MINUTES OF THE MEETING OF THE FIFE AREA DRUG AND THERAPEUTICS COMMITTEE HELD AT 12.30PM ON WEDNESDAY 22 JUNE 2016 IN THE BOARD ROOM, HAYFIELD CLINIC, KIRKCALDY.

Present: Mrs E McPhail (Chair)
Ms L Campbell (on behalf of Ms J Owens)
Dr A Doyle
Mr S Garden
Dr I Gourley
Dr D Griffith
Dr A McGovern
Mr F Notman
Dr D Reid
Mr E Reid

In attendance: Mrs S MacDonald (minutes)

1 APOLOGIES FOR ABSENCE

Apologies for absence were noted from Dr S Ainsworth, Dr R Cargill, Dr F Elliot, Dr J McLaren, Mr D Mitchell, Mr I Mohammed, Ms Janette Owen, Dr S Rogers and Mrs A Smith.

2 MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 20 April 2016 were confirmed as a true record.

3 SUMMARY OF ACTION POINTS FROM APRIL 2016 MEETING

The summary of action points was updated.

Vitamin D

Mr Notman briefed the ADTC on discussions at the recent meeting of the Vitamin D Guidelines Review Group. It was a positive meeting and work on updating the Guidelines is progressing well. The updated Guidelines will be taken to the Formulary Committee in due course. The importance of education/communication to support the introduction of the Guidelines was highlighted. It was noted that an information leaflet is being produced and a public health campaign is being explored.

Shared Care Agreements

Mrs McPhail advised that it has proven difficult confirming a date for the reconvening of the short life working group in July and potential dates for an August meeting will be circulated.
A discussion followed about the NHS Fife Shared Care Agreements for Medicines - Policy and Procedures document and the reasons for the Committee deferring a decision on its ratification.

It was agreed that the policy and procedures document should be brought back to the ADTC in August for approval. In the meantime the ADTC agreed to proceed with piloting a review of an expired Shared Care Protocol in line with the policy and associated appendices. Mr Garden advised that he had begun to explore updating the methotrexate shared care protocol. The complexities of this were noted due the different blood monitoring and toxicity protocols used by the various specialties with patients receiving treatment with methotrexate and it was agreed that this would be a suitable example for testing the process.

Details of the outstanding Shared Care Protocols should be brought to the August ADTC meeting. Mr Notman to explore whether any of the out of date Shared Care Protocols would be suitable for updating in the meantime.

4 DECLARATION OF INTERESTS

There were no declarations of interests.

5 REVISED TERMS OF REFERENCE FOR FIFE DRUG & THERAPEUTICS COMMITTEE

Mrs McPhail advised that there had been no changes to the revised Terms of Reference for the Fife Drug & Therapeutics Committee since the last meeting.

The revised Terms of Reference for the Fife Drug & Therapeutics Committee to be submitted to the Clinical Governance Committee for ratification.

5.1 Terms of Reference for Fife Formulary Committee

Mr Garden introduced the Terms of Reference for the Fife Formulary Committee and highlighted further proposed changes to the version circulated.

Changes to the Formulary process and introduction of new paperwork to support this process were highlighted. Current membership of the ADTC and the Prescribing and Formulary Development Group to be reviewed when identifying potential members of the Formulary Committee to establish whether there are any gaps. Identification of funding streams for GP attendance and communication around interaction with the Formulary Committee were also highlighted.

Mrs McPhail reiterated the importance of continued engagement with members round the table.

Mr Garden to make the proposed changes to the Terms of Reference for the Fife Formulary Committee and bring a final version to the next ADTC
The aim would be to have the first meeting of the Fife Formulary Committee prior to the ADTC meeting in August. It is expected that the August ADTC meeting will be in its revised format.

5.2 Revised Terms of Reference for Controlled Drugs Local Intelligence Network

Mrs McPhail introduced the revised Terms of Reference for the Controlled Drugs Local Intelligence Network. It was noted that this was due for review and no significant changes have been made.

The ADTC requested a change to the Terms of Reference to specify the identity of the Depute Chair.

Subject to the change noted the ADTC approved the revised Terms of Reference for the Controlled Drugs Local Intelligence Network.

6 ADTC SUB-GROUP UPDATE REPORTS

6.1 Patient Group Directions Group

Mr Notman introduced the update report from the Patient Group Directions Group. The ADTC noted that work continues on reviewing the current PGDs and new PDGs for use by orthoptists in the ophthalmology service are being developed. The ADTC noted the achievements since the last report including Dr Griffith taking over the PDG role and his involvement in the development of new paediatric antimicrobial guidelines and increased nursing representation on the group.

The ADTC noted the update report from the Patient Group Directions Group.

6.2 Controlled Drugs Local Intelligence Network

Mrs McPhail introduced the six month update report from the Controlled Drugs - Local Intelligence Network and the Safer Management of Controlled Drugs Report July 2015 to March 2016.

The ADTC noted that since production of the Safer Management of Controlled Drugs Report CD ward checks in the Acute Division are now on target to be completed for all wards by the end of July.


6.3 Code of Practice Medicines

Mrs McPhail introduced the update report from the Code of Practice Medicines Review Group.

The ADTC noted that 8 policies have been reviewed since the last report and 32 policies are currently under review. There is increased nursing membership on the group. An audit of the Code of Practice Medicines is
being explored.

The ADTC noted the update report from the Code of Practice Medicines Review Group.

6.4 Poly Pharmacy Steering Group

Dr McGovern introduced the update report from the Polypharmacy Steering Group and briefed the ADTC on the background to this. There has been a recent change to the governance arrangements for the Polypharmacy Steering Group and the group currently reports to the ADTC. The Polypharmacy Steering Group meets quarterly and the update report provides an overview of the progress and workplan for the next six months.

The ADTC noted that the proforma for the discontinuation of antipsychotics in elderly patients with dementia has stalled and there has been an increase in the use of antipsychotics in patients over 75 years. It was noted that use of antipsychotics for other clinical indications may have contributed to this rise.

The ADTC noted the update report from the Polypharmacy Steering Group.

7 NHS BIOSIMILAR UPDATE MAY 2016

Mr Garden introduced the Biosimilars May 2016 Uptake Data Report for Health Boards produced by National Services Scotland. It was noted that the report is based on sales data rather than prescribing data. The figures show the progress within NHS Fife and demonstrate that new patients are being commenced on biosimilar products.

Mr Garden advised that work within Fife is progressing and there have been positive discussions with GI, rheumatology and dermatology regarding the switching of patients currently receiving treatment with infliximab and etanercept.

8 NATIONAL ANTIMICROBIAL APP

Dr Griffith briefed the ADTC on the background to the national antimicrobial app developed by the Scottish Antimicrobial Prescribing Group and NHS Education for Scotland.

The national app has been piloted in Tayside and Lanarkshire and it is anticipated that it will be rolled out by August 2016. NHS Fife currently uses the Microguide app which has 3 years remaining of a 5 year contract, is effective and well liked within the hospital environment. The national app appears to be very similar to the Microguide app. The national app however is available free and in addition to being a platform to accommodate local antimicrobial policies and provide gentamicin and vancomycin calculators also includes a C.diff HEAT target data collection tool. It is unclear at this stage whether NHS Fife will adopt the national app in its entirety or access individual components such as data collection
materials/national calculators and migrate local protocols in due course. It was noted that the Microguide app is also currently used by NHS Lothian and discussions are required to ascertain what their intentions are with regard to adoption of the national app.

The ADTC noted the update regarding the national antimicrobial app.

8.1 Multiguide App

Mr Garden introduced the paper produced by Mr Mitchell recommending that the ADTC approve the adoption of the Multiguide app within NHS Fife and briefed the ADTC on the background to this. The Multiguide app is an extension of the Microguide app and the proposal is that the app would be used to access the Fife Formulary, Code of Practice-Medicines and potentially Clinical Guidelines and medical staff training. The challenges of the current system of accessing clinical information and guidance on the intranet including difficulties in relation to the search functionality of the intranet and inaccessibility of the intranet from outwith NHS Fife premises were highlighted. The benefits of Multiguide including the availability of a single data source which can be accessed through multiple devices or web links and can be downloaded and available offline via a mobile app were noted.

Following discussion the ADTC approved the adoption of the Multiguide app in principle. Mr Mitchell and Mr Garden to clarify the cost implications with e-health. Mr Garden to submit an SBAR to the Executive Directors Group around clinical risk management of the intranet.

9 BOARD CHIEF EXECUTIVES RESPONSE TO THE MONTGOMERY REVIEW ON ACCESS TO NEW MEDICINES 2016

The ADTC noted the Board Chief Executives Group response to the Montgomery Review on Access to New Medicines 2016.

10 WORKING WITH THE PHARMACEUTICAL INDUSTRY

Mrs McPhail advised that the guidance Working with the Pharmaceutical Industry and Healthcare Equipment Suppliers has been amended to take account of the comments received at the last ADTC. A section on the new process for the disclosure of payments to healthcare professionals by pharmaceutical companies has been included. From June 2016 pharmaceutical companies are required to publish details of payments they make to individual healthcare professionals. This information will be held on a database and publicly available through the Association of British Pharmaceutical Industry website.

A discussion followed about the appropriate level of nurse engagement with the pharmaceutical industry. Ms Campbell proposed that rather than identifying nurses by band level it may be more appropriate to hold a register of nurses with criteria for addition or removal from the register when roles change. Ms Campbell to discuss with Ms Owens and provide proposed wording for inclusion in the Guidance.
The ADTC approved the Working with the Pharmaceutical Industry and Healthcare Equipment Suppliers - Guidance for NHS Staff, subject to the agreed change around nursing engagement. Mrs McPhail to discuss launch of the Guidance with the interim Head of Communications. The Guidance to be added to the ADTC website.

11 CONTROLLED DRUG PRESCRIBING IN PRIMARY CARE

Mrs McPhail introduced the report Controlled Drug Prescribing in Primary Care in NHS Scotland 2014/2015 produced by the Controlled Drugs Accountable Officers’ Network Scotland. The ADTC noted that NHS Fife is the highest prescribers of drugs for the treatment of attention deficit hyperactivity disorder, the second highest of Tramadol and there has been an increase in prescribing of oxycodone compared to the Scottish average.

Dr Reid advised that an ADHD prescribing group has been set up to explore the issues and get consensus across hospital/community paediatrics and psychiatry. Meetings are ongoing and include General Practice representation. Guidance for the prescribing of melatonin has also been produced.

The ADTC noted the Controlled Drug Prescribing in Primary Care in NHS Scotland 2014/2015 report and welcomed the ongoing work of the ADHD prescribing group.

12 PEER APPROVED CLINICAL SYSTEM (PACS) FOR ULTRA-ORPHAN MEDICINES

Mr Garden introduced the Peer Approved Clinical Systems (PACS) paperwork for the management of requests for ultra-orphan medicines. The paperwork is currently being trialled in NHS Greater Glasgow & Clyde and has been adapted for use within NHS Fife. A change to the time-line for review to 10 working dates was noted. The process is in addition to the IPTR process. Further discussions regarding updating the IPTR, unlicensed and off-label medicines processes will take place at the Formulary Committee. A review of the newly licensed medicines policy will also be required.

There was a discussion around a communication plan around PACS, in particular inclusion in the mandatory training programme for Consultants. Mr Garden to discuss with Dr Cargill.

Mr Garden highlighted a potential issue regarding ultra orphan oncology medicines being approved through the NHS Lothian IPTR panel on behalf of SCAN. Mr Garden to discuss with Dr Elliot.

The ADTC approved the paperwork for the management of requests for ultra-orphan medicines via PACS.

13 MANAGING THE USE OF TRAZODONE LIQUID IN NHS FIFE

Mr Notman introduced the SBAR produced by Old Age Psychiatry and
Medicines for the Elderly on managing the use of trazodone within NHS Fife and the proposed step-wise approach for reviewing patients receiving trazodone liquid.

The ADTC noted the following:

Trazodone is available in a number of formulations and is often used off-label for the management of psychological and behavioural disturbances in patients with dementia in preference to antipsychotic medicines due to the risk of serious adverse events in patients with dementia. Trazodone liquid preparation is frequently used for people with dementia who either can't swallow tablets or find the oral solution more acceptable.

The cost of trazodone liquid has increased significantly with the spend in NHS Fife having risen from £190K in 2014-15 to £535K in 2015-16 and projected to increase to £826K by 2016-17 if the same volume were to continue to be used. 325 patients in Primary Care currently receive Trazodone liquid.

There is evidence to support that Trazodone capsules can be opened and the contents added to a small volume of liquid and taken immediately. Trazodone is a licensed medication and this would represent an off-label use of a licensed medication.

Following discussion the ADTC approved the proposed off-label use of trazodone capsules in preference to trazodone liquid and the step-wise approach to reviewing patients receiving trazodone liquid.

14 SBAR ON GENERIC MEDICINES

Mrs McPhail briefed the ADTC on the background to the SBAR on increases in the cost of generic medicines. The issue has been discussed at the Effective and Efficient Prescribing Group and will be raised at the Executive Directors Group.

The ADTC agreed to support the systematic review of all patients on one of the identified medicines and where appropriate switch to a more cost effective option; support the identification of Formulary drugs within the list and subsequent review of their Formulary status and seek clarity on what action is being taken at a national level.

15 MEDICINES FACTSHEET FOR PATIENTS AND THE PUBLIC

The ADTC noted the medicines factsheet “Medicines in Scotland: what’s the right treatment for you?” produced by Healthcare Improvement Scotland. The factsheet is on the ADTC website and a request has been submitted for it to be included on the NHS Fife website.

16 SMC

16.1 SMC Recommendations issued April and May 2016

The ADTC decisions are recorded in Appendix 1.
Naproxen 2150mg effervescent tablets (Stirlescent®) SMC 1154/16
Stirlescent® has been approved by the SMC for the treatment of rheumatoid arthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults, restricted to use in patients who are unable to swallow naproxen tablets. The ADTC noted that the standard naproxen tablet is more cost effective than the effervescent tablet formulation.

Following discussion the ADTC agreed that naproxen 250mg effervescent tablets (Stirlescent®) should not be included in the Fife Formulary for this indication. Naproxen 250mg effervescent tablets (Stirlescent®) may be considered in patients where existing Formulary options are ineffective/not suitable.

Mepolizumab 100mg powder for solution for injection (Nucala®) SMC 1149/16
Nucala® has been approved by the SMC for restricted use as an add-on treatment for severe refractory eosinophilic asthma patients. The ADTC noted that feedback from local specialists is that the potential number of patients in NHS Fife who may be considered for treatment would be small and local specialists were not supportive of its inclusion in the Fife Formulary.

Following discussion the ADTC agreed that mepolizumab 100mg powder for solution for injection (Nucala®) should not be included in the Fife Formulary for this indication. Mepolizumab 100mg powder for solution for injection (Nucala®) may be considered in patients where existing Formulary options are ineffective/not suitable.

16.2 SCAN Formulary Submissions Approved by Lothian Formulary Committee
There were no SCAN Formulary Submissions for consideration by the ADTC.

17 FORMULARY

17.1 Updated Diabetes Formulary Section
Mr Reid took the ADTC through the updated Diabetes Formulary Section and highlighted the key changes.

Mrs McPhail highlighted the graph included with the meeting papers which demonstrates that Fife has one of the highest costs/1,000 patients in relation to spend on anti-diabetic medicines when compared to other NHS Boards in Scotland.

Following discussion the ADTC requested that the Diabetes Formulary Section Short Life Working Group be reconvened to have further discussions around cost effectiveness. The revised Formulary section to be brought back to the next ADTC meeting.
17.2 Fife Formulary Submission - Lidocaine 5% (Versatis®)

Mr Notman took the ADTC through the Formulary Submission for lidocaine 5% for postherpetic neuralgia and other localised neuropathic pain where other formulary choices are not tolerated or are ineffective.

The ADTC noted the following:

- Current Formulary choices for the proposed indication are amitriptyline, imipramine, gabapentin second line and lidocaine patches third line.
- There is inconsistency in the submission regarding the trial duration before efficacy or otherwise can be established.
- There is lack of robust trial evidence to support the use of topical lidocaine in pain reduction.

Following discussion the ADTC did not approve the request to include lidocaine 5% in the Fife Formulary for postherpetic neuralgia and other localised neuropathic pain.

17.3 Fife Formulary Submission – Blood Glucose Strips (Omnitest® 5)

Mr Notman took the ADTC through the Formulary submission for Omnitest® 5 for people with diabetes requiring home blood glucose monitoring.

The ADTC noted the following:

- The Formulary submission follows on from work undertaken by the Diabetes MCN short life working group to review the Fife Formulary blood glucose monitoring strips.
- It is proposed that Omnitest® 5 blood glucose strips be added to the Formulary to provide an additional cost-effective third line option for people requiring blood glucose monitoring at home.
- The Omnitest® 5 meter meets current ISO standards. Patients who are using meters which do not comply with ISO requirements will be identified, provided with a new meter and advised to use up any remaining blood glucose strips prior to using the new meter and strips.

Subject to further clarification on the cost effectiveness, the ADTC approved the request to include Omnitest® 5 blood glucose strips in the Fife Formulary for people with diabetes requiring home blood glucose monitoring.

17.4 Fife Formulary Amendment - Benepali for Psoriasis

The ADTC noted the Formulary amendment submission for Benepali biosimilar etanercept for severe psoriasis. A request to include Benepali in the Fife Formulary for use in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and psoriasis was approved at the ADTC meeting on 20 April 2016.
Intra-cameral Antibiotic Prophylaxis in Ophthalmology

Mr Reid briefed the ADTC on the background to the submission relating to intra-cameral antibiotic prophylaxis in ophthalmology.

The ADTC noted that there are three options available for intra-cameral antibiotic prophylaxis in ophthalmology. NHS Fife currently uses cefotazine for this indication. Cefotazine is the most cost effective option however it is unlicensed for this indication and involves a high risk process. The other options for intra-cameral antibiotic prophylaxis in ophthalmology are cefuroxime PFS (unlicensed) and cefuroxine (Aprokam®). Aprokam is licensed for this indication however it has not been approved by the SMC for use in NHS Scotland. Aprokam is now used within NHS Lothian.

The ADTC noted the difficulties with regard to lack of consensus by NHS Fife ophthalmologists around the preferred option for this indication.

Following discussion the ADTC agreed to write to the lead clinician for ophthalmology to obtain consensus on the preferred option for intra-cameral antibiotic prophylaxis in ophthalmology within NHS Fife. The Formulary status of Aprokam in NHS Lothian to be clarified.

Fife Formulary Submission - Cefuroxime (Aprokam®)

The Formulary submission for cefuroxime (Aprokam®) for antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery was withdrawn pending further discussions with ophthalmology.

Fife Formulary Submission - Thyrotropin alfa (Thyrogen®)

Mr Reid took the Committee through the Formulary Submission for thyrotropin alfa (Thyrogen®) and briefed the ADTC on the background to this.

The ADTC noted the following:

- Previously patients requiring therapeutic radioactive iodine had been travelling to Edinburgh to receive treatment. Patients are now receiving Thyrogen® in NHS Fife saving them an additional trip to Edinburgh prior to their admission for iodine itself. Potential patient numbers are small; Thyrogen® is used in a very specific niche group of patients.
- There is no information in relation to evaluation by SMC, SIGN or NICE or clinical evidence cited within the submission.

Following discussion the ADTC deferred a decision on the Formulary status of thyrotropin alfa (Thyrogen®) pending provision of further information from the submitting clinician.
18.1 **Updated Appendix 4A - Drug Treatment of Schizophrenia**

The ADTC noted the updated Appendix 4A - Drug Treatment of Schizophrenia. This was previously agreed at the ADTC subject to minor amendments.

18.2 **Updated Cow’s Milk Protein Allergy Pathway**

Due to time constraints the updated Cow’s Milk Protein Allergy Pathway was not discussed. S MacDonald to circulate to ADTC members electronically for approval/comments by 18 July.

18.3 **Updated Gout Guidelines**

Due to time constraints the updated Gout Guidelines were not discussed. S MacDonald to circulate to ADTC members electronically for approval/comments by 18 July.

18.4 **Updated UTI Decision Aid for Older People**

Due to time constraints the updated UTI Decision Aid for Older People was not discussed. S MacDonald to circulate to ADTC members electronically for approval/comments by 18 July.

19 **ITEMS FOR NOTING**

19.1 **Individual Patient Treatment Requests - Latest Submissions**

The updated table of Individual Patient Treatment Requests was noted.

19.2 **MHRA Drug Safety Updates**

The MHRA Drug Safety Updates for April and May 2016 were noted.

19.3 **Fife Medicines Focus - April, May 2016**

Fife Medicines Focus issues 27 and 28 (April, May 2016) were noted.

20 **POINTS FOR RAISING AT CLINICAL GOVERNANCE COMMITTEE**

Dr Elliot/Mrs McPhail to discuss whether there are any issues/points that require to be raised at the Clinical Governance Committee.

21 **ANY OTHER COMPETENT BUSINESS**

There was no other business.

a **Minutes of Other ADTC Meetings**

a.1 Tayside Drug & Therapeutics Committee: Minutes of meeting 11 April 2016. For information.

a.2 Lothian Formulary Committee: Minutes of meeting 25 May 2016. For information.
b Minutes of Diabetes MCN Prescribing Sub-Group 24 May 2016. For information.

c Date of Next Meeting
The next meeting is to be held on **Wednesday 17 August 2016 at 12.30pm** in the **Seminar Room, Whyteman's Brae Hospital, Kirkcaldy**. (The deadline for submission of papers to be considered for the agenda is 1 August 2016. Apologies for meeting to be notified to Sandra MacDonald by 1 August 2016.)
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Condition being treated</th>
<th>NHS Board decision</th>
<th>Date of NHS Board decision</th>
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<tbody>
<tr>
<td>bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)</td>
<td>Indication under review: in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. Restriction: for use in combination with cisplatin and paclitaxel.</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts. Await SCAN submission and decision by Lothian Formulary Committee.</td>
<td>22 June 2016</td>
</tr>
<tr>
<td>ivacaftor 50mg and 75mg granules in sachet (Kalydeco®)</td>
<td>Indication under review: treatment of children with cystic fibrosis (CF) aged 2 years and older and weighing less than 25kg who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>22 June 2016</td>
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<tr>
<td>lumacaftor 200mg, ivacaftor 125mg film-coated tablet (Orkambi®)</td>
<td>Indication under review: treatment of cystic fibrosis (CF) in patients aged 12 years and older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>22 June 2016</td>
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<tr>
<td>elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Genvoya®)</td>
<td>Indication under review: the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.</td>
<td>Available in line with national guidance. SMC Advice</td>
<td>22 June 2016</td>
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<tr>
<td>adalimumab 40mg/0.8mL solution for injection (Humira®)</td>
<td>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.</td>
<td>Available in line with local guidance. For hospital use only.</td>
<td>22 June 2016</td>
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<tr>
<td>ceftolozane/tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa®)</td>
<td>Indication under review: for the treatment of the following infections in adults: - Complicated intra-abdominal infections - Acute pyelonephritis - Complicated urinary tract infections</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>22 June 2016</td>
</tr>
<tr>
<td>certolizumab pegol (Cimzia®) 200 mg solution for injection</td>
<td>Indication under review: Treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>22 June 2016</td>
</tr>
<tr>
<td>ramucirumab (Cymzaya®) 10 mg/ml concentrate for solution for infusion</td>
<td>Indication under review: in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>22 June 2016</td>
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<tr>
<td>Drug</td>
<td>Indication under review</td>
<td>SMC Advice</td>
<td>22 June 2016</td>
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<tr>
<td>blinatumomab, 38.5 micrograms powder for concentrate and solution for infusion (Blincyto®)</td>
<td><strong>Indication under review:</strong> The treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL)</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts. Await SCAN submission and decision by Lothian Formulary Committee.</td>
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| evolocumab, 140mg, solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS) | **Indication under review:** In adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet:  
- In combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or,  
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.  
- In adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies. | Not available as not recommended for use in NHS Scotland. **SMC Advice** | |
| mepolizumab 100mg powder for solution for injection (Nucala®) | **Indication under review:** as an add-on treatment for severe refractory eosinophilic asthma in adult patients.  
**SMC restriction:** patients who have eosinophils of at least 150 cells per microlitre (0.15 x 10⁹/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. | 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. **Fife Formulary Chapter 3** | |
| febuxostat 120mg film-coated tablet (Adenuric®) | **Indication under review:** the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS).  
**SMC restriction:** prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as:  
- Those intolerant of allopurinol  
- Those in whom allopurinol is contraindicated, e.g. patients with renal impairment | Available in line with local guidance. | |
| co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®) | **Indication under review:** treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.  
**SMC restriction:** for use in patients not eligible for deep brain stimulation. | Available in line with local guidance.  
Specialist initiation or recommendation only following discussion (assessment by national experts). | |
<p>| cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) | <strong>Indication under review:</strong> cabazitaxel, in combination with prednisone or prednisolone, is indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a | Not available as not recommended for use in NHS Scotland. <strong>SMC Advice</strong> | |</p>
<table>
<thead>
<tr>
<th>SMC Advice</th>
<th>docetaxel-containing regimen.</th>
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| **naproxen 250mg effervescent tablets (Stirlescent®)** 1154/16 SMC Advice | **Indication under review:** treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhea and acute gout in adults.  
**SMC restriction:** use in patients unable to swallow naproxen tablets.  
**SMC Advice:** 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.  
**Fife Formulary Chapter 10**  
**22 June 2016** |
| **eltrombopag olamine (Revolade®) 25 mg / 50 mg film-coated tablets** 1164/16 SMC Advice | **Indication under review:** Treatment in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.  
**SMC Advice:** Not available as not recommended for use in NHS Scotland.  
**SMC Advice**  
**22 June 2016** |
| **ramucirumab (Cymzaza®) 10 mg/ml concentrate for solution for infusion** 1165/16 SMC Advice | **Indication under review:** in combination with docetaxel for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy.  
**SMC Advice:** Not available as not recommended for use in NHS Scotland.  
**SMC Advice**  
**22 June 2016** |
| **ruxolitinib phosphate (Jakavi®) 5mg, 10mg, 15mg and 20mg tablets** 1166/16 SMC Advice | **Indication under review:** Treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea.  
**SMC Advice:** Not available as not recommended for use in NHS Scotland.  
**SMC Advice**  
**22 June 2016** |