CONFIRMED

MINUTES OF THE MEETING OF THE FIFE FORMULARY COMMITTEE HELD AT 1.00PM ON WEDNESDAY 24 JANUARY 2018 IN THE PENTLAND SUITE, WHYTEMAN’S BRAE HOSPITAL, KIRKCALDY

Present: Dr Steve Rogers, Consultant Haematologist (Chair)  
Dr Emma Christmas, GP  
Dr Lorna Fleming, GP, Local Medical Committee Representative  
Ms Fiona Eastop, Deputy Lead Pharmacist East Fife  
Dr Linda McGourty, GP  
Mr Fraser Notman, Prescribing Support Pharmacist  
Mr Euan Reid, Senior Practice Pharmacist  
Mr Iain Rivans, Acute Pharmacy Representative  
Ms Kirsten Smith, Dispensary Manager

In attendance: Mrs S MacDonald (minutes)

1 APOLOGIES FOR ABSENCE

Apologies for absence were noted for Pauline Buchanan, Jenni Sinclair and Tanya Sullivan.

Dr Rogers highlighted an email from Mr Mohammed thanking the members of the Committee for all the help and support provided to him in his role as Clinical Effectiveness Pharmacist. Dr Rogers, on behalf of the Committee, thanked Mr Mohammed and wished him well in his new role.

2 MINUTES OF PREVIOUS MEETING ON 29 NOVEMBER 2017

The minutes from the meeting on 29 November 2017 were confirmed as a true record.

3 MATTERS ARISING

There were no matters arising.

4 DECLARATION OF INTERESTS

There were no declarations of interests.

5 FORMULARY SUBMISSIONS

5.1 Formulary Amendment - Acetylcysteine 600mg Effervescent Tablets

Ms Eastop introduced the Formulary Amendment for Acetylcysteine 600mg Effervescent Tablets (NACSYS®) for use as a mucolytic in respiratory disorders.
The Formulary Committee noted the following:

- The current first line Formulary choice mucolytic is Carbocisteine. It is proposed that an amendment be made to include Acetylcysteine 600mg Effervescent Tablets (NACSYS®) in the Formulary as first line choice mucolytic. Carbocisteine to remain on the Formulary as 2nd line choice.
- Acetylcysteine 600mg Effervescent Tablets (NACSYS®) is a licensed preparation. It has benefits for the patients as it is administered as one effervescent tablet per day compared to 4/6 Carbocisteine tablets and is a cost effective option.

The Formulary Committee approved the request to include Acetylcysteine 600mg Effervescent Tablets (NACSYS®) in the Formulary as first line choice mucolytic.

5.2 Formulary Amendment - Gluten Free Food Service

Mr Notman introduced the Formulary Amendment for the Gluten Free Food Service Formulary List.

The Formulary Committee noted the following:

Six items discontinued by the manufacturer have been removed from the Gluten Free Food Service list and four proposed items added to ensure that there is adequate choice and flexibility in the diet.

The Formulary Committee approved the amendments to the Gluten Free Food Service Formulary List.

5.3 Formulary Submission - Adalimumab (Humira®)

Ms Smith introduced the Formulary Submission for Adalimumab (Humira®) for uveitis.

The Formulary Committee noted the following:

- Adalimumab (Humira®) is licensed for the treatment of non infectious uveitis and is recommended within NICE Technology Appraisal Guidance [TA460] published in July 2017. The NICE Guidance supersedes the previous SMC advice issued in 2016.
- The proposed place in therapy and criteria for starting, stopping and monitoring is as defined in the NICE Guidance.
- Adalimumab has previously been used in NHS Fife on an off label basis for this indication.

The Formulary Committee approved the request to include Adalimumab (Humira®) in the Formulary for uveitis. Hospital use only.

5.4 Formulary Submission - Dexamethasone (Ozurdex®)

Ms Smith introduced the Formulary Submission for Dexamethasone (Ozurdex®) for uveitis.
The Formulary Committee noted the following:

- Dexamethasone (Ozurdex®) is licensed for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis and is recommended within NICE Technology Appraisal Guidance [TA460] published in July 2017. The NICE Guidance supersedes the previous SMC advice issued in 2012.
- The proposed place in therapy and criteria for patient selection is as defined in the NICE Guidance.

The Formulary Committee **approved the request to include Dexamethasone (Ozurdex®) in the Formulary for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. Hospital use only.**

5.5 Formulary Submission - Clomiphene Citrate (Clomid®)

Mr Notman introduced the Formulary submission for Clomiphene Citrate (Clomid®) for infertility as a consequence of hypogonadism.

The Formulary Committee noted the following:

- The proposed place in therapy is the treatment of infertility secondary to hypogonadism.
- Testosterone treatments pose a risk of irreversible testicular tissue damage and are not suitable for use in younger men of reproductive age. Clomiphene has a postive safety profile with regard to testicular damage and is a cost effective option. Clomiphene is used routinely in NHS England in younger patients suffering from hypogonadism.
- A pathway for use with selection criteria was approved by the MSDTC in November 2017.

The Formulary Committee **approved the request to include Clomiphene Citrate (Clomid®) in the Formulary for off-label use in the treatment of infertility as a consequence of hypogonadism.**

5.6 Formulary Submission - Bevacizumab

Ms Smith introduced the Formulary submission for Bevacizumab for the treatment of wet age related macular degeneration and briefed the Committee on the background to this.

The Formulary Committee noted the following:

- Confirmation of Clinical Director approval is awaited however it was agreed that the Formulary Committee should discuss the submission at this stage prior to referral to the ADTC.
- Current treatment options for the proposed indication are ranibizumab and aflibercept both of which are licensed in the UK for this indication and have been approved by the SMC. Bevacizumab is
not licensed in the UK for this indication.

- Recent NICE Guidance on the Management of Age-Related Macular Degeneration states that no clinically significant differences in effectiveness and safety between aflibercept, ranibizumab and bevacizumab have been seen in the trials considered by the guideline committee.
- Intraocular bevacizumab is widely used in many other countries and the Royal College of Ophthalmologists are supportive of its use for this indication.
- Guidance from the MHRA and GMC advises that a licensed product should be used where this is available.
- Bevacizumab is more cost effective than current treatment options.

Following discussion the Formulary Committee were supportive in principle of the Formulary submission for bevacizumab for wet age related macular degeneration. To be referred to the ADTC for consideration.

6 SMC RECOMMENDATIONS

6.1 SMC Recommendations issued November and December 2017

The Formulary Committee decisions are recorded in Appendix 1.

6.2 SMC Recommendations beyond 90 day target

The Formulary Committee discussed the SMC Recommendations beyond the 90 day target and agreed amendments to the decisions where required (Appendix 1).

6.3 SCAN Formulary Submissions

There were no SCAN Formulary Submissions approved by the Lothian Formulary Committee for consideration.

7 GUIDELINES / FORMULARY SECTIONS

There were no Guidelines/Formulary sections requiring consideration.

8 FORMULARY COMPLIANCE CHARTS

Mr Notman took the Committee through the Formulary Compliance Charts as at October 2017 for selected Formulary Chapters.

It was noted that Formulary compliance by volume has exceeded the 80% target for the majority of these chapters.

9 SINGLE NATIONAL FORMULARY UPDATE

The Single National Formulary December update was noted.

It was noted that the initial therapeutic areas to be developed are expected to be endocrinology, respiratory, cardiovascular and gastrointestinal. There is NHS Fife representation on the Single National
Formulary Group and a local clinician has been invited to Chair one of the Formulary Section subgroups.

10  NICE/SIGN GUIDANCE

None for discussion.

11  MHRA DRUG SAFETY UPDATE NOVEMBER 2017, DECEMBER 2017, JANUARY 2018

Mr Notman took the Committee through the MHRA Drug Safety Updates September 2017 and October 2017.

Mr Notman highlighted the following:

- Advice on prescribing of antiepileptic drugs and switching between different manufacturers’ products;
- Quinine - reminder of dose-dependent QT-prolonging effects and updated interactions;
- Drug name confusion - reminder to be vigilant for potential errors.
- Co-dydramol to be prescribed and dispensed by strength to minimise risk of medication errors.

Mr Rivans highlighted an update in the “Green Book” relating to the pneumococcal vaccine. Mr Rivans to email details to Mr Notman for forwarding to William John, Public Health Pharmacist.

12  ITEMS FOR NOTING

12.1 Minutes of Lothian Formulary Committee: 13 December 2017. For information.

12.2 Minutes of Tayside Medicines Advisory Group: 7 October 2017; 21 November. For information.

Mr Notman highlighted a forthcoming meeting between NHS Fife and NHS Tayside to discuss Formulary issues. Mr Notman to feed back to the Committee in due course.

13  ANY OTHER COMPETENT BUSINESS

There was no other business.

14  DATE OF NEXT MEETING

The next meeting is on Wednesday 21 March 2018 at 1.00pm in the Pentland Suite, Whyteman’s Brae Hospital, Kirkcaldy.
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Condition being treated</th>
<th>Decision of FC</th>
<th>Date of NHS Board decision</th>
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<tbody>
<tr>
<td>aviptadil / phenolamine 25 micrograms / 2mg solution for injection (Invicorp®)</td>
<td>Indication under review: For the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology. SMC restriction: for use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications.</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by 21 March 2018.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>eliglustat 84mg hard capsules (Cerdelga®)</td>
<td>Indication under review: for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers.</td>
<td>Routinely available from a specialist centre in another health board.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>Tiotropium 2.5 microgram inhalation solution (Spiriva Respimat®)</td>
<td>Indication under review: as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).</td>
<td>Not routinely available as local clinical experts do not wish to add to the Formulary at this time or there is a local preference for alternative medicines.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>palbociclib 75mg, 100mg and 125mg hard capsules (Ibrance®)</td>
<td>Indication under review: treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer: - in combination with an aromatase inhibitor; - in combination with fulvestrant in women who have received prior endocrine therapy. In pre- or peri-menopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. SMC restriction: in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer.</td>
<td>Not routinely available as local clinical experts do not wish to add to the Formulary at this time or there is a local preference for alternative medicines.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®)</td>
<td>Indication under review: for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.</td>
<td>Not routinely available as not recommended for use in NHSScotland</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>reslizumab 10mg/mL concentrate for solution for infusion (Cinqaero®)</td>
<td>Indication under review: as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment.</td>
<td>Not routinely available as not recommended for use in NHSScotland</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>bezlotoxumab 25mg/mL concentrate for solution for infusion (Zinplava®)</td>
<td>Indication under review: Prevention of recurrence of Clostridium difficile infection (CDI) in adults at high risk for recurrence of CDI.</td>
<td>Not routinely available as not recommended for use in NHSScotland</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>fulvestrant 250 mg solution for injection (Faslodex®)</td>
<td>Indication under review: Treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women who previously treated with endocrine therapy.</td>
<td>Not routinely available as not recommended for use in NHSScotland</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>Darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®)</td>
<td>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).</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by 21 March 2018.</td>
<td>24 January 2018</td>
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<tr>
<td>Adalimumab 40mg/0.4mL pre-filled syringe and pre-filled pen / adalimumab 40mg/0.4mL 40mg/0.8mL vial for paediatric use (Humira®)</td>
<td>Indication under review: 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.</td>
<td>Not routinely available as not recommended for use in NHSScotland</td>
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### Appendix 1: SMC Advice - Formulary Decisions

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<tr>
<td>Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) 1205/17</td>
<td>Indication under review: As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. <strong>SMC restriction:</strong> for use as a fourth line treatment option</td>
<td>Not routinely available as local clinical experts do not wish to add to the Formulary at this time or there is a local preference for alternative medicines.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) 1271/17</td>
<td>Indication under review: Treatment of chronic hepatitis C virus (HCV) infection in adults. <strong>SMC restriction:</strong> in patients with genotype 2, 5 or 6 chronic HCV infection, compensated cirrhosis, irrespective of chronic HCV genotype</td>
<td>Not routinely available as local clinical experts do not wish to add to the Formulary at this time or there is a local preference for alternative medicines.</td>
<td>24 January 2018</td>
</tr>
<tr>
<td>Olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo®) 1273/17</td>
<td>Indication under review: In combination with doxorubicin for the treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.</td>
<td>Not routinely available as local clinical experts do not wish to add to the Formulary at this time or there is a local preference for alternative medicines.</td>
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<tr>
<td>Pegvisomant 10mg, 15mg, 20mg, 25mg and 30mg powder and solvent for solution for injection (Somavert&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>for use in combination with doxorubicin as first-line treatment for advanced soft-tissue sarcoma not amenable to curative treatment with surgery or radiotherapy.</td>
<td>Treatment of adult patients with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise IGF-1 [insulin-like growth factor 1] concentrations or was not tolerated.</td>
<td>Routinely available from a specialist centre in another health board.</td>
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