**NHS GRAMPIAN**
**Minute of Formulary Group Meeting held on Tuesday 20th October 2015**
**in the Aspen Room, Forest Grove House**

| **PRESENT** | **APOLOGIES** | **APPROVED** |
|---|---|---|
| Dr D Counter | Dr D Culligan | |
| Ms A Davie | Mrs L Harper | |
| Ms F Doney | Dr A MacDonald | |
| Mr A Duncan | Mr C Rore | |
| Dr C Hind | Professor John Webster | |
| Professor J McLay (Chairman) | | |
| Mrs L Montgomery | | |
| Dr W Moore | | |
| Mr M Paterson | | |
| Mr R Sivewright | | |
| Dr A Sun (from item 7) | | |

**IN ATTENDANCE**
Ms Kate Robertson, Secretary Formulary Team.

| **ITEM** | **SUBJECT** | **ACTION** |
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| | The Chairman opened the meeting, noted that a quorum was present and welcomed members to the meeting. | |
| **1.** | **APOLOGIES** | |
| | Apologies for absence were requested and noted. | **FD** |
| **2.** | **DRAFT MINUTE OF THE MEETING HELD ON THE 15TH SEPTEMBER 2015** | |
| | The Group accepted the draft note of the meeting held on the 15th September 2015 as an accurate record of the meeting subject to minor typographical changes. | **FD** |
| | The approved final minute will be in the public domain within 21 days. | **FTeam** |
| **3.** | **PRESENTATION – NONE** | |
| **4.** | **MATTERS ARISING** | |
| | ITEM NOT ON THE AGENDA - MEDICINES RELATED TO VALPROATE: RISK OF ABNORMAL PREGNANCY OUTCOMES | |
| | At the September meeting it was agreed that the Chairman would send a letter to prescribers highlighting the new information and strengthened warnings issued by the MHRA (January 2015). IMPACT will be used as the route for highlighting the information with Primary Care prescribers. | **JMcL/FD** |
| **5.** | **FORMULARY GROUP DECISIONS SEPTEMBER 2015 – PUBLISHED 29/09/2015** | |
| | The Group ratified the advice as published. | |
| **6.** | **CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE – 2015/16 YTD** | |
| | It was confirmed that for the SMC accepted medicines published April 2015 to September 2015 the Formulary Group audit standard for CMO(2012)1 reporting was achieved for the following criteria:<br>▪ Local decision on SMC accepted medicine published within 90 days: 45 of 45 - 100%<br>▪ FG decision published within 14 days of the decision being reached: 45 of 45 - 100% | |
| **7.** | **OTHER BUSINESS** | |
| | **7.1. NICE MULTIPLE TECHNOLOGY APPRAISALS - NONE** | |
| | **7.2. NHS BOARD NEW MEDICINES DECISIONS: STANDARD TEMPLATE** | |
| | It was confirmed that Healthcare Improvement Scotland is currently working with representatives from NHS Boards and public partners to review the content of the standard template for NHS board new medicines decisions (i.e. SMC accepted medicines). A draft template was sent to Area Drug And Therapeutics Committees (ADTCs) for comment, NHS Board feedback will be considered by the 'working group' at the beginning of November, | |

| ITEM | SUBJECT | ACTION |
|---|---|---|

and the final template will be submitted to the Healthcare Improvement Scotland Executive Team for final approval. Once approved the template will be circulated with the Scottish Government guidance via email to Directors of Pharmacy, ADTC Chairs, the Association of the British Pharmaceutical Industry and other key stakeholders to cascade to relevant healthcare professionals as appropriate.

The Group reviewed the draft template and agreed that the wording was clearer but there is a need for an 'in process/non-response' category. The lack of dates to show compliance with CMO(2012)1 reporting timescales was noted.

Members were asked to forward any additional feedback to Ms Doney by the end of the day 22nd October. **All**

### 7.3. OXYCODONE – FORMULARY-CHOICE BRAND SWITCH RECOMMENDATION

The Group considered the paper submitted by the Controlled Drugs Team highlighting that a number of incidents recorded in relation to (mis-)prescribing of oral solid dosage forms of oxycodone (long- and short-acting preparations) are due in part to the similarity of naming of OxyContin® and OxyNorm®.

The Group noted:
- that the proposal to change the preferred formulary brands to Longtec® modified-release tablets and Shortec® capsules (from OxyContin® and OxyNorm® respectively) provided the possibility to prevent further mis-prescribing incidents, and system advantages to staff and patients – benefits at all points of medication supply and use (prescribing, supply and administration)
- there are no differences in licences or bioavailability between the relevant medicines
- that the change is a cost-effective option

The Group supported the proposal to change the preferred oral solid dosage oxycodone long- and short-acting preparations to Longtec® modified-release tablets and Shortec® capsules. **CDTeam**

## 8. NEW PRODUCT REQUESTS

### 8.1. FG1 SMC 1048/15 – PASIREOTIDE PAMOATE (SIGNIFOR®) ▼ - UNCONTROLLED ACROMEGALY

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

The Group considered the submission for pasireotide pamoate as a treatment option for a group of adults with acromegaly who have failed or are unsuitable for surgery and are inadequately controlled on other somatostatin analogues [SMC 1048/15].

The Group noted:
- pasireotide as pamoate:
  - meets SMC ultra orphan criteria for this indication and has been designated an orphan medicine for the treatment of acromegaly by the European Medicines Agency
  - was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of the PACE process
  - is a somatostatin analogue with a higher affinity to somatostatin receptor subtype 5 and lower affinity to subtype 2 compared to octreotide and lanreotide
  - is given by deep intramuscular injection and should only be administered by a trained healthcare professional
  - could be used as a bridging therapy for post-radiotherapy patients until radiotherapy normalises growth hormone hypersecretion
- the initial dose is 40mg every four weeks and the dose may be increased to a maximum of 60mg if growth hormone and/or insulin-like growth factor-1 levels are not fully controlled after 3 months of treatment
- that acromegaly is associated with significant morbidity and mortality, and if uncontrolled patients are at greater risk of developing co-morbidities
- there are very few treatment options for patients suffering with uncontrolled acromegaly
- the flat pricing structure of the different strengths

| ITEM | SUBJECT | ACTION |
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- treatment related side-effect were common and consistent with somatostatin analogues, except the higher degree and frequency of hyperglycaemia
- the monitoring requirements at baseline and ongoing
- that the submission states the first dose would be given in secondary care
- there are 14 steps in the reconstitution of pasireotide pamoate injection (Signifor®) ▼
- there are two critical steps in reconstitution of the injection and that not following them could result in failure to deliver the injection appropriately
- that a significant proportion of patients did not respond to treatment
- the local estimate of numbers was higher than the SMC estimate, but the local estimate would include patients from other Health Boards

The Group noted the risk of patients not receiving the correct dose if the injection is not reconstituted correctly and considered that there are training implications required to allow transfer of patients to Primary Care.

The Group accepted the restricted local need for pasireotide pamoate as an option for the treatment of adult patients with acromegaly as outlined in SMC 1048/15. Transfer to Primary Care is subject to provision of an individual care plan and ensuring that Primary Care healthcare staff are trained to ensure the correct reconstitution of pasireotide pamoate (Signifor®) ▼. **Endocrine Service**

**SMC 1048/15 – Pasireotide (as pamoate) 20mg, 40mg 60mg powder and solvent for injection (Signifor®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.**
**Pasireotide administered every four weeks was significantly superior to an active control group (comprising other somatostatin analogues administered monthly) for the primary endpoint of biochemical control, in patients with inadequately controlled acromegaly following treatment with a somatostatin analogue for at least six months. 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 8c – treatment to be initiated in hospital prior to handover. Managed transfer to Primary Care is on an individual basis subject to provision of an individual care plan and training Primary Care healthcare staff on the correct reconstitution of pasireotide pamoate (Signifor®) ▼.** **FTeam**

### 8.2. FG1 SMC 1076/15 – NINTEDANIB (OFEV®) ▼ - IDIOPATHIC PULMONARY FIBROSIS

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

The Group considered the submission for nintedanib, as Ofev® ▼ capsules, for the treatment of idiopathic pulmonary fibrosis (IPF).

The Chairman commended the requestor on the clarity of the submission and their conflict of interest entry.

The Group noted:
- nintedanib (as Ofev® ▼ casules):
  - has been designated an orphan medicine for the treatment of IPF by the European Medicines Agency
  - is the second medicine, after pirfenadone, licensed for IPF
  - has a different mode of action and side-effect profile to pirfenadone
  - is an oral medication taken twice daily
  - was accepted for restricted use within NHS Scotland in the context of SMC decision modifiers and the output of the Patient and Clinician Engagement meeting
- that adverse effects were common (higher rate of gastrointestinal adverse events than placebo particularly within the first 3 months of treatment; elevation of liver enzymes), and may require dose reduction, interruption or discontinuation
- the lack of long-term data
- the poor prognosis for patients diagnosed with IPF, and that acute exacerbations can

occur and lead to death
- the lack of treatment options available and patients may not respond to or tolerate the alternative treatment option pirfenadone
- the SMC advice takes account of the benefits of a Patient Access Scheme that is available in Primary Care and improves the cost-effectiveness of Ofev® capsules
- that nintedanib is also licensed for non-small cell lung cancer, as the brand Vargatef®, which is available in the same strength capsules - 100mg and 150mg

The Group considered that supply via Primary Care would be beneficial to patients and the service. However due to the specialist nature of the management of patients with IPF (ongoing monitoring of the disease and medication) the Group requested clarification of how often patients attended the IPF clinic, and questioned if prescribing nintedanib, as the brand Ofev® ▼, on a hospital-based prescription would provide advantages to patients and the service. **FD**

The Group accepted the restricted local need for nintedanib, as Ofev® ▼ capsules, for the treatment of adult patients with IPF as outlined in SMC 1076/15.

**SMC 1076/15 - Nintedanib 100mg and 150mg capsules (Ofev®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: in adults for the treatment of idiopathic pulmonary fibrosis (IPF).**
**Restriction: for use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.**
**Nintedanib, compared to placebo, reduces the decline in pulmonary function assessed by forced vital capacity in patients with IPF.**
**This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nintedanib 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 should be initiated by physicians experienced in the diagnosis and treatment of IPF.** **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) stationary.

The Group highlighted an ongoing concern that medicines regularly issued from secondary care will not appear on a patient's Primary Care 'active' medication record.

### 8.3. FG1 SMC 1080/15 - TEDIZOLID (SIVEXTRO®) – ABSSSI (ADULTS)

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

The Group considered the formulary submission for tedizolid, an oxazolidinone antibacterial, licensed for acute bacterial skin and skin structure infections (ABSSSI) in adults.

The Group noted:
- ABSSSI are common in both the hospital and community setting and are a significant source of morbidity and mortality
- tedizolid phosphate:
  - is not generally active against Gram-negative bacteria
  - is available as oral tablets and intravenous infusion, and is given at a dose of 200mg once daily for a 6 day treatment course
- locally tedizolid would provide an alternative second- or third-line option for ABSSSI secondary to MRSA when treatment with vancomycin, teicoplanin or daptomycin fails or causes undesirable side effects
- introduction would provide advantages to patients and the service - less frequent dosing and costs less than linezolid the alternative oxazolidinone antibacterial
- use is subject to inclusion in the policy for optimising the use of alert antimicrobials

| ITEM | SUBJECT | ACTION |
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The Group accepted the restricted local need for tedizolid tablets and infusion as outlined in SMC 1080/15, subject to inclusion in the "Staff Policy for Optimising Use of Alert (restricted) Antimicrobials in Adults". **AbPhs**

**SMC 1080/15 - Tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.**
**Restriction:**

- **Use in patients with ABSSSI caused by Gram-positive *Staphylococcus aureus* (specifically methicillin-resistant *Staphylococcus aureus* [MRSA] isolates)**
- **Use of tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease.**

**In two randomised, double-blind clinical studies, tedizolid phosphate was non-inferior to another oxazolidinone antibacterial in adult patients with ABSSSI. Tedizolid is a restricted antimicrobial only available for use on the advice of an infectious disease consultant or microbiology advice and inclusion in the NHS Grampian Staff Guidance For Optimising Use Of Alert (Restricted) Antimicrobials In Adults. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.** **FTeam**
**The presenting company did not submit any evidence for SMC to consider around the use of tedizolid phosphate in "mixed infections", where the infection involves both Gram-positive and Gram-negative organisms.**

### 8.4. FG1 SMC 1081/15 – Darunavir/cobicistat (Rezolsta®) ▼ - HIV-1 (adults)

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

The Group considered the submission for the new HIV-1 treatment option, Rezolsta® ▼, a fixed-dose combination tablet that contains the antiretroviral agent, darunavir, and a pharmacokinetic booster, cobicistat.

The Group noted:

- cobicistat:
  - has no anti-viral activity
  - is an inhibitor of the cytochrome P450 3A sub-family of metabolic enzymes, and a significant proportion of medicines are metabolised by the P450 enzymes
  - is a creatinine excretion inhibitor so artificially increases creatinine
  - the manufacturer advises that cobicistat requires a baseline renal function at initiation of therapy, recheck at 4 weeks and this value is used as the new baseline. Repeat testing is suggested at 3-monthly intervals for a year and annually thereafter if no abnormalities detected. In patients with abnormal baseline results, renal function assessment should be performed at least 6-monthly.
- Rezolsta® ▼
  - is accepted by SMC, used in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults
  - as other medicines are assumed to be displaced the net medicines budget impact was estimated to be cost neutral, however the SMC costing may not take account of contract prices

The Group accepted the restricted local need for darunavir/cobicistat (Rezolsta®) ▼ as outlined in SMC 1081/15, noting the issues related to the use of cobicistat on creatinine clearance and the medication not appearing on a patient's Primary Care active medication record.

**SMC 1081/15 - Darunavir 800mg/cobicistat 150mg film-coated tablet (Rezolsta®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: In combination with other antiretroviral medicinal products**

**for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.**
**Pharmacokinetic studies have demonstrated that darunavir/cobicistat is bioequivalent (in terms of darunavir exposure) to ritonavir-boosted darunavir. No comparative efficacy studies have been reported. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated by a healthcare provider experienced in the management of HIV infection.** **FTeam**

### 8.5. FG1 SMC 1094/15 – MIDODRINE (BRAMOX®) - SEVERE ORTHOSTATIC HYPOTENSION

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

The Group considered the abbreviated submission for midodrine hydrochloride tablets indicated in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate, SMC 1094/15.

The Group noted that:

- the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine
- midodrine (as Bramox® tablets):
  - is the first licensed midodrine product available in the UK for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate
  - 5mg tablets have been shown to be bioequivalent to the unlicensed midodrine 5mg product currently in use in NHS Scotland
  - is taken orally at a dose of 2.5mg to 10mg three times a day, and the usual maintenance dose is 10mg three times a day
  - has an in-use shelf-life of up to 8 weeks
- the introduction of a licensed midodrine tablet will negate the need for the unlicensed product, and changing to the licensed preparation may entail an increase in medicine costs, but due to the low patient numbers this will have a limited impact on budgets

The Group accepted the restricted local need for midodrine, as the licensed product Bramox®, for adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate [SMC 1094/15].

The Group considered that the restricted in-use shelf-life creates a possible waste issue if original packs are not dispensed. Ms Davie to investigate if a ScriptSwitch message could be deployed to minimise the potential for waste. **ADav**

**SMC 1094/15 - Midodrine hydrochloride 2.5mg and 5mg tablets (Bramox®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate. 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.** **FTeam**

### 8.6. REQUESTS FOR SMC ACCEPTED INHALERS - (LONG-ACTING BRONCHODILATORS IN DRY POWDER INHALER DEVICES FOR COPD)

There were no declarations of interest recorded in relation to the products or manufacturers.

The Group considered the information submitted regarding dry powder inhalers (DPIs) containing long-acting bronchodilators (as single agents or in combination) and licensed to relieve the symptoms in chronic obstructive pulmonary disease (COPD).

**ITEM** **SUBJECT** **ACTION**

Items under consideration:

1. single agent long-acting muscarinic antagonists (LAMAs) - umeclidinium in the Ellipta® device [SMC 1004/14] and glycopyrronium bromide capsules with the Breezhaler® device [SMC 829/12]
2. fixed-dose combination inhalers containing a LAMA and a long-acting beta$_2$-agonist (LABA) – aclidinium/formoterol in the Genuair® device [SMC 1034/15], umeclidinium/vilanterol in the Ellipta® device [SMC 978/14], and indacaterol/ glycopyrronium capsules with the Breezhaler® device [SMC 922/13]

The Group noted:

- the recommendations of national guidance and the NHS Scotland Respiratory Prescribing Strategy
- the NHS Scotland Respiratory Prescribing Strategy published June 2014 provided strategic direction for further improvements in patient care, patient safety and the effective use of the medicines
- that since 2012 the SMC has accepted several new long-acting bronchodilators (LAMAs and LABAs) and fixed-dose combination LABA/LAMA inhalers for the symptomatic treatment of COPD
- the different durations of action of the long-acting bronchodilators and different inhaler devices offer opportunities to personalise a patient's management regimen
- all of the LAMA/LABA combinations cost less than using the individual components separately, and all cost less than the most commonly prescribed LAMA tiotropium
- that aclidinium (LAMA) and formoterol (LABA) are both included on the formulary for COPD, and the fixed-dose combination inhaler Duaklir® Genuair® is taken twice daily
- that umeclidinium and glycopyrronium are LAMAs taken once daily, and they are not included on the formulary for COPD
- glycopyrronium and indacaterol/glycopyrronium are available as capsules that are 'loaded' into an inhaler device before puncturing the capsule and inhaling the powder
- umeclidinium as a single agent and fixed-dose LAMA/LABA combination inhaler are available in a pre-loaded inhaler device, and inclusion of both products would provide the same device, Ellipta®, for all stages of COPD

The Group agreed that inclusion of additional long-acting bronchodilators, as single-agents or in fixed dose combination inhalers, provided advantage to patients and prescribers, a cost-minimisation strategy for COPD prescribing and could help address areas of concern in respiratory prescribing.

The Group accepted the local need for the following long-acting bronchodilators licensed as maintenance bronchodilator treatments to relieve symptoms in adult patients with COPD:

**SMC 1034/15 - Aclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir® Genuair®)**
**SMC 1004/14 - Umeclidinium, 55 micrograms, inhalation powder (Incruse® Ellipta®)**
**SMC 978/14 - Umeclidinium/vilanterol, 55/22 micrograms, inhalation powder (Anoro® Ellipta®)**
**Indication under review: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).**
**They were classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community.**

Due to the lack of support for glycopyrronium as a single agent the Group did not support formulary inclusion of the indacaterol/glycopyrronium combination product, as transition from the single agent bronchodilator to a combination product was unclear.

**SMC 829/12 - Glycopyrronium bromide capsules with the Breezhaler® device**
**SMC 922/13 - Indacaterol/glycopyrronium capsules with the Breezhaler® device**
**Indication under review: as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).**
**They were classified 4 – Not approved for use in NHS Grampian.**

Local advice for these medicines and indications will be included in the October 2015

| ITEM | SUBJECT | ACTION |
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decisions as:
**SMC 829/12 - Glycopyrronium bromide capsules -** "**not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question**" and **FTeam**
**SMC 922/13 - Indacaterol/glycopyrronium capsules -** "**not included on the Grampian Joint Formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary**." **FTeam**

**ITEMS 8.7 TO 8.9 – FORMULARY INCLUSION NOT SUPPORTED**

The Group noted that the relevant service areas do not support formulary inclusion for the following SMC accepted medicines:
- SMC 1049/15 entecavir (Baraclude®) (chronic hepatitis B (2-<18 years))
- SMC 1083/15 sitagliptin (Januvia®) (type 2 diabetes; add on to insulin)
- SMC 1044/15 liraglutide (Victorza®) (type 2 diabetes; additional to basal insulin)

Local advice for these medicines and indications will be included in the October 2015 decisions as: "**not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question**." **FTeam**

**9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED OCTOBER 2015**

The Group noted the SMC provisional advice issued October 2015.

If published next month the negative SMC recommendation for pembrolizumab (Kentruda®) ▼ SMC 1087/15, and the non-submission statements for regorafenib (Stivarga®) ▼ SMC 1118/15 and everolimus (Certican®) ▼ SMC 1117/15 will not be included on the Grampian Joint Formulary for the indications in question.

The Group noted the three abbreviated submissions for HIV-1 medications and agreed that individual submissions would not be requested. The paediatric and adults services will be contacted to confirm if the medicines are required locally, and a summary will be brought to the November meeting. **FTeam**

Members requested an update on the treatment options for HIV, including the current treatment pathways, medication supply routes, clarification of the current formulary HIV drugs list and if any medicines can be removed from the formulary. **FTeam**

**10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED OCTOBER 2015**

The Group noted the SMC advice published October 2015.

Following publication of the negative SMC recommendations for everolimus (Afinitor®) SMC 872/13 and budesonide (Cortiment®) SMC 1093/15, they 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:
- abiraterone (Zytiga®) ▼ SMC 873/13 (submission received)
- radium-223 dichloride (Xofigo®) ▼ SMC 1077/15 (submission received)
- trastuzumab (Herceptin®) SMC 623/10 (submission expected)
- travaprost (Travatan®) ▼ SMC 1091/15 (paediatric extension)

Local advice for these medicines and indications will be included in the October 2015 decisions as: "**not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question**." **FTeam**

SMC 1089/15 - CICLOSPORIN 1MG/ML (0.1%) EYE DROPS EMULSION (IKERVIS®)

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

It was confirmed that a submission has been received for ciclosporin 1mg/mL (0.1%) eye

| ITEM | SUBJECT | ACTION |
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drops emulsion (Ikervis®) as per SMC 1089/15 but it was not processed in time for the meeting. The Group was provided with a verbal summary of the submission.
It was confirmed that:

- ciclosporin 0.1% eye drops as Ikervis®:
  - is accepted for use in NHS Scotland, SMC 1089/15
  - is licensed for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes, and treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology
  - is the first ciclosporin eye drops licensed in the UK and treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology
  - is available as 0.3mL single-dose polyethylene containers, provided in packs of 30 at a cost of £72 (ex VAT)
- the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine
- the recommended dose is one drop once daily to the affected eye(s) at bedtime, and response to treatment should be reassessed at least every 6 months
- the service expects that 20-30 patients per year may require treatment
- current costs in Primary Care range from £71 to £80 per 3.5g pack

A member queried if Ikervis® 0.1% eye drops will replace the use of all of the other strengths of unlicensed ciclosporin eye drops current issued in Primary Care. Clarification will be sought from the service. **FTeam**

The Group accepted the restricted local need for ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®).

**SMC 1089/15 – Ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.**
**Ciclosporin eye drops, compared to vehicle, improved signs of corneal surface damage but not symptoms in patients with severe keratitis associated with dry eye disease.**
**It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology.** **FTeam**

**11. GENERAL INFORMATION FROM SMC OCTOBER 2015 – NIL OF NOTE**

**12. DOCUMENTS FOR INFORMATION**

Items 11.1 (Drug Safety Update September 2015), 11.2 (Controlled Drugs Accountable Officers' Network Scotland document 'Ketamine to become a Schedule 2 CD from 30th November 2015'), 11.3 (IMPACT September 2015), 11.4 (MGPG minutes 4th June and 23rd July 2015) and 11.6 (2016 meeting dates) were noted.

**13. AOCB**

The Group discussed two items sent by email before the meeting.

STATEMENT RELEASED BY THE HEALTH SECRETARY, FOLLOWING THE PUBLICATION OF THE SMC ADVICE ON MONDAY (19TH OCTOBER), IN RELATION TO A REVIEW OF THE SMC PROCESS CHANGES

The Group noted the statement from the Health Secretary confirming that the Scottish Government plans to review the new SMC approach to ensure it is delivering the expected improvements consistently.

SBAR: FORMULARY AMENDMENT FOR DENOSUMAB (XGEVA®) ▼ TO INCLUDE ADMINISTRATION IN PRIMARY CARE ON ADVICE OF SPECIALIST

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

| ITEM | SUBJECT | ACTION |
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The Group discussed the request from the Oncology service to reclassify the use of denosumab 120mg injection to allow prescribing and administration in Primary Care. It was confirmed that:

- denosumab 120mg:
  - is already included on the formulary as an option for preventing skeletal-related events for a sub-group of adults with bone metastases from breast cancer and from solid tumours other than prostate
  - is given by subcutaneous injection every 4 weeks
- supplementation of at least 500mg calcium and 400 units vitamin D daily is required in all patients, unless hypercalaemia is present
- patients should be given the package leaflet and patient reminder card
- the advice for Xgeva® ▼ takes account of the benefits of a Patient Access Scheme that is available in Primary Care
- to support prescribing and administration in Primary Care a shared care protocol is available and administration of the 120mg injection has been included in the current enhanced service contract

The Group noted the steps taken to address issues related to the prescribing and administration in Primary Care and supported the request to reclassify denosumab 120mg.

**Denosumab 120mg solution for injection (Xgeva®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.**
**Indication under review: as an option for preventing skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from breast cancer and from solid tumours other than prostate**
**Restriction: if bisphosphonates would otherwise be prescribed and the manufacturer provides denosumab with the discount agreed in the patient access scheme.**
**AND**
**for patients who have one or more of the following:**
**- poor intravenous access**
**- poor renal function (i.e. CrCl <60mL/minute) prior to initiating treatment**
**- deteriorating renal function on treatment with zoledronic acid**
**- unable to tolerate oral ibandronic acid**
**It was reclassified 1b – available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant. Denosumab 120mg should be administered under the responsibility of a healthcare professional.**
**Supplementation of at least 500mg calcium and 400 units vitamin D daily is required in all patients, unless hypercalcaemia is present (see SmPC section 4.4).**
**Patients treated with Xgeva® ▼ should be given the package leaflet and the patient reminder card.** **FTeam**

INTEGRATED JOINT BOARD REPRESENTATION ON FORMULARY GROUP

Members commented that the Group is accepting medicines for use in Primary Care but there is no General Practitioner/Integrated Joint Board management representation on the group. Professor McLay will write to the Chairman of the GMMG to highlight the ongoing concern about lack of Integrated Joint Board representation on the Formulary Group. **JMcL**

**DATE OF NEXT MEETING**

The date of the next meeting was confirmed as Tuesday 17th November 2015 starting at 14.30 in the Aspen Room Forest Grove House.

**CHAIRMAN'S SIGNATURE** **DATE** **17th November 2015**