Minutes of the Formulary Committee meeting held on 24th January 2018 from 14.10 to 16.15
in Room (6+7), 5th Floor, Waverley Gate

Present:
Dr Thulani Ashcroft General Practitioner, NHS Lothian (arrived 2.20pm)
Dr Drummond Begg General Practitioner, NHS Lothian (left 3.20pm)
Carol Holmes Primary Care Pharmacist, NHS Lothian
Dr James Dear Consultant Clinical Pharmacologist, Royal Infirmary of Edinburgh (left 3pm)
Dr Jane Goddard Renal Consultant, Royal Infirmary of Edinburgh (arrived 3.15pm)
Dr Sara Hornibrook General Practitioner, NHS Lothian
Liz Leitch Formulary Pharmacist, NHS Borders
Dr Emma Morrison Clinical Pharmacology Trainee, Royal Infirmary of Edinburgh (in the chair)
Jane Pearson Lead Pharmacist, NHS Lothian
Alison Rowe Formulary Pharmacist, NHS Lothian
Laura Shaw Lead Pharmacist, Royal Hospital for Sick Children

In attendance:
Helen Crozier Medicines Management Team Co-ordinator

Apologies for absence:
Dr Maria Corretge Consultant Geriatrician, St John’s Hospital, Livingston
Dr Peter Hall Consultant Medical Oncologist, Western General Hospital
Dr Simon Hurding General Practitioner, NHS Lothian
Garry Todd Lead Pharmacist, Royal Edinburgh Hospital and Roodlands Hospital
Dr Lucy Wall Consultant Medical Oncologist, Western General Hospital
Dr Andrew Watson Consultant Psychiatrist, Royal Edinburgh Hospital

Membership
It was noted that Fraser Notman, Pharmacist, NHS Fife will join the committee as a new member to replace Ishtiaq Mohammed. It was noted the committee are still looking for nurse representation and a nomination from paediatrics is being requested at their next PNDTC.

Declarations of interest:
The Chair reminded members to declare any interests in any of the products to be discussed.

1. Minutes of the previous meeting held on 13 December 2017

1.1 The minutes were approved as an accurate record of the meeting.

2. Matters arising from previous minutes

2.1 LJF Smoking Cessation Review
2.1.1 The committee noted the circulated PGD for varenicline supply and flowcharts to summarise the client pathway. These were requested following the section amendment adding varenicline as joint first choice along with NRT in July 2017.
2.1.2 The flowchart will be linked on the LJF website.

ACTION: AR
2.2 Treatment algorithm for the use of idebenone

2.2.1 The committee noted the information on idebenone on patient numbers and treatment length which was requested following the meeting in December 2017. An updated flow chart has also been received.

2.2.2 The committee agreed to classify idebenone (Raxone) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only

   ACTION: AR

2.3 Freestyle Libre

2.3.1 The committee noted the letter received from Dr Nicola Zammitt following the meeting in December 2017.

2.3.2 It was noted that this is a device and not an intervention so it’s unlikely any further clinical evidence or robust data on cost effectiveness will become available.

2.3.3 It was agreed that whilst it is preferred that prescribing should take place in secondary care for the first 6 months, that wasn’t possible due to logistics of HPBs not being routinely used. It was agreed to approve for prescribing in primary care following referral from secondary care. Follow up and review of patients to be undertaken by secondary care as proposed in the submission.

2.3.4 The committee decided to raise the issue of HBP use at ADTC, to ensure the issue is resolved to allow prescribing in secondary care for other similar situations in the future.

2.3.5 The committee noted that national work is ongoing to further define which patients will benefit from using Freestyle Libre. Any changes in patient selection would need to be mirrored in NHS Lothian patient choice. Eligible patients are as per Scottish Diabetes Group (SDG) guidance.

2.3.6 The committee agreed to classify Freestyle Libre as routinely available. Included on the Lothian Joint Formulary, for Specialist initiation only

   ACTION: AR

2.4 buprenorphine transdermal patch

2.4.1 The committee noted the response provided following previous discussion and agreed that not all the questions had been answered.

2.4.2 It was noted this is a generic drug and the costs have been taken from the Scottish drug tariff.

2.4.3 Patients criteria was discussed with concerns raised about use in the over 65s, and the partial agonist mode of action.

2.4.4 The committee agreed that there was no change to the previous decision made.

3. SMC Recommendations

3.1 progesterone (Utrogestan® Vaginal)

3.1.1 The committee noted and discussed the previously circulated submission and SMC report. Declarations of interest forms were included with the application and noted by the committee.
micronised progesterone vaginal capsules 200mg (Utrogestan®)  
SMC No. (935/13)

**ADVICE**: following a full submission

**micronised progesterone (Utrogestan®)** is accepted for use within NHS Scotland.

**Indication under review**: in women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.

In women receiving luteal support during ART cycles, micronised progesterone 200mg vaginal capsules administered three times daily were non-inferior to another progesterone preparation administered vaginally with respect to ongoing pregnancy rate at the end of the 12th week of gestation.

This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of progesterone (Utrogestan®) 200mg vaginal tablets. This advice is contingent on the continuing availability of the PAS in Scotland or a list price that is equivalent or lower.

3.1.2 It was noted that subsequent papers were received after distribution of the papers with amended costs and this is now cost neutral.

3.1.3 It was noted this is a replacement drug but there is no direct comparative data with Cyclogest and should be accepted as additional list rather than second choice as per the original request.

3.1.4 The committee agreed to classify micronised progesterone vaginal capsules (Utrogestan®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only

**ACTION**: AR

4. SMC latest ‘Not Recommended’ Medicines

4.1 nivolumab (Opdivo®) SMC 1285/18 is not recommended for use within NHS Scotland as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy.

4.2 obinutuzumab (Gazyvaro®) SMC 1286/18 is not recommended for use within NHS Scotland in combination with chemotherapy, followed by obinutuzumab maintenance therapy in patients achieving a response, for the treatment of patients with previously untreated advanced follicular lymphoma.

4.3 carbetocin (Pabal®) SMC 309/06 is not recommended for use within NHS Scotland for the prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anaesthesia.

4.4 eluxadoline (Truberzi®) SMC 1292/18 309/06 is not recommended for use within NHS Scotland in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D).

4.5 adalimumab for paediatric use (Humira®) SMC No 1305/18 is not recommended for use within NHS Scotland for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.
4.6 **ceftaroline fosamil infusion (Zinforo®) SMC No 1306/18** is not recommended for use within NHS Scotland for the treatment of:
- complicated skin and soft tissue infections in children from the age of 2 months
- community-acquired pneumonia in children from the age of 2 months

4.7 **ceftazidime/avibactam (Zavicefta®) SMC No 1307/18** is not recommended for use within NHS Scotland for the treatment of the following infections in adults:
- complicated intra-abdominal Infection (cIAI)
- complicated urinary tract infection (cUTI), including pyelonephritis
- hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)
- infections due to aerobic Gram-negative organisms in adult patients with limited treatment options

4.8 **metformin hydrochloride (Glucophage SR®) SMC No 1308/18** is not recommended for use within NHS for reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with impaired glucose tolerance and/or impaired fasting glucose, and/or increased HbA1C who are:
- at high risk for developing overt type 2 diabetes mellitus and
- still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months.

5. **Other Medicines Proposed for Use**

5.1 **pembrolizumab (Keytruda®)**
   5.1.1 The committee noted the FAF3 submission for pembrolizumab as monotherapy for the first line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults.
   5.1.2 This is a proposal to use this medicine for SMC approved indication but using a different dosing schedule which is off-label for this indication. (SMC No. 1239/17)
   5.1.3 It was noted that originally the costs were £7 million but it has been reassessed by the clinical team looking at weight based dosing instead and by doing so would reduce costs by £1.8 million.
   5.1.4 The Lung team will discuss with patients the alternate dosing schedule.
   5.1.5 It was noted that there is an impact on additional resources which will have implications for the service.
   5.1.6 The committee agreed to classify pembrolizumab (Keytruda®) as routinely available in line with local guidance — Added to the Additional List for Specialist use only. It has been categorised RED under the ADTC Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian. Included on the Additional List, for Specialist Use only

5.2 **melatonin 3mg capsules**
   5.2.1 The committee noted the FAF3 submission for unlicensed melatonin capsules for the management of sleep disorders in children with neurodevelopmental disorders (including ADHD, ASD & LD).
   5.2.2 This immediate release preparation would provide an additional formulation to the 2mg MR tablets, which is used off-label in this patient group. A recent change to the LJF, removed the 3mg tablets from the formulary and replaced them with the 2mg MR tablets
   5.2.3 The committee noted the challenges faced with this patient group. However, off-label use of a licensed medicine is preferred to using an unlicensed medicine. The 2mg MR tablets can be crushed to provide an immediate release preparation.
   5.2.4 It was agreed the committee’s previous decision still stands. Further discussion between CAMHS and the paediatric teams would be required to get consistency.

   **ACTION: AR**
6. SMC Abbreviated Submissions

6.1 darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®) (SMC No.1290/18)

<table>
<thead>
<tr>
<th>darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®)</th>
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<tr>
<td>SMC No.1290/18</td>
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**ADVICE:** following an abbreviated submission

darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza®) is accepted for use within NHS Scotland.

**Indication under review:** the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40kg).

SMC has previously accepted darunavir/cobicistat (Rezolsta®) and emtrictabine/tenofovir alafenamide (Descovy®). Symtuza® (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) provides a single-tablet alternative to Rezolsta® plus Descovy® at no additional cost.

6.1.1 It was noted that RHSC, RIDU at WGH and Chalmers at RIE have requested this to be used. Patient numbers are likely to be small (<20).

6.1.2 The committee agreed to classify darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

**ACTION:** AR

7. Non-submissions to Formulary Committee (90-day target)

7.1 eliglustat (Cerdelga®) (SMC No 1277/17)
Not routinely available as local clinical experts do not wish to add the medicines to the formulary at this time or there is a local preference for alternative medicines.

7.2 palbocicib (Ibrance®) (SMC No 1276/17)
Not routinely available as local clinical experts do not wish to add the medicines to the formulary at this time or there is a local preference for alternative medicines.

7.3 aviptadil phentolamine mesilate (Invicorp®) (SMC No 1284/17)
Not routinely available as local clinical experts do not wish to add the medicines to the formulary at this time or there is a local preference for alternative medicines.

8. Formulary Additions and Amendments

8.1 Formulary additions

**ADULT**

8.1.1 Chapter 3 Respiratory

8.1.1.1 The committee discussed and approved the changes to this section. Some late comments have been received from the working group and these will be incorporated in the final version. The LJF website will be updated.

**ACTION:** AR
8.1.2 Chapter 2 cardiovascular
8.1.2.1 The committee discussed and approved the changes to this section. The LJF website will be updated.

ACTION: AR

8.1.3 9.6 vitamins
8.1.3.1 The committee discussed and approved the changes to this section. The LJF website will be updated.

ACTION: AR

8.2 Formulary amendment request forms

8.2.1 ferric carboxymaltose (Ferinject®)
8.2.1.1 The committee noted the amendment request form for ferric carboxymaltose (Ferinject®)
8.2.1.2 There was discussion about whether this request was within licence and clarification is needed if patients are going straight to IV administration or trying oral.
8.2.1.3 It was noted that this would be a new section in the LJF and the committee felt that cardiology did not merit a section on its own to cover the use of ferric carboxymaltose (Ferinject®) and that it should be a consistent choice for all.
8.2.1.4 There was discussion about who would administer it and by whom and clarification on patient numbers.
8.2.1.5 The committee agreed to discuss with the clinical team to decide if use is within licence and therefore submit either a FAF1 or FAF3 rather than an amendment form.

ACTION: AR

8.2.2 leuprorelin (Prostap®)
8.2.2.1 The committee noted the amendment request form for leuprorelin (Prostap®)
8.2.2.2 It was noted there is no section in the LJF for drugs used in the Assisted Conception Unit. The team have submitted the amendment form for the purpose of Medicines Governance.
8.2.2.3 The use of leuprorelin (Prostap®) for down regulation in IVF cycle was accepted by the committee. Included on the Additional List, for Specialist Use only

ACTION: AR

8.2.3 adrenaline (Emerade®)
8.2.3.1 The committee noted the amendment request form for adrenaline (Emerade®)
8.2.3.2 It was noted that other brands of adrenaline do not manufacture a 500microgram dose.
8.2.3.3 No national guidance could be found to confirm that patients self-administer a 500mcg dose. Resus guidance advises this should be administered by a health professional. Emerade® is not licensed for use in children.
8.2.3.4 The committee agreed to seek further clarification on guidance and evidence from the clinical team

ACTION: AR

8.2.4 mesalazine (Mezavant® XL)
8.2.4.1 The committee noted the amendment request form for mesalazine (Mesavant® XL) with the declaration of interest.
8.2.4.2 It is proposed this will replace the Pentasa® brand following the new National Procurement GI contract. Mesavant® XL is now on contract.
8.2.4.3 This price only relates to secondary care cost and it was noted that the majority of prescribing takes place in primary care. Pentasa® is still cheaper than Mesavant® XL in primary care. It would therefore be inappropriate to switch brands.
8.2.4.4 The committee agreed to amend the prescribing note relating to cost in the LJF

ACTION: AR
9. NICE/SIGN/HIS Clinical Guidance
9.1 TA492 - atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable
   9.1.1 The committee noted and discussed the NICE technology appraisal.
9.2 TA493 - cladribine tablets for treating relapsing–remitting multiple sclerosis
   9.2.1 The committee noted and discussed the NICE technology appraisal.
9.3 TA494 - naltrexone–bupropion for managing overweight and obesity
   9.3.1 The committee noted and discussed the NICE technology appraisal
9.4 TA495 - palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer
   9.4.1 The committee noted and discussed the NICE technology appraisal.
9.5 TA496 - ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer
   9.5.1 The committee noted and discussed the NICE technology appraisal.

10.1 Volume 11, Issue 5, December 2017
   10.1.1 The committee noted the drug safety update
10.2 Volume 11, Issue 6, January 2018
   10.2.1 The committee noted the drug safety update

11. Single National Formulary
11.1 The committee noted the circulated proposed SNF chapter development process and the presentation from a Area Drugs and Therapeutics Committee collaborative meeting in December.
11.2 It was agreed that updates as available would come to Formulary Committee for information.

12. For Information Only
12.1 Formulary Committee Reports and Letters:
The committee noted the following Formulary Committee reports and letters:
   idebenone (Raxone®)
   • glecaprevir-pibrentasvir (Maviret®)
   • pegvisomant (Somavert®)
   • Freestyle Libre Sensor
   • tiotropium (Spiriva Respimat®)
   • olaratumab (Lartruvo®)

13. AOCB

14. Date of Next Meeting
   Wednesday 14th March 2018, 2.00pm, Meeting Room (8+9), Waverley Gate.

24th January 2018
Formulary Committee Administrator
prescribing@nhslothian.scot.nhs.uk
LOTHIAN FORMULARY COMMITTEE

(Please note submission date for papers is Tuesday 27th February 2018)

Apologies are to be sent to Committee Administrator prior to the submission deadline.