two phase III randomised studies in virologically-suppressed adults.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dolutegravir/rilpivirine and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Juluca® ▼ should be prescribed by physicians experienced in the management of HIV infection. **FTeam**

Note: 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.

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED NOVEMBER 2018

The Group noted the SMC provisional advice issued November 2018.

ITEM	SUBJECT	ACTION

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

Ms Doney highlighted the provisional abbreviated SMC advice for the paediatric extension of brivaracetam. The licence extension will be checked against the current formulary approval and if the two are consistent, the Group agreed to consider inclusion on the formulary without the need for a full submission. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED NOVEMBER 2018

The Group noted the SMC advice published November 2018.

Following publication of the negative SMC recommendations, for atezolizumab (Tecentriq®) ▼ SMC 2103 and fampridine (Fampyra®) SMC 2107, and the non-submission statement for evolocumab (Repatha®) ▼ SMC 2133, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The following SMC accepted medicine has not been processed within a 60-day timescale:

- SMC 2105 dinutuximab beta (Qarziba®) ▼ (submission expected)

Local advice for this medicine will be included in the November 2018 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

SMC 2108 - FOSAPREPITANT 150MG POWDER FOR SOLUTION FOR INFUSION (IVEMEND®)

Ms Doney confirmed that the abbreviated SMC advice for the paediatric extension of fosaprepitant infusion was not completed in time for the meeting but will be submitted for the December meeting. **FTeam**

11. GENERAL INFORMATION FROM SMC NOVEMBER 2018

OCRIPLASMIN (JETREA®)

It was reported that ocriplasmin (Jetrea®) is now only available as a 0.375mg/0.3mL 'ready-diluted' formulation. The new formulation is out of SMC remit. Since there is no change to the licensed indication and the cost remains the same as the previous formulation (0.5mg/0.2mL concentrate for solution for injection) the SMC has confirmed that the advice for ocriplasmin, SMC 892/13, remains valid.

Ms Doney confirmed the information will be shared with the service, and that there are no implications for formulary [ocriplasmin, SMC 892/13 is currently recorded as non-formulary].

12. DOCUMENTS FOR INFORMATION

Items 12.1 (2019 Formulary Group meeting dates), 12.2 (Antimicrobial Management Team minute August 2018), 12.3 (Grampian Primary Care Prescribing Group minute July 2018), and 12.4 (Grampian Primary Care Prescribing Group minute September 2018).

ITEM 12.5 DRUG SAFETY UPDATE NOVEMBER 2018

The Chairman highlighted the article regarding hydrochlorothiazide.

HYDROCHLOROTHIAZIDE: RISK OF NON-MELANOMA SKIN CANCER, PARTICULARLY IN LONG-TERM USE
Although non-formulary and not often used, hydrochlorothiazide is included as a treatment choice in the British and Irish Hypertension Society hypertension management guidelines (Clinical Guideline (CG127): Hypertension in Adults: Diagnosis and Management).

Ms Doney will check the local prescribing figures for hydrochlorothiazide including combination products. **FD**

ITEM	SUBJECT	ACTION

13. AOCB

CILEST® (NORGESTIMATE/ETHINYLESTRADIOL) DISCONTINUATION

There were no declarations of interest recorded in relation to this product or the competitor product manufactured by Consilent Health Limited.

It was confirmed that:

- Janssen Cilag has taken a commercial decision to discontinue marketing of the oral contraceptive Cilest®. Marketing will cease in July 2019, and this timeline will allow for review of patients currently receiving Cilest®.
- branded prescribing of combination contraceptive products is generally supported
- other equivalent norgestimate/ethinylestradiol products are available, and this combination is not included on the Scottish Drug Tariff
- at current costs Cilique®, manufactured by Consilient Health Limited, is a cost-effective choice

The Group supported noting Cilique® as the preferred formulary-choice norgestimate 0.25mg/ethinylestradiol 0.035mg combination product. **FTeam**

The discontinuation will be highlighted with colleagues in Primary Care/Family Planning Practitioners to allow review of people currently taking Cilest®. The timeline for discontinuation will allow clinicians to discuss appropriate birth control options and transition people to an alternative contraceptive product as appropriate. **AD/FD**

Ms Doney confirmed that the change has been highlighted with colleagues involved in the development of Patient Group Directions, and will check the shelf-life of Cilique®. **FD**

DATE OF NEXT MEETING

Tuesday 18 December 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE 18 December 2018**