Minutes of the Formulary Committee meeting held on 18th April 2012
in Room 004, Ground Floor, Pentland House

Present:
J Bradie Clinical Nurse Manager, Royal Infirmary of Edinburgh
Dr E Brown Consultant Oncologist, Western General Hospital
J Carson Lead Directorate Pharmacist, Royal Infirmary of Edinburgh
Dr P Conaglen Specialist Registrar in Public Health
Dr J Forbes Formulary Committee Co-Chair and Reader in Health Economics, University of Edinburgh
Dr SC Hornibrook General Practitioner, Lothian
Dr S Hurding General Practitioner, NHS Lothian
Dr W Jamieson General Practitioner, Lothian
S Kerr Lead Pharmacist, Western General Hospital
Professor S Lawrie Formulary Committee Co-Chair and Professor and Honorary Consultant Psychiatrist, Royal Edinburgh Hospital (in the chair)
I Mohammed Clinical Effectiveness Pharmacist, NHS Fife
J Pearson Formulary Pharmacist, NHS Lothian
Z Stofankova Formulary Committee Administrator
Dr D Wilks Consultant in Infectious Diseases, Western General Hospital

Apologies for absence:
Dr J Dear Consultant Clinical Pharmacologist, Royal Infirmary of Edinburgh
Dr H Gillett Consultant Gastroenterologist, St John’s Hospital
L Leitch Formulary Pharmacist, NHS Borders
L Shaw Lead Directorate Pharmacist, Royal Infirmary of Edinburgh
T Slaughter Clinical Effectiveness Pharmacist, North Cumbria Medicines Management Group
G Todd Lead Pharmacist, Royal Edinburgh Hospital and Roodlands Hospital
Dr R Williams General Practitioner, Lothian

Welcome:
The Chair welcomed new member Jackie Bradie, Clinical Nurse Manager, Royal Infirmary of Edinburgh to the Committee and members introduced themselves in turn.

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

1. Minutes of the previous meeting held on 7th March 2012

1.1 The minutes of the meeting of 7th March 2012 were approved as an accurate record of that meeting.

2. Matters arising from previous minutes

2.1 mycophenolate mofetil for nephrotic syndrome

2.1.1 A FAF3 submission for mycophenolate mofetil for the management of steroid-dependent nephrotic syndrome in paediatric patients was presented to Formulary Committee in September 2011. It was agreed that this treatment should be secondary care only so the draft Shared Care Protocol (SCP) provided with the submission was not supported.

2.1.2 The committee received an appeal to reconsider this decision and support the use of SCP.

2.1.3 It was noted that all of the current patients already receive mycophenolate mofetil from their GPs and there were no difficulties encountered with this so far. The GPs are familiar with prescribing this medication for transplant patients, but the use of mycophenolate in nephrotic syndrome is different and therefore a SCP would be required.

2.1.4 It was noted that patients are closely monitored and followed up by the specialist team. Those patients who are stable would be seen at clinic at 3 monthly intervals.

2.1.5 The committee agreed to change the classification on mycophenolate mofetil from RED to AMBER and to support the submission of the SCP to GPPC.

ACTION: JP/SL

2.2 bendamustine hydrochloride (Levact®) SMC No. 694/11

2.2.1 A FAF1 submission was made to Formulary Committee in March 2012. At that time, classification was deferred pending the receipt of more evidence for the use of bendamustine in combination with rituximab, although the committee acknowledged that it may only be possible through additional information on peer use by other hospitals in Scotland. Confirmation that there would be an additional benefit from the inclusion of rituximab was also required.

2.2.2 The committee noted and discussed the resubmitted FAF1 application received which included information from a current phase III German CLL trial comparing R-Bendamustine with FCR for first line therapy for CLL. An analysis of the first 100 patients was presented and it was found that response rates are similar in both arms (indicating that R-Bendamustine has a higher response rate to single agent bendamustine) with no safety concerns. However these data have not been published and have not been subject to peer review yet.

2.2.3 It was noted that there is good evidence for using bendamustine as single agent, but that until the outcomes from the German study are finalised there isn’t sufficient evidence to prove the benefit of using bendamustine in combination with rituximab.
2.2.4 It was noted that no information was provided by the clinical team on whether this combination of drugs is used by other hospitals in Scotland.

2.2.5 The committee agreed to approve the use of bendamustine hydrochloride (Levact®) as per the SMC advice and to add it to the Additional List as a first line treatment.

2.2.6 Bendamustine hydrochloride (Levact®) will be included on the Lothian Joint Formulary for the indication in question.

2.2.7 It was agreed that until further evidence is provided, the use of bendamustine in combination with rituximab can be undertaken via the non-formulary route.

ACTION: JP/SL

3. SMC Recommendations - FAF1s

3.1 rilpivirine (Edurant®)

3.1.1 The committee noted and discussed the previously circulated submission and SMC report. No declarations of interests were included with the application. A committee member noted a personal, non-specific interest.

<table>
<thead>
<tr>
<th>rilpivirine 25mg film-coated tablet (Edurant®)</th>
<th>No. 758/12</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVICE: following a full submission:</td>
<td></td>
</tr>
<tr>
<td>rilpivirine 25mg film-coated tablet (Edurant®)</td>
<td>is accepted for use within NHS Scotland.</td>
</tr>
</tbody>
</table>

Indication under review: rilpivirine in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/mL.

The non-inferiority of rilpivirine over another non-nucleoside reverse transcriptase inhibitor (when given in combination with two nucleoside reverse transcriptase inhibitors) for virological response was demonstrated in two phase III, comparative, multi-centre studies in antiretroviral treatment-naive patients.

3.1.2 The committee noted the FAF1 submission for the use of rilpivirine 25mg film-coated tablet (Edurant®) in combination with other antiretroviral medical products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/mL.

3.1.3 It was noted that the evidence is based on two similarly designed phase III double-blind, randomised studies conducted in anti-retroviral naïve adults comparing oral treatment with rilpivirine 25mg once daily versus efavirenz 600mg once daily given in conjunction with a background regimen of two nucleoside reverse transcriptase inhibitors.

3.1.4 It was noted that in both studies, more patients discontinued treatment because of an adverse event (AE) in the efavirenz group than in the rilpivirine group and there were higher rates of rash, neurological and psychiatric AEs in the efavirenz group compared to the rilpivirine group.
3.1.5 The committee noted that the economic model did not take account of the virological response rate between weeks 48 and 96 of the studies and this may have been in favour of rilpivirine as the data at 96 weeks were poorer.

3.1.6 It was noted that there are 30 patients per annum to be treated with this medication and a local Lothian protocol has not been developed.

3.1.7 It was agreed to add rilpivirine 25mg film-coated tablet (Edurant®) to the Additional List for Specialist Use only.

3.1.8 Rilpivirine 25mg film-coated tablet (Edurant®) will be included on the Lothian Joint formulary for the indication in question.

ACTION: JP/SL

3.2 rilpivirine / emtricitabine / tenofovir (Eviplera®)

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

| emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) | No. 759/12 |

ADVICE: following an abbreviated submission:

emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) is accepted for use within NHS Scotland.

Indication under review: treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤100,000 HIV-1 RNA copies/ml.

As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.

3.2.2 The committee noted the FAF1 submission for the use of emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤100,000 HIV-1 RNA copies/ml.

3.2.3 It was noted that there are 40 patients per annum to be treated with this medication and a local Lothian protocol has not been developed.

3.2.4 The committee noted that some patients require a once daily antiretroviral formulation which is a combination of these three drugs and there are additional benefits to the patients in using this combination of medication rather than the individual components.

3.2.5 The committee agreed to add emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) to the Additional List for Specialist Use only.
3.2.6 Emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) will be included on the Lothian Joint formulary for the indication in question.

ACTION: JP/SL

4. SMC latest ‘Not Recommended’ Medicines (March 2012)
The committee noted the following medicine not recommended for use by SMC in NHS Scotland:

4.1 belimumab (Benlysta®), Report No. 775/12, is not recommended for use within NHS Scotland as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive antidsDNA and low complement) despite standard therapy.

4.2 tocilizumab (RoActemra®), Report No. 774/12, is not recommended for use within NHS Scotland as monotherapy in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

4.3 NON-SUBMISSIONS

- catumaxomab (Removab®), Report No. 788/12, is not recommended for use within NHS Scotland as intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.

- everolimus (Votubia®) No. 787/12, is not recommended for use within NHS Scotland for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

- fampridine (Fampyra®), Report No. 789/12, is not recommended for use within NHS Scotland for improvement of walking in adult patients with multiple sclerosis with walking disability.

5. Other Medicines Proposed for Use - FAF2s and FAF3s

5.1 alemtuzumab (Mabcampath®)

5.1.1 The committee noted the FAF3 submission for the use of alemtuzumab (Mabcampath®) for the treatment of relapsed chronic lymphocytic leukaemia (CLL).

5.1.2 No declarations of interests were included with the application.

5.1.3 It was noted that alemtuzumab would be given to patients via a subcutaneous injection route, which is an off label use as the license is for intravenous use.
5.1.4 It was noted that the clinical team intends to use this drug as second line treatment; however, there has never been a phase III study for the treatment of relapsed CLL.

5.1.5 It was noted that The South East Scotland Cancer Group (SCAN) has considered the available data, and recently approved the CLL clinical management guideline which includes the use of alemtuzumab in relapsed/refractory disease for selected patients. A copy of the guideline has been included in the application. A local Lothian protocol has also been provided.

5.1.6 It was noted that there are no existing medicines on the formulary for the treatment of fludarabine refractory CLL.

5.1.7 The committee noted that due to small numbers of patients (3 in Lothian) who fit the criteria, the overall cost per annum to NHS Lothian is relatively small and the drug is currently used via the non-formulary request route. However alemtuzumab is associated with CMV reactivation in 9% of recipients which could potentially cause additional costs.

5.1.8 The committee agreed to add alemtuzumab (Mabcampath®) to the Additional List, for Specialist Use only, categorised RED under the ADTC policy for unlicensed and off label medicines.

**ACTION: JP/SL**

5.2 methylphenidate (Concerta XL®)

5.2.1 The committee noted the FAF3 submission for the use of methylphenidate (Concerta XL®) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adults (>18yr).

5.2.2 No declarations of interests were included with the application. A committee member noted a personal, non-specific interest.

5.2.3 The committee noted that methylphenidate is already approved and used under Shared Care Protocol (SCP) in children.

5.2.4 It was noted that the clinical team are proposing to add methylphenidate to the formulary as a first choice drug.

5.2.5 It was noted that the prevalence is high (15,900 patients = 3-4% in adult population) with 280 patients per annum treated in Lothian.

5.2.6 The committee noted that this medication would be used in patients with a diagnosis of ADHD requiring continuation of therapy commenced during childhood and adults diagnosed with ADHD following specialist assessment meeting criteria for trial of medication.

5.2.7 It was noted that the treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.2.8 It was noted that methylphenidate is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.2.9 The committee noted that the evidence is based on a few trials where some clinical effectiveness was demonstrated, but that more data is required on long-term effectiveness and in larger samples.

5.2.10 The main concern of the committee was that there is no indication about the length of treatment to be provided and therefore it is hard to predict the long-term use and safety of this drug in practice.

5.2.11 It was noted that because the duration of the treatment is not specified, and most of the patients are likely to be treated for several years, the cost implications could...
5.2.12 The committee were unclear on how the treatment would be reviewed and potentially discontinued in patients. The committee members felt that ongoing review by a specialist would be required and should be included in the SCP.

5.2.13 The committee agreed to add methylphenidate (Concerta XL®) to the LJF as a first choice drug, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: JP/SL

5.3 **atomoxetine (Strattera®)**

5.3.1 The committee noted the FAF3 submission for the use of atomoxetine (Strattera®) for the treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr).

5.3.2 No declarations of interests were included with the application.

5.3.3 The committee noted that atomoxetine is already approved and used under Shared Care Protocol (SCP) in children.

5.3.4 It was noted that the clinical team are proposing to add atomoxetine to the formulary as a second choice drug. The treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.3.5 It was noted that atomoxetine is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.3.6 It was proposed that atomoxetine would be used in 43 patients per annum in Lothian.

5.3.7 The committee noted that the patient criteria are the same as in methylphenidate. Atomoxetine will be considered as alternative to methylphenidate where this has been ineffective following an adequate trial, usually over 6 weeks, when methylphenidate has not been tolerated due to side effects or where co-morbidities make it a more appropriate choice. It may also be considered as first choice where there are concerns with drug misuse or the diversion of stimulants.

5.3.8 The committee noted that some clinical effectiveness was demonstrated but that more data is required on long-term effectiveness. It was noted that atomoxetine can affect blood pressure and heart rate, suicide-related behaviour and adversely effect patients with history of seizure. Therefore atomoxetine should be used with caution.

5.3.9 It was noted that, as with methylphenidate the main concerns of the committee were the duration of the treatment, long-term safety implications, review of patient treatment and the cost implications.

5.3.10 The committee agreed to add atomoxetine (Strattera®) to the LJF as a second choice drug, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: JP/SL
5.4  dexamphetamine (Dexetrine®)

5.4.1 The committee noted the FAF3 submission for the use of dexamphetamine (Dexetrine®) for the treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr).

5.4.2 No declarations of interests were included with the application.

5.4.3 The committee noted that dexamphetamine is already approved and used under Shared Care Protocol (SCP) in children.

5.4.4 It was noted that the clinical team are proposing to add dexamphetamine to the formulary as a third line therapy where other stimulant and non-stimulant medication has failed.

5.4.5 It was noted that the treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.4.6 It was noted that dexamphetamine is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.4.7 It was proposed that use would be in 7 patients per annum in Lothian.

5.4.8 The committee noted that the patient criteria are the same as for methylphenidate.

5.4.9 The committee noted that the evidence is based on one short-term randomised, double-blind, placebo-controlled study demonstrating the clinical effectiveness of dexamphetamine. The only significant side effect was weight loss. However studies of long-term efficacy have not been carried out yet.

5.4.10 It was noted that, as with the previously discussed ADHD drugs, the main concerns of the committee were the duration of the treatment, long-term safety implications, review of patient treatment and the cost implications.

5.4.11 The committee agreed to add dexamphetamine (Dexetrine®) to the LJF as a prescribing note, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: JP/SL

5.5  etonogestrel (Nexplanon®)

5.5.1 The committee noted the FAF3 submission for the use of etonogestrel (Nexplanon®) for the treatment of:

- Postpartum contraception for women with substance use issues whose lives are chaotic, find it difficult to access services and who are at high risk of an unintended pregnancy. For insertion within first 72 hours post delivery.

- Postpartum contraception for all other groups of women who find it difficult to access services and who are at high risk of an unintended pregnancy. For insertion within first 72 hours post delivery.

- Following abortion or miscarriage in second trimester – insertion within first 72 hours of abortion or miscarriage for all other groups of women who find it difficult to access services and who are at high risk of an unintended pregnancy.

5.5.2 One declaration of interest (personal specific) was included with the application.

5.5.3 It was noted that currently Depo-Provera, an injectable progestogen, is used immediately after delivery but it does require further injections every 12 weeks where Nexplanon® provides effective reversible contraception for 3 years.
5.5.4 The committee noted that Nexplanon® is currently the first choice contraceptive implant (only progestogen implant method available).

5.5.5 It was noted that there is a safety concern about bleeding after implant but there is no evidence that off label insertion within 72 hours of delivery would enhance this problem.

5.5.6 The committee agreed to add etonogestrel (Nexplanon®) to the Additional List, for Specialist Use only, categorised RED under the ADTC policy for unlicensed and off label medicines.

ACTION: JP/SL

5.6 domperidone (Motilium®)

5.6.1 The committee noted the FAF3 submission for the use of domperidone (Motilium®) for the augmentation of lactation.

5.6.2 No declarations of interests were included with the application.

5.6.3 It was noted that there are no licensed galactagogues in the UK. Domperidone is the galactagogue of choice based on its safety and efficacy. It can be effective in augmentation of lactation when used in combination with established non-pharmacological support and breastfeeding measures and only after these measures have failed to increase breast milk adequately.

5.6.4 It was noted that the evidence is based on a several small studies which proved that the milk production was significantly higher in women taking domperidone.

5.6.5 The committee noted that no cardiac side effects have been reported during the studies however use of domperidone should be avoided in women with known cardiac disease and those with a diagnosis or family history of premenstrual onset of breast cancer. There are also theoretical concerns about long-term effects on the maturation of central dopamine mechanism in the newborn.

5.6.6 It was noted that the applicants have drafted guidelines for domperidone for augmentation of lactation. It was suggested that it would be beneficial to involve a group of GPs in this work to finalise the guideline.

5.6.7 The committee noted that Medicines and Healthcare products Regulatory Agency has issued a warning regarding the use of domperidone which should be included in the maternity guidelines.

5.6.8 The committee agreed to add domperidone (Motilium®) to the formulary, categorised AMBER under the ADTC policy for unlicensed and off label medicines.

5.6.9 It was noted that this classification is provisional, pending the D&TC minutes being homologated.

ACTION: JP/SL
6. SMC Abbreviated Submissions

6.1 adrenaline tartrate pre-filled syringes (Jext®)

<table>
<thead>
<tr>
<th>Adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Jext®)</th>
<th>No. 687/11</th>
</tr>
</thead>
</table>

**ADVICE:** following an abbreviated submission:

adrenaline tartrate pre-filled syringes (Jext®) is accepted for use within NHS Scotland.

**Indication under review:** emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

For patients at risk of anaphylaxis and requiring adrenaline, this is a new presentation of adrenaline for emergency use. It has an extended shelf life (24 months) compared with some existing products.

6.1.1 It was noted that an amendment to the LJF section has been approved at the meeting in March 2012.

6.1.2 The committee agreed to add adrenaline tartrate pre-filled syringes (Jext®) to the Lothian Joint Formulary.

6.1.3 Adrenaline tartrate pre-filled syringes (Jext®) will be included on the Lothian Joint Formulary for the indication in question.

**ACTION:** JP

6.2 bupivacaine + fentanyl (as citrate) (Bufyl®)

<table>
<thead>
<tr>
<th>Bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®)</th>
<th>No. 738/11</th>
</tr>
</thead>
</table>

**ADVICE:** following an abbreviated submission:

bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) is accepted for use within NHS Scotland.

**Indication under review:** epidural analgesia to relieve pain during labour and to control post operative pain.

For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.

6.2.1 The decision made regarding this drug are no longer relevant, as following the meeting further information became available. This item will be brought back to the next FC meeting.

**ACTION:** JP
7. Formulary Additions and Amendments

7.1 Formulary Additions
None.

7.2 Formulary amendment request forms

7.2.1 Pentasa 1g tablets
7.2.1.1 The committee noted the request to amend the gastrointestinal section of the LJF where Pentasa tablets are currently as first choice for the treatment of mild to moderate exacerbations of ulcerative colitis and the maintenance of remission of ulcerative colitis. It was requested to add Pentasa 1g strength to the formulary.
7.2.1.2 The committee noted that Pentasa 1g tablets offer less (half) tablet burden to patients compared to Pentasa 500mg tablets. Currently patients have to take 8 tablets daily for treatment of an acute attack of colitis and 4 tablets for maintenance treatment. As a result, patients are often switched to Mezavant XL or Pentasa granules as these preparations allow less tablet burden.
7.2.1.3 It was noted that although Pentasa 1g tablets are slightly more expensive than Pentasa 500mg, this will be offset by less patients being switched to Mezavant XL which is a significantly more expensive preparation.
7.2.1.4 The committee agreed to amend the gastrointestinal section and add Pentasa 1g strength to the formulary.

ACTION: JP

7.2.2 Lidocaine 5% medicated plaster
7.2.2.1 The committee noted the request from paediatric pain team to change lidocaine 5% medicated plaster from second line treatment to first line for the treatment of neuropathic pain in children.
7.2.2.2 No declarations of interest were included with the application.
7.2.2.3 It was noted that lidocaine plasters are well tolerated, effective and often facilitate weaning of other medications.
7.2.2.4 The committee noted that lidocaine plasters will be obtained from secondary care outlets only and patients will remain under regular review by the pain management team while lidocaine patches are being prescribed.
7.2.2.5 It was noted that lidocaine is more expensive than the current first line treatment but this may be balanced by a likely reduced number of outpatient appointments and possibly a decrease in the use of other analgesics if the treatment is successful. It also has a more patient friendly side-effect profile and has less effect on patients’ daily routines.
7.2.2.6 The committee agreed to amend the pain management section of the paediatric LJF, section 4.7 analgesics and move lidocaine 5% medicated plaster to first choice.

ACTION: JP

7.2.3 Magnesium aspartate (Magnaspartate®)
7.2.3.1 The committee noted the formulary amendment request to replace magnesium glycerophosphate capsules with magnesium aspartate (Magnaspartate®).
7.2.3.2 No declarations of interests were included with the application.
7.2.3.3 It was noted that Magnaspartate® is licensed as a food supplement whereas magnesium glycerophosphate is an unlicensed special medicine.
LOTHIAN FORMULARY COMMITTEE

7.2.3.4 It was noted that Magnaspartate® has also reduced dosing, at 2 sachets per day, as compared to magnesium glycerophosphate capsules at 12 capsules per day. It was noted that potential cost savings in secondary care, based on the 2010/11 usage could be £7,000 per annum.

7.2.3.5 The committee noted that the oncology GP information sheet would need to be reviewed with a view to changing it to cover other clinical areas. Magnaspartate® does have high sugar content; therefore, keeping some glycerophosphate for diabetic patients may need to be considered.

7.2.3.6 The committee agreed to amend the section 9 of the LJF and replace magnesium glycerophosphate capsules with magnesium aspartate (Magnaspartate®). It was noted that the oncology GP information sheet needs to be reviewed.

ACTION: JP

8. NICE/SIGN/NHS QIS Clinical Guidance

March 2012
8.1 CG 139 Infection control – prevention and control of healthcare-associated infections
8.1.1 The committee noted and discussed the above NICE clinical guideline.

8.2 TA 249 Atrial fibrillation - dabigatran etexilate
8.2.1 The committee noted and discussed the above NICE technology appraisal guideline.

April 2012
8.7 TA 250 Breast cancer (advanced) - eribulin
8.7.1 The committee noted and discussed the above NICE technology appraisal guideline.


March 2012
9.1 MHRA Drug Safety Update, Volume 5, Issue 8, March 2012
9.1.1 The committee noted the drug safety update.

9.2 Ketoprofen-containing topical formulations
http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con146472.pdf
9.2.1 The committee noted the updated information.

9.3 Victrelis (boceprevir)
9.3.1 The committee noted the updated information.

9.4 Rasilez (aliskiren)
9.4.1 The committee noted the updated information.

9.5 Halaven (eribulin)
9.5.1 The committee noted the updated information.
9.6 Benlysta (belimumab)
9.6.1 The committee noted the updated information.

9.7 Onglyza (saxagliptin)
9.7.1 The committee noted the updated information.

9.8 Perfalgan (intravenous paracetamol)
9.8.1 The committee noted the updated information.

9.9 Samsca (tolvaptan)
9.9.1 The committee noted the updated information.

10. Antimicrobial Management Team Minutes
The committee noted the following AMT minutes for information:

- 15th February 2012

11. For Information Only

11.1 Formulary Committee Reports and Letters
The committee noted the following Formulary Committee reports and letters:

- boceprevir (Victrelis®) and telaprevir (Incivo®)
- levobupivacaine, sodium chloride, ketorolac and adrenaline
- prilocaine hydrochloride (Priloketal®)
- bendamustine hydrochloride (Levact®)
- erlotinib (Tarceva®)
- botulinum toxin type A (Botox®)
- epoetin (Eporatio®)
- exenatide (Byetta®)
- filgrastim (Nivestim®)
- filgrastim (Zarzivo®)
- iron isomaltoside (Monofer®)
- moxifloxacin (Avelox®)
- ticagrelor (Brilique®)
- valganciclovir (Valcyte®)
- valsartan (Diovan®)
- magnesium sulphate
12. AOCB

12.1 Formulary Management Audit
12.1.1 Further to the Formulary Management Audit Terms of Reference circulated to the FC members it was noted that the audit will commence from Monday 23rd April.
12.1.2 It was noted that it is not clear yet whether there would be any implications for FC members on an individual basis.

12.2 Formulary Committee Annual Reports for 2010/11 and 2011/12
12.2.1 It was noted that the annual reports were finalised and will be circulated to the FC members for their information.

13. Date of Next Meeting

13.1 The committee noted that the next meeting would be held on Wednesday 30th May 2012. (The deadline for submission of papers for this meeting is close of play Tuesday 15th May 2012.)

Apologies: Jenny Carson, Dr Philip Conaglen, Professor Stephen Lawrie