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

PRESENT	APOLOGIES	APPROVED
Dr D Counter	Dr D Culligan	
Ms F Doney	Ms A Davie	
Dr L Elliot	Ms M Galvin	
Dr J Fitton	Dr A MacDonald	
Mrs L Harper (from item 3)	Dr W Moore	
Professor J McLay (Chairman)	Mr M Paterson	
Mrs L Montgomery		
Mr C Rore		
Mr R Sivewright		
Mrs A Smith (for Ms Davie)		

IN ATTENDANCE
Mrs Sally-Ann Chadha, Secretary, Formulary Team.
Ms Johanna Hanschell, Medicines Information/Medical team pharmacist (observer).
Dr Henry Watson, Consultant Haematologist, for item 3.

Note some items were taken outwith agenda order.

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	The Chairman opened the meeting, welcomed members and noted that a quorum was present. The Chairman welcomed Mrs Smith (deputising for Ms Davie) and Ms Hanschell (attending the meeting as an observer).	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTES OF THE MEETING HELD 19 DECEMBER 2017 AND 16 JANUARY 2018** The draft minutes of the December 2017 and January 2018 meetings were issued the day before the meeting. An error was noted on the December minute, correction required to Dr Fitton's title in the apologies section. Members were asked to return any comment to Ms Doney by the end of the week. The final approved minutes will be in the public domain within 21 days.	**FD** **All** **FD**
4.	**MATTERS ARISING** **4.1. ACTION LOG** The Chairman reviewed the Action log with the Group to clarify the status of items that were not included on the agenda. FREESTYLE LIBRE® The local proposal to introduce FreeStyle Libre® for patients with Type 1 diabetes mellitus was not supported by the Grampian Medicines Management Group (GMMG). 9 February a holding position was issued by the GMMG. It stated that FreeStyle Libre® should not be prescribed on the NHS in Grampian, and that North of Scotland Boards were awaiting the outcome of the Scottish Health Technologies Group planned appraisal of FreeStyle Libre®. This item will remain on the Action log.	
3.	**EDOXABAN FOR THE TREATMENT OF CANCER-ASSOCIATED VENOUS THROMBOEMBOLISM** Dr Henry Watson provided the Group with an overview of the use of anticoagulants in patients with active cancer, and discussed The New England Journal of Medicine original article "Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism".	

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The Chairman thanked Dr Watson for attending the meeting, and Dr Watson left before decision-making.

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

The Group noted:
- (for this patient group) treatment would be required for as long as the risk of venous thromboembolism (VTE) exists
- when edoxaban is used for the treatment of VTE, the recommended dose is taken once daily following at least 5 days of parenteral anticoagulant
- the study was a company sponsored non-inferiority study (comparing edoxaban to dalteparin)
- the primary end point was a composite outcome of recurrent VTE or major bleed
- the increased risk of bleeding for patients taking edoxaban (major bleeding and clinically relevant non-major bleeding) compared to patients taking dalteparin
- the paper did not provide a breakdown of the bleeding profile/patient characteristics, however this may be available in the supplementary information

The Group considered that use for patients with active cancer would be off-label, that recommendations [for use in this patient group] should be restricted to consultant oncologists or haematologists, and that a guideline would be required.
Due to concerns regarding the increased risk of bleeding shown in the edoxaban arm of the study, a decision was deferred pending further information.

To allow discussion at the March meeting Mr Rore will: **CR**
- source the supplement and email to members
- (if not available in the supplement) request the bleeding profile from the Marketing Authorisation Holder (MAH)
- confirm the definition of 'major bleeding', 'clinically relevant minor bleed' used in the study, and if not available in the supplement clarify the patient characteristics/profile for the number of minor bleeds leading to hospitalisation

4. MATTERS ARISING (CONTINUED)

4.1. ACTION LOG (CONTINUED)

The Chairman continued review of the Action log.

NALOXONE NASAL SPRAYS
These products are outwith remit for SMC. This item will remain on the Action log pending clarification (by the Specialist Pharmacists in Substance Misuse) of the national position for these products.

SHORT LIFE WORKING GROUP FOR DIRECT ORAL ANTICOAGULANTS
Invites for the short life working group have been sent, but no further information is available. This item will remain on the Action log.

SIGN ALGORITHM
Ms Doney will email the SIGN 154 treatment algorithm to members. This item will be removed from the Action log. **FD**

PRESCRIBING ADVICE VITAMIN D
Ms Doney confirmed that Dr Moore is working with colleagues in Public Health to produce formal advice regarding the use of vitamin D supplements as a primary preventative measure. Some access issues have been identified and will be clarified before policy sign off. This item will remain on the Action log. **WM**

SMC 1276/17 PALBOCICLIB
Patient numbers and budget impact will be confirmed at the March meeting.
This item will remain on the Action log. **MG/FD**

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4.2. SMC 1277/17 - ELIGLUSTAT (CERDELGA®) ▼

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

January 2018 the list of drugs included in the Ultra Orphan Drugs Risk Share Arrangement was updated to include the SMC advice for eliglustat (Cerdelga®) ▼ SMC 1277/17 (http://www.nsd.scot.nhs.uk/Documents/2018-01-19%20Drugs%20List%20Jan%202018.pdf).
The Group approved a minor addition to the decision published December 2017. The current non-formulary decision will be updated to include the statement that "***If local need identified National Services Scotland Ultra Orphan Drug Risk Share Arrangement may apply, see http://www.nsd.scot.nhs.uk/services/riskshare/.***" **FTeam**

5. FORMULARY GROUP DECISIONS JANUARY 2018 - PUBLISHED 31/01/2018

The Group ratified the advice as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. PHOSPHATE BINDERS

The Group considered the SBARs that reviewed the current formulary choice phosphate binders, and SMC advice number 1304/18 [paediatric extension for sevelamer carbonate 2.4g sachet, as the brand Renvela®].

The Group noted that:
- calcium acetate (475mg and 950mg tablets, Renacet®) remains the first-choice calcium-containing phosphate binding agent
- sevelamer is the first-choice non calcium-containing phosphate binding agent, carbonate is the preferred salt, and prescriptions should be written generically
- lanthanum remains the third-choice agent; prescriptions should be written generically
- Osvaren® and sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®) remain non-formulary
- aluminium hydroxide (Alu-Cap® 475mg capsules) is a last choice phosphate binding agent, and although local use is very low, the service would prefer that it remains available for prescribing as a phosphate binding agent [non-formulary as antacid]. Use is restricted due to the risk of toxicity/accumulation.
- sevelamer was previously accepted for off-label use in paediatrics
- sevelamer carbonate 2.4g sachet, as the brand Renvela®, is the only sevelamer-containing product licensed for use in paediatrics

The Group agreed that aluminium hydroxide should be noted as non-formulary.

Aluminium hydroxide 475mg capsules (Alu-Cap®) is not routinely available as there is a local preference for alternative medicines.
Indication under review: for use as a phosphate binding agent in the management of renal failure.
Not routinely available as there is a local preference for alternative medicines. **FTeam**

The Group accepted the restricted local need for sevelamer carbonate 2.4g powder for oral suspension (Renvela®) as outlined in SMC 1304/18 without the need for a submission.

SMC 1304/18 - Sevelamer carbonate 2.4g powder for oral suspension (Renvela®) is routinely available in line with national guidance (SMC 1304/18).
Indication under review: the second-line management of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area of >0.75m^2) with chronic kidney disease receiving haemodialysis.
SMC has previously accepted sevelamer carbonate for restricted use in the second-line management of hyperphosphataemia in adult patients receiving haemodialysis. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. **FTeam**

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6.2. NHS GRAMPIAN HIV MEDICINES LIST FEBRUARY 2018

The Group noted that the updated human immunodeficiency virus (HIV) medicines list reflects the formulary changes since February 2017, including the availability of generic medicines.

The Group accepted the updated HIV medicines list (February 2018) for publication on the formulary website. **FTeam**

6.3. TRELEGY® ELLIPTA® SMC 1303/18 AND TRIMBOW® SMC 1274/17 FOR COPD

Dr Fitton and Mr Rore declared personal specific interests in GlaxoSmithKline UK (GSK) and took no part in decision-making.
Mrs Harper declared a non-personal non-specific interest in GSK and took part in decision-making.

The Group considered the SBAR reviewing the two new triple component inhalers licensed for Chronic Obstructive Pulmonary Disease (COPD). Both products have been reviewed by SMC and accepted for restricted use in NHS Scotland.

The Group noted:

- there are no single ingredient inhaled corticosteroid (ICS) devices licensed for use in COPD. Stepping up treatment to include ICS requires clinicians to change patients from a long-acting anti-muscarinic (LAMA)/long-acting beta-agonist (LABA) combination inhaler to an ICS/LABA combination inhaler plus a single ingredient LAMA inhaler.
- ICS treatment in COPD is associated with increased risk of pneumonia and other adverse effects. ICS in COPD is limited to patients with more severe disease, i.e. those with forced expiratory volume in one second <50% AND those with frequent exacerbations.
- local respiratory clinicians/and the Respiratory Managed Clinical Network (MCN) support inclusion of these products on the local formulary
- if accepted to formulary, the two inhalers will be included in the updated MCN prescribing advice
- there are differences between the NICE COPD guidance (last updated 2010) and GOLD (Global Initiative for Chronic Obstructive Lung Disease)
- both inhalers are licensed as "*maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA*", but that treatment would be restricted to patients with severe COPD (FEV1 <50%), and the proposed COPD pathway would allow patients to move from a LAMA/LABA combination inhaler to an ICS/LAMA/LABA inhaler
- for patients with severe COPD stepping up treatment to include an inhaled corticosteroid inhaler would be simplified if patients move from a single LAMA/LABA combination inhaler to a single ICS/LAMA/LABA combination inhaler

The Group agreed that the availability of fixed-dose combination ICS/LAMA/LABA inhalers would avoid the need for patients to use separate inhalers (dual plus a single ingredient), have the potential to improve compliance with therapy and reduce the risk of inadvertent duplication of therapy. In light of the differences between national guidance documents the Group supported use of the new combination inhalers as proposed by the MCN.

The Group accepted the local need for the fixed-dose combination inhalers Trelegy® Ellipta® and Trimbow® without the need for full submissions.

SMC 1303/18 - Trelegy® Ellipta® ▼ 92micrograms/55micrograms/22micrograms inhalation powder (fluticasone furoate/umeclidinium/vilanterol (as trifenatate)) is routinely available in line with local guidance.
Indication under review: maintenance treatment in adult patients with severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in one second [FEV1] <50% predicted normal) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.
Trelegy® Ellipta® costs less than inhalers containing fluticasone furoate / vilanterol (as trifenatate) 92micrograms/22micrograms and umeclidinium 55micrograms

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administered separately. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

SMC 1274/17 - Trimbow® 87micrograms/5micrograms/9micrograms metered dose inhaler (beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium) is routinely available in line with local guidance.
Indication under review: maintenance treatment in adult patients with severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in one second [FEV1] <50% predicted normal) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.
Trimbow® costs less than inhalers containing beclometasone dipropionate/formoterol fumarate 100micrograms/6micrograms and glycopyrronium 44micrograms. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

6.4. NON-FORMULARY ITEMS FOR INFORMATION

ACETYLCYSTEINE FOR IDIOPATHIC PULMONARY FIBROSIS
N-acetylcysteine, as unlicensed products, was previously included on the formulary for cystic fibrosis and idiopathic pulmonary fibrosis (IPF) patients. Licensed acetylcysteine effervescent tablets are now available, but acetylcysteine is no longer used in the management of IPF. A review of the mucolytic agents is underway with advice expected in the next quarter.

The Group noted that N-acetylcysteine is non-formulary for the management of IPF. **FTeam**

LIOTHYRONINE AND ARMOUR THYROID
The Group noted the liothyronine and Armour Thyroid prescribing advice issued by the Primary Care Prescribing Group.

7. OTHER BUSINESS

7.1. Scottish National Formulary (SNF) – December update

The Group noted the Single National Formulary (SNF) – December Update.
Work is commencing on review of sections, e.g. respiratory and diabetes, with Boards invited to nominate individuals to participate.

7.2. HEALTHCARE IMPROVEMENT SCOTLAND – INTERIM STATEMENT ABIRATERONE IN NEWLY DIAGNOSED HORMONE NAIVE PROSTATE CANCER

The Group noted the Healthcare Improvement Scotland interim statement regarding abiraterone in newly diagnosed hormone naïve prostate cancer.

7.3. EUROPEAN MEDICINES AGENCY'S (EMA) PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) MEETING HIGHLIGHTS FEBRUARY 2018

7.3.1. ESMYA® (ULIPRISTAL) FOR UTERINE FIBROIDS

Following reports of serious liver injury, including liver failure leading to transplantation, the PRAC is reviewing the benefits and risks with Esmya®.
While the review is ongoing, women taking Esmya® for uterine fibroids should have regular liver monitoring, and no patients should start treatment. The Medical Director issued the medicines safety alert to Primary Care.

7.3.2. VALPROATE – NEW RESTRICTIONS ON USE

The PRAC recommends new measures to avoid valproate exposure in pregnancy.

7.3.3. REVIEW OF RETINOID MEDICINES CONCLUDED

The PRAC has concluded its review of retinoid medicines and has recommended updating the measures for pregnancy prevention and including a warning on the

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possible risk of neuropsychiatric disorders (such as depression, anxiety and mood changes).

8. NEW PRODUCT REQUESTS

8.1. FG1 397/16 - ZOLEDRONIC ACID 4MG/5ML CONCENTRATE FOR SOLUTION FOR INFUSION (OFF-LABEL)

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

The Group considered the request to extend the use of zoledronic acid 4mg infusion to include off-label use of adjuvant bisphosphonates in women with early breast cancer (EBC).

The Group noted:

- that generic zoledronic acid (4mg) is included on the formulary as a cost-effective treatment option for the prevention of skeletal related events in patients with bone metastases
- that no bisphosphonates are currently licensed as adjuvant treatment in post-menopausal women with EBC
- evidence has shown that bisphosphonates reduce the frequency of bone metastases and improve survival in postmenopausal women with EBC [most commonly used agents zoledronic acid, clodronate and ibandronic acid]
- that the treatment regimen is zoledronic acid 4mg intravenous infusion, given every 6 months for 3 years (i.e. 6 doses)
- patients should receive calcium and vitamin D unless contra-indicated
- that eligible patients are estimated at less than 100 per year, and costs are manageable
- treatment should be limited to hospital use only, which would include Community Hospitals
- guidance to support use of bisphosphonate in malignancy-related indications is required **MG**
- other Health Boards in Scotland have adopted or are in the process of considering the adjuvant use of bisphosphonates [for this patient group]

The Group accepted the restricted local need for the off-label use of zoledronic acid as adjuvant bisphosphonate treatment for some women with a diagnosis of early invasive breast cancer.

FG1 397/16 - Zoledronic acid 4mg/5mL concentrate for solution for infusion is routinely available in line with local guidance.
Indication under review: (off-label use) as adjuvant bisphosphonate treatment for women with a diagnosis of early invasive breast cancer (EBC) who are:

- **post-menopausal and considered of sufficient clinical risk for treatment with an adjuvant aromatase inhibitor or HER2 positive or ER low/negative**
- **pre-menopausal treated with ovarian suppression.**

It was classified 3b – licensed product available for restricted off-label use and 8b - recommended for hospital use only. Informed consent should be obtained and documented. Treatment should only be initiated by physicians experienced in the treatment of cancer. Treatment must only be prescribed and administered by healthcare professionals experienced in the administration of intravenous bisphosphonates. Patients should be given the package leaflet and the patient reminder card. **FTeam**

8.2. FG1 TA449 - EVEROLIMUS (UNRESECTABLE OR METASTATIC, WELL-DIFFERENTIATED (GRADE 1 OR GRADE 2) NON-FUNCTIONAL NEUROENDOCRINE TUMOURS OF GASTROINTESTINAL OR LUNG ORIGIN IN ADULTS WITH PROGRESSIVE DISEASE)

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

The Group reviewed the submission for everolimus for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease.

Ms Doney confirmed that SMC 1215/17 published February 2017 was superseded by TA449 (ratified by Healthcare Improvement Scotland July 2017). The SMC advice took

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account of the views from a Patient and Clinician Engagement (PACE) meeting.

The Group noted that:
- (for this indication) the recommendations of SMC and NICE are consistent
- everolimus is the only treatment option for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of lung origin
- the advice takes account of the benefits of a PAS that improves the cost-effectiveness of everolimus

The Group accepted the restricted local need for everolimus for the treatment of unresectable or metastatic, well-differentiated non-functional neuroendocrine tumours of gastrointestinal or lung origin as outlined in TA449.

TA449 - Everolimus 2.5mg, 5mg, 10mg tablets (Afinitor®) is routinely available in line with national guidance (TA449).
Indication under review: for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus 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. Treatment should be initiated and supervised by a physician experienced in the use of anticancer therapies. **FTeam**

8.3. FG1SMC 1161/16 - TRAMETINIB (UNRESECTABLE OR METASTATIC MELANOMA WITH A BRAF V600 MUTATION)

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

The Group considered the request for trametinib, in combination with dabrafenib, for the first-line treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

The Group noted:
- trametinib is an oral medication that is taken in combination with another oral medicine dabrafenib
- the combination regimen is more effective than BRAF inhibitor monotherapy
- (for this indication) trametinib in combination with dabrafenib meets SMC end of life and ultra-orphan criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process and after application of the appropriate SMC modifiers
- that there are no patients waiting for treatment, any eligible patients have received combination therapy, and the cost of introduction of trametinib are already in the system

The Group accepted the restricted local need for trametinib used in combination with dabrafenib as outlined in SMC 1161/16.

SMC 1161/16 - Trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) ▼ is routinely available in line with regional guidance.
Indication under review: in combination with dabrafenib for the first-line treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
In two phase III studies, trametinib in combination with dabrafenib improved progression-free survival and overall survival compared with BRAF inhibitor monotherapy for the first-line treatment of unresectable or metastatic melanoma with BRAF V600 mutation in adults.
This advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of trametinib and dabrafenib and is contingent upon the continuing availability of these patient access schemes in NHS Scotland or list prices that are equivalent or lower.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.

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Trametinib is also licensed as monotherapy. As the company submission related only to combination therapy, SMC cannot recommend use as monotherapy. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should only be initiated and supervised by a physician experienced in the administration of anti-cancer medicinal products. **FTeam**

8.4. FG1SMC 1187/16 - NIVOLUMAB (UNRESECTABLE OR METASTATIC MELANOMA)

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

The Group considered the request for nivolumab, in combination with ipilimumab, as a first-line option for the treatment of advanced (unresectable or metastatic) melanoma in adults.

The Group noted:

- nivolumab used in combination with ipilimumab has an increased frequency and severity of toxicity, and this combination will only be used first-line for fitter patients
- the combination regimen is more effective (higher response rate and progression-free survival) than single agent immunotherapy
- the licence notes that '*relative to nivolumab monotherapy, an increase in progression-free survival (PFS) and overall survival (OS) for the combination of nivolumab with ipilimumab is established only in patients with low tumour PD-L1 expression'*
- the high cost of the treatment regimen
- there are no patients waiting for treatment
- (for this indication) nivolumab in combination with ipilimumab meets SMC end of life and ultra-orphan criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process and after application of the appropriate SMC modifiers

The Group accepted the restricted local need for nivolumab used in combination with ipilimumab as outlined in SMC 1187/16.

SMC 1187/16 - Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) ▼ is routinely available in line with regional guidance.
Indication under review: in combination with ipilimumab for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults.
In a randomised, double-blind, phase III study of adults with previously untreated advanced melanoma nivolumab in combination with ipilimumab was associated with a clinically important and statistically significant improvement in progression-free survival when compared with a single-agent immunotherapy. Overall survival data are immature.
The base-case economic analysis submitted by the company assumed that responding patients were treated for a maximum of 18 months.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nivolumab 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 the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment must be initiated and supervised by physicians experienced in the treatment of cancer.
Patients must be given the patient alert card and be informed about the risks of nivolumab (see also package leaflet). [Patient alert card: https://www.medicines.org.uk/emc/rmm/213/Document]. **FTeam**

8.5. FGASMC 1279/17 – MIDAZOLAM 10MG/ML OROMUCOSAL SOLUTION PREFILLED SYRINGE (TREATMENT OF PROLONGED, ACUTE, CONVULSIVE SEIZURES IN CHILDREN AND ADOLESCENTS AGED 10 TO LESS THAN 18 YEARS)

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

The Group considered the submission for midazolam 10mg/mL oromucosal solution available in a 1mL prefilled syringe licensed and marketed as Epistatus®.
Ms Doney confirmed that the unlicensed 'specials' formulary of midazolam, Epistatus®

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10mg/mL oromucosal solution (sugar free syrup, supplied as a 5mL bottle), has been widely used in NHS Scotland for many years.

The Group noted:
- the licensed Epistatus® prefilled syringe will be used for patients requiring a 10mg dose
- the syringe is not graduated and can only deliver a fixed dose of 10mg
- the Epistatus® (10mg/1mL) 5mL bottle will remain on formulary for patients who are prescribed doses less than 10mg
- the concerns regarding the introduction of Buccolam® (midazolam 10mg/2mL) remain, and the recent product defect notice issued November 2017 means that the non-formulary position for Buccolam® remains unchanged
- inclusion of the licensed Epistatus® prefilled syringe on formulary will not alter current protocols or individual patient care plans

Mrs Smith reported that the Grampian Guidance website includes guidelines for the use of buccal midazolam, and this advice will need to be reviewed. **FD**

The Group accepted the restricted local need for the licensed preparation Epistatus® 10mg/1mL oromucosal solution pre-filled oral syringes for children prescribed a dose of 10mg.
Information will be issued to clinicians in Primary Care to highlight the differences between the two Epistatus® products. **FTeam**

SMC 1279/17 - Midazolam (as maleate) 10mg/1mL oromucosal solution prefilled syringe (Epistatus®) is routinely available in line with local guidance.
Indication under review: treatment of prolonged, acute, convulsive seizures in children and adolescents aged 10 to less than 18 years.
The availability of midazolam (Epistatus®) provides a licensed alternative to a previously available unlicensed preparation (10mg/mL). It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED FEBRUARY 2018

The Group noted the SMC provisional advice issued February 2018.

If published next month the negative SMC recommendation, for atezolizumab (Tencentriq®) ▼ SMC 1297/18, and the non-submission statements, for clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) SMC 1321/18, dexamethasone (Neofordex®) SMC 1322/18, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya®) ▼ SMC 1323/18, lacosamide (Vimpat®) SMC 1324/18, nilotinib (Tasigna®) SMC 1325/18 and sofosbuvir (Sovaldi®) ▼ SMC 1326/18, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The Chairman noted that the paediatric licence extension for nilotinib in chronic myelogenous leukaemia (CML) is not recommended for use due to non-submission.
Ms Doney will confirm if there is a local need for nilotinib for paediatric CML patients. **FD**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED FEBRUARY 2018

The Group noted the SMC advice published February 2018.

Following publication of the non-submission statements, for daptomycin (Cubicin®) SMC 1309/18, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil (as fumarate) (Stribild®) ▼ SMC 1310/18, pasireotide (as pamoate) (Signifor®) SMC 1311/18 and peginterferon alfa-2a (Pegasys®) SMC 1312/18, 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 1260/17 5-aminolaevulinic acid (as hydrochloride) (Ameluz®)
- SMC 1300/18 cladribine (Mavenclad®) (submission received)
- SMC 1299/18 levonorgestrel (Kyleena®) (submission expected)

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- SMC 1291/18 pembrolizumab (Keytruda®) ▼ (submission received)
- SMC 1298/18 tofacitinib citrate (Xeljanz®) ▼ (submission expected)

Local advice for these medicines and indications will be included in the February 2018 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 1302/18 - KALETRA® (HIV INFECTION IN INFANTS)

Mrs Harper declared a non-personal non-specific interest in AbbVie Limited and took part in decision-making.

The Group considered the licence extension of Kaletra® oral solution to include children aged from 14 days to ≤2 years.

The Group noted:
- Kaletra® is already included on the formulary in line with SMC 326/06
- the indication for the new and previous SMC advice is consistent, but the lower age range only applies to the oral solution. The tablet formulation is only licensed for children, adolescents and adults above the age of 2 years.
- there are no patients requiring treatment at present, however inclusion on formulary would prevent delay in treatment should a need arise

The Group accepted the restricted local need for Kaletra® oral solution as outlined in SMC 1302/18, without the need for a full submission.

SMC 1302/18 - Kaletra® 80mg/20mg oral solution (lopinavir/ritonavir) is routinely available in line with national guidance (SMC 1302/18).
Indication under review: in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to ≤2 years.
SMC has previously accepted lopinavir/ritonavir for use in children above the age of 2 years. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be prescribed by physicians who are experienced in the treatment of HIV infection. **FTeam**

SMC 1301/18 – LACOSAMIDE (REFRACTORY EPILEPSY IN PAEDIATRICS)

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

The Group considered the abbreviated SMC advice for the paediatric extension of lacosamide as adjunctive therapy in the management of patients with refractory epilepsy [SMC 1301/18]. The Group noted that lacosamide is already included on the formulary for the same indication for patients aged 16 years and older (SMC 532/09), and that accepting this advice will extend use to patients from age 4 years.

The Group accepted the restricted local need for lacosamide as outlined in SMC 1301/18 without the need for a full submission.

SMC 1301/18 - Lacosamide 50mg, 100mg, 150mg, 200mg tablets, 10mg/mL syrup, 10mg/mL solution for intravenous infusion (Vimpat®) is routinely available in line with national guidance (SMC 1301/18).
Indication under review: as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age with refractory epilepsy.
SMC has previously accepted lacosamide for restricted use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. Treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy. **FTeam**

ITEM	SUBJECT	ACTION

11. GENERAL INFORMATION FROM SMC FEBRUARY 2018 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update February 2018), 12.2 (Grampian Medicines Management Group minute 6 September 2017), and 12.3 (Grampian Primary Care Prescribing Group minute 13 December 2017) were noted.

13. **AOCB**

GLUCODRATE® WITHDRAWN 5 FEBRUARY 2018

Glucodrate®, manufactured by Vitaflo Ltd, is a food for medical purposes that must only be given under medical supervision to patients with a diagnosis of short bowel-associated intestinal failure and intestinal insufficiency. June 2017 Glucodrate® was included on the formulary for patients that cannot make up St Mark's solution. 5 February 2018 Glucodrate® was withdrawn from the market.

The Group noted that Glucodrate® has been withdrawn by the manufacturer and recorded it as non-formulary.

Glucodrate® sachets are withdrawn from the market.
Indication under review: for adults in the dietary management of short bowel-associated intestinal failure and intestinal insufficiency.
In view of the withdrawal, effective from Monday 5 February 2018, Glucodrate® has been removed from the Grampian Joint Formulary. **FTeam**

DATE OF NEXT MEETING

Tuesday 20 March 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE** **20 March 2018**