CONFIRMED

MINUTES OF THE MEETING OF THE FIFE FORMULARY COMMITTEE HELD AT 1.00PM ON WEDNESDAY 7 NOVEMBER 2018 IN THE PENTLAND SUITE, WHYTEMAN’S BRAE HOSPITAL, KIRKCALDY

Present:  Dr Steve Rogers, Consultant Haematologist (Chair)
          Dr Emma Christmas, GP
          Ms Fiona Eastop, Deputy Lead Pharmacist East Fife
          Dr David Griffith, Consultant Microbiologist
          Dr Glyn McCrickard, GP, LMC Representative
          Dr Linda McGourty, GP
          Mr Fraser Notman, Prescribing Support Pharmacist
          Ms Angela Sinclair, Acute Pharmacy Representative
          Ms Jenni Sinclair, Mental Health Pharmacist
          Ms Kirsten Smith, Dispensary Manager

In attendance:  Dr Anne Sergeant, Consultant Dermatologist (item 5)
                Mr Duncan Wilson, Senior Pharmacist - Medical
                Mrs S MacDonald, Admin Support (minutes)

1  APOLOGIES FOR ABSENCE

   Apologies were noted for Dr Sean Ainsworth and Mr Iain Rivans.

2  MINUTES OF PREVIOUS MEETING ON 29 AUGUST 2018

   The minutes from the meeting on 29 August 2018 were confirmed as a true record.

3  MATTERS ARISING

3.1 Committee Membership - Chair/Vice-Chair

   It was noted that no expressions of interest in the Chair/Vice-Chair positions had been received. Following discussion, Dr D Griffith agreed to take on the role of Vice-Chair. Ms F Eastop and Ms K Smith to discuss taking on the Chair role on a joint basis.

   Mr Notman highlighted that Ruth Cameron, Urology Clinical Nurse Specialist, has expressed an interest in Committee membership. A formal invitation has been extended to Ms Cameron and future Committee dates forwarded.

4  DECLARATION OF INTERESTS

   There were no declarations of interests.
FORMULATORY SUBMISSIONS

5.1 Formulary Submission - Brodalumab (Kynthem®)

5.2 Formulary Submission - Guselkumab (Tremfya®)

5.3 Formulary Submission - Ixekizumab (Taltz®)

Dr Sergeant took the Committee through the Formulary Submissions for Brodalumab (Kynthem®), Guselkumab (Tremfya®) and Ixekizumab (Taltz®) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.

The Formulary Committee noted the following:

- Brodalumab, guselkumab and ixekizumab have been accepted by the SMC for this indication, restricted to patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments.
- The core biologic medicines recommended for the treatment of moderate to severe plaque psoriasis target a different cytokine: brodalumab (IL17 receptor); guselkumab (IL23); and ixekizumab (IL17). There is evidence to support that if one agent fails, a subsequent therapy may be effective.
- Supply would be via Homecare and patients would be monitored through dermatology clinics.
- Use would be in line with the Pathway for Adults with Psoriasis which was approved by the MSDTC in October 2018.
- There is a favourable side effect profile compared to anti-tnf medicines. A slight increase in thrush was noted in relation to brodalumab and ixekizumab.

The Formulary Committee approved the request to include Brodalumab (Kynthem®), Guselkumab (Tremfya®) and Ixekizumab (Taltz®) in the Formulary for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy, restricted to patients who have failed to respond to standard systemic therapies, are intolerant to, or have a contraindication to these treatments.

5.4 Formulary Submission - Dupilumab (Dupixent®)

Dr Sergeant introduced the Formulary Submission for dupilumab (Dupixent®) for the treatment of moderate to severe eczema.

The Formulary Committee noted the following:

- Dupilumab (Dupixent®) was accepted by the SMC in August 2018 for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy, restricted to patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.
- Prescribing would be by Consultant Dermatologist only in line with
the treatment pathway. A Homecare national agreement is in place.

- Criteria for patient selection are moderate to severe disease and inadequate response or contraindication to systemic therapy.
- Dupilumab would provide an alternative treatment to a cohort of difficult to manage adult patients with atopic eczema.
- Cost implications to be highlighted to the Horizon Scanning Group.

The Formulary Committee approved the request to include dupilumab (Dupixent®) in the Formulary as second line choice after systemic therapy for moderate to severe atopic eczema.

5.5 Formulary Submission - Flexitol 10% Urea Cream

Mr Notman introduced the Formulary Submission for flexitol 10% urea cream for the treatment of rough, dry scaling and anhidrotic skin conditions.

The Formulary Committee noted the following:

- The criteria for patient selection are patients with dry anhidrotic skin, including ichthyosis and in diabetic foot care.
- Flexitol 10% urea cream is more cost effective than the current Formulary choice product for the proposed indication (hydromol intensive 10% urea cream).
- Switching of patients on repeats to be carried out by the Primary Care pharmacy teams.

The Formulary Committee approved the request to include flexitol 10% urea cream in the Formulary for the proposed indication.

5.6 Formulary Submission - Tocilizumab (RoActemra®)

Mr Notman introduced the Formulary Submission for Tocilizumab (RoActemra®) for the treatment of Giant Cell Arteritis (GCA) in adult patients.

The Formulary Committee noted the following:

- Tocilizumab (RoActemra®) was approved by the SMC in August 2018 for restricted use for this indication, subject to a 12 month clinical stopping rule.
- The request is to use Tocilizumab (RoActemra®) first line in patients with a diagnosis of GCA under the care of the Fife Rheumatic Disease Unit. Use would be in combination with a tapering course of prednisolone. A protocol for the treatment of GCA in adult patients has been produced.
- Any requests to use tocilizumab (RoActemra®) beyond the 12 month clinical stopping rule would require a PACS2 submission.
- To be supplied via Homecare. Additional rheumatology specialist nurse clinics to be set up to review and record patient outcomes. Real life data on treatment effectiveness and adverse events will also be recorded and reported.
• Clear guidance for GP practices around the tapering of steroid doses is required. Capacity issues within GP practices to carry out additional monitoring/blood tests were highlighted. It was suggested that any additional monitoring be undertaken within the rheumatology specialist nurse clinics and removed from GP responsibility within the protocol. Guidance for GPs on abnormal laboratory results would be useful.
• There is no Shared Care Agreement in place for Tocilizumab for this indication however a Shared Care Agreement was previously accepted for Tocilizumab for severe rheumatoid arthritis.

The Formulary Committee **approved the request to include Tocilizumab (RoActemra®) in the Formulary as first line treatment of GCA in adult patients, subject to a 12 month clinical stopping rule.**

5.7 **Formulary Submission - Edoxaban (Lixiana®)**

Mr Duncan Wilson took the Committee through the resubmitted request to add Edoxaban to the Formulary for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF). Mr Wilson briefed the Committee on the background to his involvement with the NHS Fife DOAC Short Life Working Group and the rationale for the group’s decision to put forward recommendations for two DOACS for different indications. A separate submission for apixaban for the treatment/prevention of DVT and PE is expected to be submitted to the Committee once appropriate guidance has been finalised. In the meantime rivaroxaban would remain on the Formulary for this indication.

The Committee noted the DOAC comparison information including trial evidence, safety, efficacy, potential costs/savings and information on DOAC use for AF/DVT/VTE across other Scottish Health Boards. The DOAC implementation plan detailing the proposed education and training events within the Acute Service and for Primary Care/GPs was also noted.

A concern was highlighted that including more than one DOAC on the Formulary could result in potential dosing error and an increased risk of significant events.

It was noted that NVAF accounts for approximately 75% of DOAC use within NHS Fife. Edoxaban is cost effective compared to apixaban and the current Formulary choice DOAC (rivaroxaban) for this indication.

A discussion about the proposed switch from rivaroxaban to edoxaban followed. Issues around resources within GP Practices to undertake switches and deal with any patient queries/issues were highlighted. Greater clarification with regard to doses/interactions is also required. It was noted that any proposed switch would be undertaken with pharmacy support. It was agreed that the proposed switch should be progressed in discussion with the LMC.

Following discussion the Formulary Committee **approved the request to include edoxaban (Lixiana®) in the Formulary for NVAF for new**
initiations only. The proposed switch programme to be discussed with the LMC.

5.8 Formulary Amendment - NRT

Mr Notman introduced the Formulary Amendment for nicotine replacement therapy (NRT). A change to the current Fife Formulary list of NRT formulations to reflect changes in the National Procurement Contract is proposed.

It was highlighted that NRT products are currently classified as specialist initiation/recommendation only by specialist stop smoking services and community pharmacies. It was noted that there is currently no inpatient NRT smoking cessation service and prescribing would be undertaken at ward level. Mr Notman to clarify if any change to the specialist initiation/recommendation Formulary classification is required to support prescribing by ward staff/GPs.

The Committee approved the Formulary Amendment request for NRT products.

5.9 Formulary Amendment - Varenicline (Champix®)

Mr Notman introduced the Formulary Amendment for Varenicline (Champix®).

The amendment is proposed to change the Formulary status of Varenicline from 2nd line option to joint 1st line. It was noted that safety concerns regarding varenicline have been allayed following publication of the Eagles Study in 2016. The study reported no increased risk in neuropsychiatric events in patients (with and without a history of psychiatric disorder) treated with varenicline or bupropion compared to nicotine replacement patch or placebo.

The Committee approved the Formulary Amendment request to change the status of Varenicline from 2nd line option to joint 1st line. Specialist initiation/recommendation only.

5.10 Formulary Submission - Dolutegravir/Rilpivirine (Juluca®)

Withdrawn from the agenda pending Clinical Director signature.

5.11 Formulary Submission - Bictegravir/Emtricitabine/Tenofovir alafenamide (Biktarvy®)

Withdrawn from the agenda pending Clinical Director signature.

5.12 Formulary Submission - Hydrocortisone (Alkindi®)

Mr Notman introduced the Formulary Submission for Hydrocortisone (Alkindi®) for replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old).
The Formulary Committee noted the following:

- The proposed indication for use is not in line with the SMC recommendation. Hydrocortisone (Alkindi®) was approved by the SMC in September 2018, restricted to the first-line treatment of infants and young children with adrenal insufficiency aged from birth to less than six years of age for whom hydrocortisone must otherwise be individually prepared by manipulation such as by compounding (or crushing) or by production of special solutions in order to produce age-appropriate doses, or hydrocortisone given as off-label buccal tablets.
- Hydrocortisone (Alkindi®) is the only licensed preparation for the dose required for use in children.
- Any requests to use outwith the SMC recommendation would require to be submitted through the PACS tier 2 process.
- The financial section in the Formulary Application does not reflect that larger doses would be required in adolescents potentially resulting in escalation of costs.
- The table in the Emergency Dosing Protocol requires clarification regarding the dose required for children aged 5 years (there are different doses for children 6m-5yr and 5yr-10yr).

The Formulary Committee did not approve the request to include Hydrocortisone (Alkindi®) for replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old).

6 SMC RECOMMENDATIONS

6.1 SMC Recommendations issued August/September/October 2018

The Formulary Committee decisions are recorded in Appendix 1.

Mr Notman advised that the table detailing SMC recommendations beyond the 90 day target will no longer be produced. Consultants will continue to be invited to make a submission and if no Formulary application is received within the 90 day period the medicine will automatically be classified as not available, in line with Health Improvement Scotland/ADTC-Collaborative guidance.

6.2 SCAN Formulary Submissions

The SCAN Formulary Submissions approved by the Lothian Formulary Committee are recorded in Appendix 1.

7 GUIDELINES / FORMULARY SECTIONS

7.1 Updated Wound Formulary

Mr Notman introduced the updated Wound Formulary and highlighted minor amendments including the substitution of more cost effective preparations where appropriate.
The Committee noted the updated Wound Formulary.

7.2 Antibiotic Guidance

- Hospital at Home

Dr Griffith advised that the Antibiotic Guidance for Hospital at Home Guidance has been updated in discussion with the Hospital at Home team, Pharmacy and Microbiology.

The Committee noted the updated Hospital at Home Guidance.

- Diagnosis and Management of Lyme Disease - GP Advice

Dr Griffith advised that the Diagnosis and Management of Lyme Disease guidance for General Practice has been updated to reflect NICE guidance released in April 2018. It was noted that treatment in patients under 12 years old should be discussed with Paediatrics and/or Microbiology.

Feedback from GP Committee members was that this was useful guidance.

The Committee noted the updated Diagnosis and Management of Lyme Disease - GP Advice.

- Neonatal Conjunctivitis Protocol

The Formulary Committee noted the updated Appendix 11A - Management of Neonatal Conjunctivitis.

7.3 Respiratory Appendices

- Appendix 3D - Choosing Asthma Inhaler Devices in Children
- Appendix 3E - Choosing Asthma Inhaler Devices in Children < 5 years

Ms Eastop advised that the respiratory appendices 3D and 3E had approached their review date and following review, no changes were required.

The Formulary Committee noted the revised appendices 3D and 3E.

8 SINGLE NATIONAL FORMULARY UPDATE

Mr Notman advised that project management responsibility for the Single National Formulary has been transferred to the Medicines Policy Team, Pharmacy and Medicines Division of the Scottish Government.

9 MHRA DRUG SAFETY UPDATE AUGUST/SEPTEMBER/OCTOBER 2018

Mr Notman took the Committee through the MHRA Drug Safety Updates for August, September and October 2018 and highlighted the following:
- *Esmya (ulipristal acetate)* - New restrictions for use and requirements for liver function monitoring before, during and after treatment.
- *Valproate Pregnancy Prevention Programme*. It was noted that a SLWG has been convened to take forward the actions required in NHS Fife.
- *Transdermal fentanyl patches* - Guidance on use and disposal of patches, particularly around children. It was agreed that this information should be highlighted to GP Practices.

10 **ITEMS FOR NOTING**

10.1 Minutes of Lothian Formulary Committee: 29 August, 3 October 2018. For information.


11 **ANY OTHER COMPETENT BUSINESS**

**Dr Rogers’ Retiral**

It was noted that this was Dr Rogers’ last meeting as he is retiring in mid December. Mr Notman thanked Dr Rogers for his work on behalf of the Formulary Committee and valuable insight from an SMC/NDC perspective.

12 **DATE OF NEXT MEETING**

The next meeting is on **Wednesday 16 January 2019** at 1.00pm in the Pentland Suite, Whyteman’s Brae Hospital, Kirkcaldy.
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Condition being treated</th>
<th>Recommendation to FC</th>
<th>Date of NHS Board decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>bictegovir / emtricitabine / tenofovir alafenamide (Biktarvy® SMC2093)</td>
<td>Indication under review: Treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.</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 16 January 2019.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>dupilumab SMC2011 (Dupixent®)</td>
<td>Indication under review: the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.</td>
<td>Routinely available in line with national guidance. SMC2011</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>tocilizumab, 16mg solution for injection in pre-filled syringe and pre-filled pen (RoActemra® SMC2014)</td>
<td>Indication under review: the treatment of Giant Cell Arteritis (GCA) in adult patients SMC restriction: treatment with tocilizumab is subject to a 12 month clinical stopping rule.</td>
<td>Routinely available in line with national guidance. SMC2014</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>dolutegravir / rilpivirine film-coated tablet (Juluca® SMC2091)</td>
<td>Indication under review: The treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA &lt;50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor.</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 16 January 2019.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>obinutuzumab SMC2015 (Gazyvaro®)</td>
<td>Indication under review: 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.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>pembrolizumab SMC No 1339/18 (Keytruda®)</td>
<td>Indication under review: as monotherapy, for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS)≥10.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>denosumab (Prolia® SMC2117)</td>
<td>Indication under review: Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>anakinra (Kinera® SMC 2194)</td>
<td>Indication under review: in adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still’s disease, including Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still’s Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs).</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 16 January 2019.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>gemtuzumab ozogamicin 5mg powder for concentrate for infusion (Mylotarg® SMC No 2099)</td>
<td>Indication under review: For combination therapy with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL). SMC restriction: use in patients with a favourable, intermediate or unknown cytogenetic profile.</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 16 January 2019.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>hydrocortisone 0.5mg, 1mg, 2mg and 5mg granules in capsules for opening (Alkindi® SMC2098)</td>
<td>Indication under review: replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to &lt;18 years old). SMC restriction: for the first-line treatment of infants and young children with adrenal insufficiency aged from birth to less than six years of age for whom hydrocortisone must otherwise be individually prepared by manipulation such as by compounding (or crushing) or by production of special solutions in order to produce age-appropriate doses, or hydrocortisone given as off-label buccal tablets.</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 16 January 2019.</td>
<td>7 November 2018</td>
</tr>
<tr>
<td>ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy® SMC2094)</td>
<td>Indication under review: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adolescents 12 years of age and older.</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts -</td>
<td>7 November 2018</td>
</tr>
</tbody>
</table>
Appendix 1: SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Indication under review</th>
<th>Decision</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fampridine 20mg, 40mg, and 60mg film-coated tablets (Cabometyx) SMC2095</strong></td>
<td>Indication under review: advanced renal cell carcinoma (RCC) in treatment-naive adults with intermediate or poor risk.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Cenegermin (Oxervate) SMC2124</strong></td>
<td>Indication under review: Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
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<tr>
<td><strong>Lenalidomide (Revlimid) SMC2125</strong></td>
<td>Indication under review: As monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
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<tr>
<td><strong>Sirolimus (Rapamune) SMC2126</strong></td>
<td>Indication under review: treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Dinutuximab beta 4.5mg/mL concentrate for solution for infusion (Qarziba) SMC2105</strong></td>
<td>Indication under review: for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.</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 16 January 2019</td>
<td>7 November 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Fosaprepitant (Ivemend 150mg) SMC2108</strong></td>
<td>Indication under review: prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to 17 years. Fosaprepitant is given as part of a combination therapy.</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 16 January 2019</td>
<td>7 November 2018</td>
<td></td>
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<tr>
<td><strong>Fampridine (Fampyra) SMC2107</strong></td>
<td>Indication under review: For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Talozolizumab (Tecentriq) SMC2103</strong></td>
<td>Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Evolocumab (Repatha) SMC2133</strong></td>
<td>Indication under review: In adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.</td>
<td>Not routinely available as not recommended for use in NHSScotland.</td>
<td>7 November 2018</td>
<td></td>
</tr>
</tbody>
</table>

SCAN Formulary Submissions to Lothian Formulary Committee August-October 2018

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Indication under review</th>
<th>Lothian Formulary Committee Decision</th>
<th>Add to Fife Formulary Yes / No Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regorafenib 40mg film-coated tablets (Stivarga) SMC116/18</strong></td>
<td>Indication under review: as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib</td>
<td>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</td>
<td>Yes, To be prescribed in line with SCAN protocol</td>
<td></td>
</tr>
<tr>
<td><strong>Talostat ethyl 250mg film-coated tablets (Xermelo) SMC 1327/18</strong></td>
<td>Indication under review: Treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue therapy in adults inadequately controlled by somatostatin analogue therapy. SMC restriction: patients with CS diarrhoea who experience an average of four or more bowel motions per day, despite receiving somatostatin analogue therapy.</td>
<td>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</td>
<td>Yes, To be prescribed in line with SCAN protocol</td>
<td></td>
</tr>
</tbody>
</table>