Minutes of the Formulary Committee meeting held on
31st May 2017 from 14.00 – 16.35
in Room 004, Ground Floor, Pentland House

Present:
Clare Andrews          Clinical Pharmacist, Western General Hospital
Dr Drummond Begg      General Practitioner, NHS Lothian
Krista Clubb           Nurse Prescribing Coordinator, NHS Lothian
Dr Jane Goddard        Renal Consultant, Royal Infirmary of Edinburgh
Dr Sara Hornibrook    General Practitioner, NHS Lothian
Liz Leitch             Formulary Pharmacist, NHS Borders (arrived at 14.10)
Dr Emma Morrison       Clinical Pharmacology Trainee, Royal Infirmary of Edinburgh
Alison Rowe            Formulary Pharmacist, NHS Lothian
Laura Shaw             Lead Pharmacist, Royal Hospital for Sick Children (in the chair)
Garry Todd             Lead Pharmacist, Royal Edinburgh Hospital and Roodlands Hospital
Dr Lucy Wall           Consultant Medical Oncologist, Western General Hospital

In attendance:
Zuzana Krajičovič     Medicines Management Committee Administrator

Apologies for absence:
Dr Maria Corretge     Consultant Geriatrician, St John’s Hospital, Livingston
Dr James Dear         Consultant Clinical Pharmacologist, Royal Infirmary of Edinburgh
Anne Gilchrist        Lead Pharmacist, Medicines Management Team
Dr Peter Hall          Consultant Medical Oncologist, Western General Hospital
Carol Holmes          Primary Care Pharmacist, NHS Lothian
Dr Simon Hurding      General Practitioner, NHS Lothian
Dr Walter Jamieson    General Practitioner, NHS Lothian
Ishthiaq Mohammed     Clinical Effectiveness Pharmacist, NHS Fife
Dr Andrew Watson      Consultant Psychiatrist, Royal Edinburgh Hospital

Welcome
The Chair welcomed Dr Drummond Begg, General Practitioner as a new member of the committee. Members introduced themselves in turn.

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 19th April 2017

1.1 The minutes were approved as an accurate record of the meeting subject to few typographical amendments.

ACTION: AR

31st May 2017
Formulary Committee Administrator
prescribing@nhslothian.scot.nhs.uk
2. Matters arising from previous minutes

2.1 diazepam
2.1.1 In March 2016 the committee reviewed an amendment request form to add diazepam 5mg tablets back on the formulary for the treatment of substance dependence. This was following a change where 5mg and 10mg diazepam were removed from the LJF due to the high street value and to allow for easier reduction regimes.

2.1.2 At the time of the meeting the committee agreed to an interim decision to add diazepam 5mg back on the LJF for short-term to allow work to be undertaken to reduce doses at a smaller cost implication for the service. It was agreed to re-evaluate this decision after 12 months.

2.1.3 The committee noted that the substance misuse team will be contacted to provide data on current usage of diazepam and to confirm whether they are at the stage to allow removal of 5mg tablets from the formulary. Feedback will be provided at the next meeting.

2.1.4 It was agreed to highlight this issue to the Medicines Utilisation and Review Group to monitor the usage of diazepam.

ACTION: AR

2.2 ibuprofen 5% gel
2.2.1 A formulary amendment request form was reviewed by the Formulary Committee in March 2017 for the use of ibuprofen 5% gel for the treatment of acute musculoskeletal (MSK) pain.

2.2.2 The committee agreed to include this product on the LJF and suggested referencing the advice related to patients with renal impairment with paracetamol and oxycodone guidance. In addition the committee asked for the reasons for excluding the oral NSAIDs from the inpatient analgesic strategy for severe or distressing acute MSK pain in patients aged >65 years old.

2.2.3 The committee discussed correspondence received from the clinical team. It was noted that the response included all requested information.

2.2.4 The committee thought that the rationale behind excluding the oral NSAIDs from the analgesic strategy for frail elderly patients would be good to highlight to prescribers. It was therefore agreed to add this information as a prescribing note in the relevant LJF section.

ACTION: AR

2.3 pregabalin
2.3.1 A FAF3 submission was made to the Formulary Committee in January 2017 for the use of pregabalin for the treatment of persistent/chronic pain in children aged 12-18 years where first-line treatments, amitryptiline and gabapentin, are not tolerated or ineffective.

2.3.2 The committee were unable to make a decision at the meeting and asked the applicants to revise the application to include treatment protocol and more accurate financial information.

2.3.3 The committee discussed the information received from the clinical team. It was noted that the response was very comprehensive and included all requested information. The applicants have confirmed that only capsules would be used.

2.3.4 It was noted that the treatment protocol is to be approved by the Paediatric and Neonatal Drug and Therapeutic Committee.
2.3.5 The committee agreed to classify pregabalin as routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as RED under the ADTC ‘Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian’.

ACTION: AR

2.4 Nutilis Clear powder

2.4.1 A formulary amendment request form was reviewed by the Formulary Committee in March 2017 for the use of Nutilis Clear powder for the management of dysphagia.

2.4.2 It was noted that the committee approved Nutilis Clear powder for the use by specialists only. However as the specialists in this area are not prescribers the clinical team requested the classification to be changed to Specialist initiation with prescribing in primary care or for use under specialist supervision.

2.4.3 The committee therefore agreed to change classification of Nutilis Clear powder to routinely available in line with local or regional guidance. Included on the LJF as a prescribing note, for Specialist initiation.

ACTION: AR

3. SMC Recommendations

3.1 deferasirox (Exjade®)

3.1.1 The committee noted and discussed the previously circulated submission and SMC report. No declarations of interest were included with the application.

deferasirox 125mg, 250mg, 500mg dispersible tablets (Exjade®) SMC No. (347/07)

ADVICE: following a resubmission considered under the ultra-orphan process:

deferasirox (Exjade®) is accepted for restricted use within NHS Scotland.

Indication under review: Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias.

The current advice relates only to use in the myelodysplastic syndrome (MDS) population.

SMC restriction: use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate -1 risk.

Plasma ferritin levels were statistically significantly reduced from baseline to end of study in two phase II/III open-label, single-arm studies of patients with MDS with an IPSS score of low or intermediate -1 risk.

SMC has previously accepted deferasirox for restricted use for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. This advice remains valid.

This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
3.1.2 The committee noted the FAF1 submission for the use of deferasirox (Exjade®) for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias.

3.1.3 It was noted that the local protocol has been developed and the prescribing will take place in secondary care only.

3.1.4 It was noted that deferasirox will be used as an additional treatment for patients with low or intermediate -1 risk myelodysplasia.

3.1.5 The committee noted that deferasirox has already been used via the Individual Patient Treatment Request route.

3.1.6 The committee agreed to classify deferasirox (Exjade®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

**ACTION:** AR

3.2 obinutuzumab (Gazyvaro®)

3.2.1 The committee noted and discussed the previously circulated submission and SMC report. Two declarations of interest were included with the application and noted by the committee.

<table>
<thead>
<tr>
<th>obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMC No. (1219/17)</td>
</tr>
</tbody>
</table>

**ADVICE:** following a full submission considered under the ultra-orphan medicine process

**obinutuzumab (Gazyvaro®)** is accepted for use within NHS Scotland.

**Indication under review:** obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.

Obinutuzumab plus bendamustine induction therapy followed by obinutuzumab maintenance significantly increased progression free survival compared with bendamustine monotherapy induction without any maintenance treatment, in patients with rituximab-refractory follicular lymphoma.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obinutuzumab. This advice 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.

3.2.2 The committee noted the FAF1 submission for the use of obinutuzumab (Gazyvaro®) in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.

3.2.3 It was noted that a master prescription chart has been developed and prescribing will take place in secondary care only.

31st May 2017  
Formulary Committee Administrator  
[prescribing@nhslothian.scot.nhs.uk](mailto:prescribing@nhslothian.scot.nhs.uk)
3.2.4 The committee noted that this product will replace R-CHOP. It was also noted that rituximab maintenance treatment in the relapse setting is currently given only to patients who had not received maintenance following first-line therapy.

3.2.5 The committee were concerned that the incidence would be higher than the estimated patient numbers noted in the application.

3.2.6 It was noted that a PAS is available for the use of this medicine.

3.2.7 The committee agreed to classify obinutuzumab (Gazyvaro®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

**ACTION: AR**

### 3.3 adalimumab (Humira®)

3.3.1 The committee noted and discussed the previously circulated submission and SMC report. No declarations of interest were included with the application.

<table>
<thead>
<tr>
<th>adalimumab 40mg/0.8mL solution for injection (Humira®)</th>
<th>SMC No. (1143/16)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADVICE:</strong> following a full submission:</td>
<td></td>
</tr>
<tr>
<td>adalimumab (Humira®) is accepted for use within NHS Scotland.</td>
<td></td>
</tr>
</tbody>
</table>

**Indication under review:** treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

Evidence from two double-blind, randomised studies demonstrated significant reductions in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks with adalimumab compared with placebo.

3.3.2 The committee noted the FAF1 submission for the use of adalimumab (Humira®) for the treatment of active moderate to severe HS (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

3.3.3 It was noted that the local protocol has been developed and that prescribing will take place in secondary care.

3.3.4 It was noted that adalimumab would be used in patients who have failed to respond to conventional systemic therapy for HS or are intolerant to or have contra-indications to these treatments.

3.3.5 It was noted that the applicants have not included sufficient information in regards to the pre-screening and responsibility for monitoring of patients, including the estimated costs for these services. Confirmation is also required on who will provide the training to patients on self-administration of the injections.

3.3.6 It was therefore agreed to ask the applicants to add a section for monitoring in the treatment protocol where they would clearly define the requirements and whether the responsibility to carry these out would lie with secondary or primary care.

3.3.7 The committee agreed to classify adalimumab (Humira®) as not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 5th October 2017.

**ACTION: AR**
3.4 trastuzumab emtansine (Kadcyla®)

3.4.1 The committee noted and discussed the previously circulated submission and SMC report. Two declarations of interest were included with the application and noted by the committee.

<table>
<thead>
<tr>
<th>trastuzumab emtansine 100mg and 160mg powder for concentrate for solution for infusion (Kadcyla®)</th>
<th>SMC No. (990/14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVICE: following a resubmission assessed under the orphan and end of life process:</td>
<td></td>
</tr>
<tr>
<td>trastuzumab emtansine (Kadcyla®) is accepted for use within NHS Scotland.</td>
<td></td>
</tr>
</tbody>
</table>

**Indication under review:** as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for locally advanced or metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

In a randomised phase III open-label study, trastuzumab emtansine (Kadcyla®) conferred a significant survival benefit compared with an active comparator.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of trastuzumab emtansine (Kadcyla®). This advice 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.

3.4.2 The committee noted the FAF1 submission for the use of trastuzumab emtansine (Kadcyla®) as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.

3.4.3 It was noted that a master prescription chart has been developed and that prescribing will take place in secondary care only.

3.4.4 It was noted that this is an additional treatment option and will not replace any existing therapies. Once use is established it will most often be used in the third-line setting following two lines of treatment with trastuzumab and chemotherapy and occasionally in the second-line setting. There is however currently a prevalent population of patients with HER2+ve metastatic breast cancer who will receive it in later lines of treatment.

3.4.5 It was noted that in patients who develop disease recurrence during or within six months of completing adjuvant therapy this may be used as a first-line treatment for advanced / metastatic disease.

3.4.6 It was noted that a PAS is available for the use of this medicine.
3.4.7 The committee agreed to classify trastuzumab emtansine (Kadcyla®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

ACTION: AR

3.5 micronised progesterone (Utrogestan Vaginal®)

3.5.1 The committee noted and discussed the previously circulated SMC report.

| micronised progesterone vaginal capsules 200mg (Utrogestan Vaginal®) |
| SMC No. (935/13) |

ADVICE: following a full submission:

micronised progesterone (Utrogestan Vaginal®) 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 micronised progesterone (Utrogestan Vaginal®). This advice is contingent on the continuing availability of the PAS in Scotland or a list price that is equivalent or lower.

3.5.2 The committee noted and discussed the feedback received from the clinical team regarding the use of micronised progesterone (Utrogestan Vaginal®) for the use in women for supplementation of the luteal phase during ART cycles.

3.5.3 It was noted that a PAS is available for the use of this medicine.

3.5.4 The committee agreed to classify micronised progesterone (Utrogestan Vaginal®) as not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines.

ACTION: AR

3.6 emtricitabine / tenofovir disoproxil (Truvada®)

3.6.1 It was noted that due to the absence of Clinical Director's authorisation the formulary application for emtricitabine / tenofovir disoproxil will not be considered at this meeting.

3.6.2 The committee agreed to classify emtricitabine / tenofovir disoproxil (Truvada®) as not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 5th October 2017.

ACTION: AR
3.7 idarucizumab (Praxbind®)

3.7.1 The committee noted and discussed the previously circulated submission and SMC report. One declaration of interest was included with the application and noted by the committee.

<table>
<thead>
<tr>
<th>idarucizumab 2.5g/50mL solution for injection/infusion (Praxbind®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMC No. (1178/16)</td>
</tr>
</tbody>
</table>

**ADVICE:** following a full submission:

idarucizumab (Praxbind®) is accepted for use within NHS Scotland.

**Indication under review:** idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

In a phase III, non-randomised, case series study, treatment with idarucizumab reversed the effect of dabigatran, with a median maximum percentage reversal of 100%.

3.7.2 The committee noted the FAF1 submission for the use of idarucizumab (Praxbind®) as a specific reversal agent for dabigatran. It is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

3.7.3 It was noted that the local protocol has been developed and that prescribing will take place in secondary care.

3.7.4 It was noted that idarucizumab will be used in adult patients presenting to Accident and Emergency who require rapid reversal of anticoagulant effect of dabigatran due to life threatening or uncontrolled bleeding.

3.7.5 It was noted that dabigatran is not routinely available in NHS Lothian and therefore it is anticipated that the patient numbers would be low. The clinical team proposed to keep a small supply for emergency use only.

3.7.6 The committee agreed to classify idarucizumab (Praxbind®) as routinely available in line with national guidance. Included on the Additional List, for Specialist Use only on advice of a Haematologist.

3.7.7 It was also agreed to add a stronger message into the treatment protocol to highlight that idarucizumab should only be used if advised to do so by a haematologist.

**ACTION:** AR

4. **SMC latest ‘Not Recommended’ Medicines**

4.1 alectinib hydrochloride (Alecensa®) SMC No. 1257/17 is not recommended for use within NHS Scotland as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib.

4.2 ibritinib (Imbruvica®) SMC No. 1258/17 is not recommended for use within NHS Scotland in combination with bendamustine and rituximab for the treatment of adult...
patients with chronic lymphocytic leukaemia who have received at least one prior therapy.

4.3 *liraglutide (Saxenda<sup>®</sup>) SMC No. 1247/17* is not recommended for use within NHS Scotland as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of

- $\geq 30\text{kg/m}^2$ (obese), or
- $\geq 27\text{kg/m}^2$ to $< 30\text{kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

4.4 *pertuzumab (Perjeta<sup>®</sup>) SMC No. 897/13* is not recommended for use within NHS Scotland for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

4.5 *safinamide (Xadago<sup>®</sup>) SMC No. 1259/17* is not recommended for use within NHS Scotland for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

4.6 *talimogene laherparepvec (Imlygic<sup>®</sup>) SMC No. 1248/17* is not recommended for use within NHS Scotland for the treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.

5. Other Medicines Proposed for Use

5.1 *silver alginate dressing (Silvercel<sup>®</sup>)*

5.1.1 The committee noted the FAF2 submission for the use of silver alginate dressing (Silvercel<sup>®</sup>) for the treatment of colonised and infected wounds in adult patients at the Spittal Street Centre (Substance Misuse Directorate).

5.1.2 No declarations of interest were included with the submission.

5.1.3 It was noted that a local protocol has not been developed and prescribing will be carried out by an independent nurse prescriber.

5.1.4 It was noted that silver alginate dressing is currently being used via the non-formulary request route in adult patients with wounds that appear to be heavily colonised with micro-organisms and which would benefit from a short burst of broad-spectrum topical anti-microbial therapy. This is aimed at preventing progression to full blown wound infection requiring systemic antibiotics.

5.1.5 It was noted that silver dressings were removed from the formulary due to the lack of evidence on their clinical effectiveness. There is no new evidence that merits a review of this decision.

5.1.6 The committee were concerned that by including this product on the formulary its use may become more widespread.

5.1.7 The committee therefore agreed that the classification of silver alginate dressing (Silvercel<sup>®</sup>) remains as not routinely available as local clinical experts do not wish to
5.1.8 The silver alginate dressing (Silvercel®) will continue to be available via the non-formulary request route after all formulary products have failed or are considered unsuitable for the individual.

ACTION: AR

6. SMC Abbreviated Submissions

6.1 adalimumab (Humira®)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Description</th>
<th>SMC No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen</td>
<td></td>
<td>(1243/17)</td>
</tr>
<tr>
<td>adalimumab (Humira®) 40mg/0.8mL vial for paediatric use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ADVICE: following an abbreviated submission

adalimumab (Humira®) is accepted for use within NHS Scotland.

Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.

SMC has previously accepted adalimumab for the treatment of active moderate to severe HS (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

6.1.1 Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 5th October 2017.

ACTION: AR

6.2 budesonide / formoterol (Symbicort® SMART®)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Description</th>
<th>SMC No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>budesonide / formoterol 100micrograms / 6micrograms and 200micrograms / 6micrograms inhalation powder (Symbicort® SMART®)</td>
<td></td>
<td>(1244/17)</td>
</tr>
</tbody>
</table>

ADVICE: following an abbreviated submission

budesonide / formoterol (Symbicort® SMART®) is accepted for use within NHS Scotland.

Indication under review: the regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and “as needed” short-acting β2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.

This advice relates to the extension of the license for Symbicort maintenance and reliever therapy (SMART®) to adolescents aged 12 to <18 years. SMC has previously accepted Symbicort maintenance and reliever therapy (SMART®) in adults.
6.2.1 Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

ACTION: AR

6.3 buprenorphine oral lyophilisate (Espranor®)

<table>
<thead>
<tr>
<th>buprenorphine 2mg, 8mg oral lyophilisate (Espranor®)</th>
<th>SMC No. (1245/17)</th>
</tr>
</thead>
</table>

**ADVICE:** following an abbreviated submission

**buprenorphine oral lyophilisate (Espranor®)** is accepted for restricted use within NHS Scotland.

**Indication under review:** Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.

**SMC restriction:** to patients in whom methadone is not suitable.

Buprenorphine oral lyophilisate provides an alternative to buprenorphine/naloxone sublingual (SL) tablets at reduced cost. The oral lyophilisate formulation has the advantage of a faster dissolution time.

Prescribers should be aware that available buprenorphine preparations are not interchangeable.

Generic buprenorphine SL tablets are available at lower cost.

This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improves the cost effectiveness of buprenorphine oral lyophilisate. This advice is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower.

6.3.1 It was noted that PAS is available for the use of this medicine.
6.3.2 Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

ACTION: AR
6.4 deferasirox (Exjade®)

Deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®)  
SMC No. (1246/17)

**ADVICE:** following an abbreviated submission

Deferasirox film-coated tablets (Exjade®) is accepted for restricted use within NHS Scotland.

**Indication under review:**
- Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.
- Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:
  - in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years,
  - in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older,
  - in adult and paediatric patients with other anaemias aged 2 years and older.

**SMC restriction:** deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07).

Deferasirox film-coated tablets will replace deferasirox dispersible tablets which are to be discontinued. Deferasirox film-coated tablets demonstrated higher bioavailability compared to the deferasirox dispersible tablet formulation and therefore a dose adjustment is required when switching from dispersible tablets to film-coated tablets. Deferasirox film-coated tablets cannot be accepted for use in treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older as a full submission has not been received by SMC for this indication.

6.4.1 Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.

**ACTION:** AR
6.5  nepafenac (Nevanac®)

<table>
<thead>
<tr>
<th>Nepafenac 3mg/mL eye drops, suspension (Nevanac®)</th>
<th>SMC No. (1228/17)</th>
</tr>
</thead>
</table>

**ADVICE:** following an abbreviated submission

**nepafenac (Nevanac®)** 3mg/mL eye drops are accepted for use within NHS Scotland.

**Indication under review:** reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

Nepafenac 3mg/mL eye drops provide a once daily alternative to nepafenac 1mg/mL eye drops (administered three times daily). The cost of a course of treatment is the same for both formulations.

Nepafenac 3mg/mL is also licensed for the prevention and treatment of postoperative pain and inflammation associated with cataract surgery. The company submission related only to reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. SMC cannot recommend the use of nepafenac eye drops for postoperative pain and inflammation associated with cataract surgery.

6.5.1  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  daclizumab (Zinbryta®) SMC No. 1216/17

7.1.1  Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines.

**ACTION:** AR

7.2  ibrutinib (Imbruvica®) SMC No. 1151/16

7.2.1  Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 5th October 2017.

**ACTION:** AR

7.3  ixekizumab (Taltz®) SMC No. 1223/17

7.3.1  Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines.

**ACTION:** AR
8. Formulary Additions and Amendments

8.1 Formulary Additions

ADULT
8.1.1 Section 1.3 (b) – Drugs for the treatment of H. pylori-associated dyspepsia
8.1.1.1 The committee discussed and approved the changes to this section. The LJF website will be updated.

ACTION: AR

CHILD
8.1.2 Section 9.6.4 – Calcium and vitamin D supplements
8.1.2.1 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 calcipotriol 50micrograms/g and betamethasone 0.5kg/g cutaneous foam (Enstilar®)
8.2.1.1 The committee noted the amendment request form to include calcipotriol 50micrograms/g and betamethasone 0.5kg/g cutaneous foam (Enstilar®) on the LJF for topical treatment of psoriasis vulgaris in adults.
8.2.1.2 No declarations of interest were included with the submission.
8.2.1.3 It was noted that Enstilar® has been shown to have greater antipsoriatic effect over four weeks of treatment in comparison to Dovobet® ointment with a comparable tolerability profile.
8.2.1.4 It was noted that Enstilar® is a cutaneous foam which is simple and fast to apply, quickly absorbent and non-greasy.
8.2.1.5 The committee agreed to classify calcipotriol 50micrograms/g and betamethasone 0.5kg/g cutaneous foam (Enstilar®) as routinely available in line with national guidance. Included on the LJF as a prescribing note, for General Use.

ACTION: AR

8.2.2 Zarzio filgrastim
8.2.2.1 The committee noted the amendment request form to include Zarzio filgrastim on the LJF for primary or secondary prophylaxis of neutropenia; treatment of profound neutropenia associated with sepsis and mobilisation of autologous stem cells for transplants.
8.2.2.2 No declarations of interest were included with the submission.
8.2.2.3 It was noted that this product will replace lenograstim which is no longer used.
8.2.2.4 It was noted that lipegfilgrastim will remain on formulary as second choice agent for patients unable to self-inject.
8.2.2.5 The committee agreed to classify Zarzio filgrastim as routinely available in line with local or regional guidance. Included on the LJF as a first choice, for Specialist initiation.

ACTION: AR

31st May 2017
Formulary Committee Administrator
prescribing@nhslothian.scot.nhs.uk
9. **NICE/SIGN/NHS QIS Clinical Guidance**

9.1 **MTA439 – Cetuximab and panitumumab for previously untreated metastatic colorectal cancer**

9.1.1 The committee noted and discussed the NICE technology appraisal.
9.1.2 It was noted that the LJF recommendations are in line with this guideline.

9.2 **CG61 – Irritable bowel syndrome in adults: diagnosis and management**

9.2.1 The committee noted and discussed the NICE clinical guideline.
9.2.2 It was noted that the LJF recommendations are in line with this guideline.

9.3 **CG158 – Antisocial behaviour and conduct disorders in children and young people: recognition and management**

9.3.1 The committee noted and discussed the NICE clinical guideline.
9.3.2 It was noted that some implications have been identified for the LJF.
9.3.3 It was agreed to contact the Working Group to review the formulary section in relation to this guideline.

**ACTION: AR**

9.4 **NG28 – Type 2 diabetes in adults: management**

9.4.1 The committee noted and discussed the NICE guideline.
9.4.2 It was noted that the LJF recommendations are in line with this guideline. An algorithm which is part of the guideline has been highlighted to the members and it was suggested to consider including a link to this algorithm on the LJF.

**ACTION: AR**

9.5 **CG174 – Intravenous fluid therapy in adults in hospital**

9.5.1 The committee noted and discussed the NICE clinical guideline.
9.5.2 It was noted that the LJF recommendations are consistent with this guideline.

10. **Drug Safety Issues – MHRA Advice**

10.1 **MHRA Drug Safety Update, Volume 10, Issue 9, April 2017**

10.1.1 The committee noted the drug safety update.
10.1.2 The committee noted the new alert regarding the use of valproate and neurodevelopmental disorders, asking for patient review and further consideration of risk minimisation measures.
10.1.3 It was noted that this information has been widely communicated to the relevant audience via various routes.

11. **Guidelines for consideration**

11.1 **NHS Lothian Primary Care Summary Guidance for the Investigation and Management of Hypertriglyceridaemia, April 2017**

11.1.1 The committee discussed the above guidance and noted that it is consistent with the current formulary recommendations.
11.1.2 It was agreed to feed this back to the ADTC.

**ACTION: AR**
11.2 Lothian Hypertension Guidelines 2017
11.2.1 The committee discussed the above guidelines and noted that they are consistent with the current formulary recommendations.
11.2.2 It was agreed to feed this back to the ADTC.

ACTION: AR

11.3 Lothian Lipid Management in Adults Guideline 2017
11.3.1 The committee discussed the above guideline and noted that it is consistent with the current formulary recommendations.
11.3.2 It was agreed to feed this back to the ADTC.

ACTION: AR

12. Formulary Committee Annual Report 2016/17
12.1 The committee discussed and approved the annual report.
12.2 It was agreed to send this to the ADTC and the Medical Director for information.

ACTION: AR

13. Single National Formulary Event - feedback
13.1 Feedback was given to the committee members following the Single National Formulary Event held in May. It was noted that further stakeholder events will be held in the early future.

14. For Information Only

14.1 Formulary Committee Letters and Reports
The committee noted the following Formulary Committee reports and letters:
- cabazitaxel (Jevtana®)
- everolimus (Afinitor®)
- osimertinib (Tagrisso®)
- trifluridine, tipiracil (Lonsurf®)
- vortioxetine (Brintellix®)
- bendamustine (Levact®)
- PCV – procarbazine, lomustine (CCNU) and vincristine
- pirenzepine (Gatrozepin®)
- rituximab, methotrexate, cytarabine and thiotepa (MATRIX)
- botulinum toxin type A (BOTOX®)
- evolocumab (Repatha®)
- obinutuzumab (Gazyvaro®)

15. AOCB
None to note.
Date of Next Meeting
Wednesday 5th July 2017, 2.00pm, Room 004, Ground Floor, Pentland House
(Please note submission date for papers is Tuesday 20th June 2017). **Apologies are to be sent to Committee Administrator prior to the submission deadline.**

Apologies: Dr M Corretge