CONFIRMED

MINUTES OF THE MEETING OF THE FIFE AREA DRUG AND THERAPEUTICS COMMITTEE HELD AT 12.30PM ON WEDNESDAY 15 OCTOBER 2014 IN THE BOARD ROOM, HAYFIELD CLINIC, KIRKCALDY.

Present: Dr B Montgomery (Acting Chair)  
Dr L Anderson  
Dr S Ainsworth  
Dr I Gourley  
Dr A McGovern  
Dr J McLaren  
Mr I Mohammed  
Mr E Reid  
Dr S Rogers  
Dr S Smith

In attendance: Ms K McDougall, Non Medical Prescribing Advisor  
Ms I McGonnigle, Senior Strategic Healthcare Planner  
Dr V Row, Paediatric Registrar  
Mrs S MacDonald (minutes)

APOLOGIES FOR ABSENCE

Apologies for absence were noted from G Birnie, S Garden, E McPhail, D Mitchell, C Potter, D Reid, P Small and S Tyson.

Dr Montgomery welcomed the following observers to the meeting and introductions took place round the table:  
Kecia McDougall, Non Medical Prescribing Advisor;  
Irene McGonnigle, Senior Strategic Healthcare Planner;  
Dr Vanessa Row, Paediatric Registrar.

1 MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 20 August 2014 were confirmed as a true record.

Dr Smith queried the rationale behind the recommendation that membership of the AMT should include a representative from sexual health (item 9.2 Role & Remit of the AMT). Dr Smith agreed to discuss with the AMT and report back at the next ADTC meeting.

2 MATTERS ARISING FROM THE MINUTES

2.1 Finance Representative for ADTC

Dr Montgomery advised that Carol Potter, Assistant Director of Finance,
has agreed to represent finance at the ADTC (apologies submitted for today’s meeting).

2.2 **SAPG Letter re PPIs and Clostridium Difficile Infection**

Dr Smith advised that this is in progress.

2.3 **Cefalexin for UTIs**

Mr Mohammed advised that microbiology have confirmed that sensitivity results for cefalexin will not be routinely reported and will only be available to GPs if they contact microbiology. It was noted that this is in line with current practice for fosfomycin.

The ADTC confirmed the decision to add cefalexin to the formulary for restricted use for the treatment of urinary tract infection. Use restricted to microbiology approval only.

3 **DECLARATION OF INTERESTS**

A non-personal declaration of interest was noted for agenda item 7.

4 **ROLE & REMIT OF ADTC SUB-GROUPS**

4.1 **Prescribing Efficiency Group (PEG)**

4.2 **Patient Access Scheme Group (PAS)**

Dr Montgomery introduced the Roles and Remits of the Prescribing Efficiency Group and Patient Access Scheme Group.

Mr Reid highlighted a minor typographical error in the Role and Remit of the Patient Access Scheme Group.

Dr Montgomery noted that the Roles and Remits presented were not in the standard format agreed by the ADTC. Mrs MacDonald to amend in line with the ADTC template.

No further comments were received and the ADTC approved the Roles and Remits of the Prescribing Efficiency Group and Patient Access Scheme Group.

5 **HIS 2015-2018 STRATEGIC DELIVERY PLAN FOR MEDICINES**

Dr Montgomery introduced the draft Healthcare Improvement Scotland 2015-18 Strategic Delivery Plan for Medicines. ADTC members were asked to send any comments to Mrs MacDonald for collation by 14 November (post meeting, deadline extended to 21 Nov.). Mr Mohammed highlighted that HIS are specifically seeking comments in relation to secondary drivers (Appendix 1).
6 SHARED CARE PROTOCOLS

6.1 Approval Process for Shared Care Protocols within NHS Fife

Dr Anderson led a discussion on the approval process for Shared Care Protocols within Fife. Historically the clinical appropriateness of Shared Care Protocols has been reviewed by the Prescribing and Formulary Development Group (PFDG) and Dr Anderson sought clarity from the ADTC on whether the PFDG should continue to undertake that role. It was noted that the PFDG includes representation from four General Practitioners, pharmacy groups and the LMC.

Dr McGovern highlighted some overlap with the General Practice Clinical Steering Group which was set up principally to look at the workload around enhanced services. The General Practice Clinical Steering Group has discussed the practicality of a minority of Shared Care Protocols however the clinical suitability of Shared Care Protocols is not discussed by the group.

After discussion the ADTC agreed that the PFDG should remain the forum to undertake clinical assessments of Shared Care Protocols.

A lengthy discussion followed around wider issues in relation to Shared Care Protocols including capacity, workload pressures, transfer of work and safety. Dr Gourley highlighted the formal arrangements for Shared Care Protocols within NHS Tayside. Dr McLaren highlighted the Rheumatology Shared Care Protocols which are on the ADTC website and suggested that they be used as a model for Shared Care Protocols within NHS Fife.

Dr Montgomery advised that Mrs McPhail is convening a group to look at the wider issues of Shared Care Protocols. Dr Montgomery to discuss further with Mrs McPhail outwith the meeting.

7 SMC

7.1 SMC Recommendations issued August and September 2014

The ADTC decisions are recorded in Appendix 1.

8 FORMULARY

8.1 Domperidone Safety Advice - Revised Formulary Sections 1.2 and 4.6 and Prescribing Advice for Prescribers

Mr Mohammed briefed the Committee on amendments that have been made to Formulary Sections 1.2 and 4.6 to reflect recent safety issues with domperidone. Updated prescribing advice has been circulated to all GPs. The amendments have been made in consultation with GI physicians, Paediatricians and Diabetes Consultants.
The ADTC approved the amended formulary sections and noted the updated prescribing advice.

8.2 Chapter 9 - Nutrition and Blood

Mr Mohammed introduced revised Fife Formulary Chapter 9 - Nutrition and Blood and highlighted the key changes.

Mr Reid highlighted a change required to section 9.5.1.3.

Subject to amendment to take account of the comment received, the ADTC approved the revised Fife Formulary Chapter 9 - Nutrition and Blood.

8.3 Chapter 15 - Anaesthesia

Mr Mohammed introduced the revised Fife Formulary Chapter 15 - Anaesthesia and highlighted the key changes to the dental anaesthesia and topical anaesthesia sub-sections.

No comments were received and the ADTC approved the revised Fife Formulary Chapter 15 - Anaesthesia.

8.4 British Association of Dermatology - Specials List 2014

Mr Mohammed briefed the ADTC on the background to the document Specials Recommended by the British Association of Dermatologists for Skin Disease.

Mr Mohammed advised that the list has been forwarded to dermatologists and to the pharmacists responsible for approving specials within NHS Fife.

The ADTC noted the Specials List and requested that it be taken to the PFDG to establish if it would be useful to circulate the list to GPs.

A link to the document will be added to the Fife Formulary skin section when the Chapter is next reviewed.

8.5 Gluten Free Food Formulary Updated List

Mr Mohammed introduced the Gluten Free Food Formulary Updated List and highlighted the following key changes:

- Glutafin wheat free crackers and fibre mix has been added.
- Orgran self raising flower has been removed due to high delivery charges.

The ADTC approved the updated Gluten Free Food Formulary List.

8.6 Improving Formulary Compliance - Acute Division/Community Hospitals

Mr Reid briefed the ADTC on measures agreed by the Acute Services...
Pharmacy Management Team to improve compliance with the Fife Formulary in the acute division/community hospitals.

The ADTC noted that non formulary products will not be held as pharmacy stock, on ward stock lists, in the Emergency Cupboard and will not be available as patient packs. A number of non formulary products are still being used routinely and where this use is considered appropriate formulary submissions should be made to the ADTC.

Dr Gourley highlighted difficulties with consultants from tertiary centres recommending medicines which are not approved for use in the Fife Formulary.

9 GUIDELINES

9.1 Appendix 2A - Guidance on Management of Hypertension

Mr Mohammed introduced Fife Formulary Appendix 2A - Guidance on Management of Hypertension which has been reviewed and updated by the Heart Disease MCN and highlighted the minor changes.

Dr McGovern raised the issue of balancing the need to treat to target levels recommended in national guidance with risks of co-prescribing multiple medications to achieve the target goal. This was especially a concern in frail elderly patients at particular risk of polypharmacy. A change to the wording around targets in frail elderly patients was suggested.

Subject to modification, the ADTC approved the revised Appendix 2A – Guidance on Management of Hypertension.

9.2 Appendix 2B - Prevention of Cardiovascular Disease

Mr Mohammed introduced the revised Fife Formulary Appendix 2B - Prevention of Cardiovascular Disease and highlighted the key changes.

Changes to Appendix 2B were agreed in line with changes to be made to Appendix 2A.

Subject to modification, the ADTC approved the revised Appendix 2B - Prevention of Cardiovascular Disease.

9.3 Appendix 2E - Medical Management of Chronic Stable Angina

Mr Mohammed introduced the revised Fife Formulary Appendix 2E - Medical Management of Chronic Stable Angina and highlighted the minor changes.

Mr Reid suggested a change to the wording from “beta blockers” to “cardio selective beta blockers”.

Subject to modification, the ADTC approved the revised Appendix 2E - Medical Management of Chronic Stable Angina.
Appendix 9A - Prescribing Guidelines for the Appropriate Use of Oral Nutritional Supplements (ONS) in the Community (Adults)

Mr Mohammed introduced the updated Fife Formulary Appendix 9A - Prescribing Guidelines for the Appropriate Use of Oral Nutritional Supplements (ONS) in the Community (Adults). The ADTC noted that changes were mainly around formatting and lay-out.

No comments were made and the ADTC approved the updated Fife Formulary Appendix 9A - Prescribing Guidelines for the Appropriate Use of Oral Nutritional Supplements (ONS) in the Community (Adults).

Appendix 9B - Diagnosis and Management of Infants with Suspected Cow’s Milk Protein Allergy

Mr Mohammed introduced the updated Fife Formulary Appendix 9B - Diagnosis and Management of Infants with Suspected Cow’s Milk Protein Allergy. The ADTC noted the minor changes.

No comments were made and the ADTC approved the updated Fife Formulary Appendix 9B - Diagnosis and Management of Infants with Suspected Cow’s Milk Protein Allergy.

National Palliative Care Guidelines

The ADTC noted that the National Palliative Care Guidelines website is now operational. The information on the ADTC website will be updated accordingly.

Guidelines for Supply of Medication to Hospital Outpatients

It was noted that the incorrect version of the Guidelines for Supply of Medication to Hospital Outpatients had been circulated with the papers. It was agreed that this item be deferred to the next ADTC meeting.

INDIVIDUAL PATIENT TREATMENT REQUESTS

Latest Submissions

The updated table of Individual Patient Treatment Requests for 2014-15 was noted.

HOMECARE GROUP UPDATE

S.C. Tocilizumab (RoActemra®)

Mr Reid advised that subcutaneous tocilizumab (RoActemra®) has received a favourable response from the Homecare Group, however clarity from the ADTC is being sought in relation to the manufacturers’ recommendation of increased monitoring for the first six months.

The ADTC noted the following:
Patients would already be on established i.v. therapy and receiving regular monitoring by GPs.
Prescribing would continue to be undertaken by rheumatology.
There is evidence to support the view that a change to the mode of delivery of the medication does not require increased monitoring.
When initiated as a new drug both preparations require more frequent monitoring.

The ADTC agreed that for patients who are already on established therapy and receiving regular monitoring an increase in the frequency of monitoring would not require to be undertaken by GPs if patients were switched to the S.C. formulation of tocilizumab.

12 **ANTIMICROBIAL MANAGEMENT TEAM UPDATE**

Dr Smith highlighted the MHRA safety information that Nitrofurantoin is now contraindicated in most patients with an eGFR of less than 45 ml/min (information included in agenda item 16.2). Local guidance is being updated to reflect this advice. It was agreed that the amended guidance did not require to be brought to the ADTC. The AMT to highlight the change to GPs.

13 **PRESCRIBING AND FORMULARY DEVELOPMENT GROUP UPDATE**

Dr Anderson provided an update on behalf of the Prescribing and Formulary Development Group. Discussions at recent meetings have included:

- Issues with Shared Care Protocols and prescribing for rheumatology drugs.
- The Prescribing Action Plan and pressures on GPs to engage with this process.
- Waste issues, including stoma and urinary products. It was noted that there have been discussions between Mrs McPhail, Scott McLean and Nicky Connor. Ms McDougall agreed to follow up at the Non Medical Prescribing Group.

The Role and Remit of the PFDG was discussed and potential overlap with the Fife Medicines Management Team (FMMT). Mr Mohammed advised that the FMMT is not a subgroup of the ADTC however there had been some suggestions about potential amalgamation of the groups. Dr Montgomery stated that once all of the Roles and Remits of the ADTC subgroups have been received any potential overlap and gaps would be explored at that stage.

14 **PRESCRIBING EFFICIENCY GROUP UPDATE**

Dr Montgomery provided an update on behalf of the Prescribing Efficiency Group.

The group continues to focus on efficiencies and quality issues in relation
to prescribing. Mrs McPhail has been asked to prepare a paper to SMT on the work of the group over the last year and progress with the Prescribing Action Plan. Once the paper is finalised it will be shared with the ADTC.

Dr Gourley highlighted issues with medicines waste as a result of repeat ordering by community pharmacies. It was suggested that the role of the community pharmacist in the repeat prescribing chain be explored as a potential area to target.

15 NON MEDICAL PRESCRIBING GROUP UPDATE

Ms McDougall provided an update on behalf of the Non Medical Prescribing Group.

- The role and remit has been amended to include the 6 monthly reporting arrangements to the ADTC.
- Fifteen students have commenced the non medical prescribing course in Tayside and one in Edinburgh. Recruitment is underway for the next course commencing in January.
- The Non Medical Prescribing Group is due to meet in November. (Ms McDougall to raise point about stoma and catheter waste.)

16. MEDICATION SAFETY

16.1 Medication Safety Group Update

Dr Montgomery advised that the Medication Safety Group have not met for some time. Medication safety work is continuing as part of the Getting Together in Fife process and Patient Safety Programmes in Primary and Secondary Care.

16.2 Safety Information sent out to Healthcare Professionals

The Medication Safety Information and MHRA Drug Safety Updates for August and September 2014 were noted.

17 ANY OTHER COMPETENT BUSINESS

There was no other business.

18 ITEMS FOR NOTING

18.1 ADTC Bulletin August - September 2014

For information.

18.2 Fife Medicines Focus July 2014, August 2014, September 2014

For information.

18.3 HIS Meeting Feedback - Strengthening Collaborative Working Between ADTCs across Scotland
18.4 NICE CG 183 - Drug allergy: diagnosis and management of drug allergy in adults, children and young people - September 2014

For information.

18.5 NICE CG 184 - Dyspepsia and gastro-oesophageal reflux disease - Investigation and management of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease, or both - September 2014

For information.

18.6 NICE CG 30 (update) - Long-acting reversible contraception - September 2014

For information.

18.7 2015 ADTC Meeting Dates

For information.

OTHER INFORMATION

a Minutes of Other ADTC meetings
a.1 Lothian Formulary Committee: Minutes of meeting on 27 August 2014. For information.

a.2 Tayside Drug & Therapeutics Committee: Minutes of meeting on 18 August 2014. For information.


c Minutes of Antimicrobial Management Team: 21 July 2014 For information.

d Minutes of Medication Safety Group
There was no meeting.

e Minutes of the NHS Fife Prescribing Efficiency Group: 13 August 2014; 10 September 2014 For information.

f Minutes of Non Medical Prescribing Group
Not available.

g Date of Next Meeting
The next meeting is to be held on **Wednesday 17 December 2014 at 12.30pm** in the **Board Room, Hayfield Clinic, Kirkcaldy**. (The deadline for submission of papers to be considered for the agenda is 1 December 2014.)
### Scottish Medicines Consortium Recommendations

<table>
<thead>
<tr>
<th>Date</th>
<th>Product/Manufacturer</th>
<th>SMC Advice</th>
<th>Decision of ADTC</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| August 2014 988/14 | **Simeprevir 150mg hard capsules (Olysio®)**  
**Janssen**  
*Comparator Medicines:*  
The standard treatment for genotype 1 HCV is peginterferon and weight-based ribavirin plus a telaprevir, boceprevir or sofosbuvir with RGT determining treatment duration in certain groups (24 to 48 weeks). For patients with genotype 4, standard treatment is with PR ± sofosbuvir. The only peginterferon-free comparator regimen is sofosbuvir plus ribavirin.  
| **Simeprevir (Olysio®)** is accepted for use within NHS Scotland.  
**Indication under review:** in combination with other medicinal products for the treatment of chronic hepatitis C in adult patients.  
In four double-blind phase III studies, when given as part of triple regimen in combination with peginterferon-alfa and ribavirin, simeprevir was superior to placebo in treatment naive and prior relapsed patients and non-inferior to another direct acting antiviral drug in treatment experienced patients with genotype 1 hepatitis C virus.  
| Included on the Fife Formulary.  
Hospital specialist use only.  
Boceprevir to be removed from the Fife Formulary.  
SMC simeprevir (Olysio®) | | | |
| August 2014 992/14 | **Fingolimod, 0.5mg, hard capsules (Gilenya®)**  
**Novartis Pharmaceuticals UK**  
*Fingolimod is indicated as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:*  
- Patients with high disease activity despite treatment with at least one disease modifying therapy.  
These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least one relapse in the previous year while on therapy, and have at least nine T2-hyperintense lesions in cranial magnetic resonance imaging (MRI) or at least one Gadolinium enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.  
| **Fingolimod (Gilenya®)** is accepted for restricted use within NHS Scotland.  
**Indication under review:** as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:  
- Patients with high disease activity despite treatment with at least one disease modifying therapy.  
- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.  
**SMC restriction:** For use in patients with rapidly evolving severe relapsing remitting multiple sclerosis. SMC has previously published advice concerning patients with high disease activity despite treatment with beta-interferon but not other disease modifying therapies.  
Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active relapsing remitting multiple sclerosis.  
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.  
| Included on the Fife Formulary for the treatment of patients with rapidly evolving severe relapsing remitting multiple sclerosis.  
Alternative to natalizumab.  
Hospital use only.  
SMC fingolimod (Gilenya) | |

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**APPENDIX 1**
SMC Advice - Formulary Decisions

brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

**Comparator Medicines:**
There are a number of medicines licensed for the treatment of RRMS, including interferon beta, glatiramer acetate, teriflunomide, dimethyl fumarate and natalizumab. Of these, only natalizumab is specifically licensed for the treatment of RES RRMS, as defined above, and it has been accepted for use within NHS Scotland for this indication. Dimethyl fumarate has only recently been accepted for use within NHS Scotland, so was not considered a comparator in the economic analysis.

<table>
<thead>
<tr>
<th>August 2014 937/14</th>
<th>alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) Takeda Pharma A/S</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Indication under review: For adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.</td>
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<tr>
<td></td>
<td>SMC restriction: dual therapy</td>
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<td></td>
<td>• In combination with metformin, when metformin alone, together with diet and exercise does not provide adequate glycaemic control in patients for whom the addition of a sulfonylurea is inappropriate.</td>
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<tr>
<td></td>
<td>• In combination with a sulfonylurea, when sulfonylurea alone, together with diet and exercise does not provide adequate glycaemic control in patients for whom the addition of metformin is inappropriate due to contra-indications or intolerance.</td>
</tr>
<tr>
<td></td>
<td>Treatment with alogliptin reduces glycosylated haemoglobin, HbA1c, significantly more than placebo when used in combination with metformin or sulfonylurea.</td>
</tr>
<tr>
<td></td>
<td>SMC cannot recommend the use of alogliptin as single therapy or triple therapy as the company’s submission related only to its use in dual therapy.</td>
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<thead>
<tr>
<th>August 2014 946/13</th>
<th>golimumab, 50mg and 100mg solution for injection (Simponi®) Merck Sharp &amp; Dohme Ltd</th>
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<tbody>
<tr>
<td></td>
<td>Indication under review: treatment of moderately to severely active ulcerative colitis in adult patients who have had inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.</td>
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</tbody>
</table>
|                    | In a study of adults with moderately to severely active ulcerative colitis who had inadequate response or intolerance to conventional therapy, a greater proportion of patients given golimumab induction therapy achieved a clinical response compared with placebo. In patients who had a clinical response to golimumab induction, golimumab maintenance

<table>
<thead>
<tr>
<th>August 2014 946/13</th>
<th>golimumab (Simponi®) is not recommended for use within NHS Scotland.</th>
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<tbody>
<tr>
<td></td>
<td>Not recommended for the treatment of moderately to severely active ulcerative colitis.</td>
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<tr>
<td></td>
<td>Requires submission and approval of an IPTR for this indication.</td>
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<tr>
<th>Fife Formulary choice gliptins are –</th>
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<tbody>
<tr>
<td>1st choice sitagliptin</td>
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<td>2nd choice saxagliptin</td>
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<tr>
<td><a href="http://www.fifeadtc.scot.nhs.uk/formulary/6-endocrine.aspx">http://www.fifeadtc.scot.nhs.uk/formulary/6-endocrine.aspx</a></td>
</tr>
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<table>
<thead>
<tr>
<th>SMC alogliptin (Vipidia)</th>
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<tbody>
<tr>
<td>Not included on the Fife Formulary as clinicians do not support formulary inclusion.</td>
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<tr>
<td>Not preferred.</td>
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<td>Fife Formulary choice gliptins are –</td>
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<td>1st choice sitagliptin</td>
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<td>2nd choice saxagliptin</td>
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<th>SMC golimumab (Simponi)</th>
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<td>Not recommended for the treatment of moderately to severely active ulcerative colitis.</td>
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<td>Requires submission and approval of an IPTR for this indication.</td>
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<tr>
<td>Lack of robust economic analysis.</td>
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<td>August 2014 1000/14</td>
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<tr>
<td>September 2014 673/11</td>
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<td>September 2014 989/14</td>
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</tbody>
</table>
SMC Advice - Formulary Decisions

SMC restriction: treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):
1. following autologous stem cell transplant (ASCT) or
2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option

In an open-label, single-arm study, patients with relapsed or refractory Hodgkin lymphoma treated with brentuximab vedotin achieved an objective response rate of 75%. Controlled data with clinical outcomes are currently lacking.

This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

Brentuximab is also indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).
SMC cannot recommend use in sALCL as the company did not include evidence for use in this indication in its submission.

Comparator Medicines:
There is no current standard of care for patients with relapsed or refractory disease after ASCT and patients may be treated with a range of salvage options with multi-agent chemotherapy (including off-label use of gemcitabine, vinblastine or vinorelbine). For patients who have received at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, further treatment options are limited.

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### SMC Advice - Formulary Decisions

**SMC lurasidone (Latuda®)** is accepted for restricted use within NHS Scotland.

**Indication under review:** For the treatment of schizophrenia in adults aged 18 years and over. Lurasidone demonstrated benefit over placebo in mean change from baseline in Positive and Negative Syndrome Scale (PANSS) total score after six weeks of treatment and was non-inferior to another second generation antipsychotic medicine for time to relapse over 12 months.

**SMC Restriction:** as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.

**Not included on the Fife Formulary because NHS Fife’s decision is that the medicine does not represent sufficient added benefit to other comparator medicines.**

<table>
<thead>
<tr>
<th>Month</th>
<th>Reference Number</th>
<th>Medicine</th>
<th>Comparator Medicines:</th>
<th>SMC Restriction:</th>
<th>Not preferred.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septemb 994/14</td>
<td>994/14</td>
<td>Lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda®)</td>
<td>Experts consulted by SMC indicate that aripiprazole is the relevant comparator as it would be used where avoidance of weight gain/metabolic adverse events is important.</td>
<td>as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.</td>
<td>Current Fife Formulary antipsychotics are – 1st Choice Chlorpromazine, Olanzapine and Risperidone. 2nd Choice Amisulpride, Aripiprazole (Abilify®), Haloperidol and Quetiapine (standard tablets).</td>
</tr>
<tr>
<td>Septemb 998/14</td>
<td>998/14</td>
<td>Alogliptin 12.5mg plus metformin1000mg combination tablet (Vipdomet®)</td>
<td></td>
<td></td>
<td><a href="http://www.fifeadtc.scot.nhs.uk/formulary/6-endocrine.aspx">http://www.fifeadtc.scot.nhs.uk/formulary/6-endocrine.aspx</a></td>
</tr>
</tbody>
</table>

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**SMC alogliptin plus metformin combination tablet (Vipdomet®)** is accepted for restricted use within NHS Scotland.

**Indication under review:** in the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus:

- as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.
- in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.

**Not included on the Fife Formulary as clinicians do not support formulary inclusion.**

<table>
<thead>
<tr>
<th>Month</th>
<th>Reference Number</th>
<th>Medicine</th>
<th>Comparator Medicines:</th>
<th>SMC Restriction:</th>
<th>Not preferred.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septemb 998/14</td>
<td>998/14</td>
<td>Alogliptin 12.5mg plus metformin1000mg combination tablet (Vipdomet®)</td>
<td></td>
<td></td>
<td>Fife Formulary choice gliptins are – 1st choice sitagliptin 2nd choice saxagliptin</td>
</tr>
</tbody>
</table>

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**SMC misoprostol (Mysodelle®)**

**Indication under review:** Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.

**SMC Restriction:** Misoprostol vaginal delivery system significantly reduced the time to vaginal delivery, with a similar rate of caesarean section, compared with an active comparator

**Not included on the Fife Formulary pending protocol.**

<table>
<thead>
<tr>
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<th>SMC Restriction:</th>
<th>Not preferred.</th>
</tr>
</thead>
</table>

---

**SMC alogliptin plus metformin combination tablet (Vipdomet®)**

**Indication under review:** in the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus:

- as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.
- in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.

**Not included on the Fife Formulary as clinicians do not support formulary inclusion.**

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</table>
### SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>SMC Advice</th>
<th>Relevant Medication</th>
<th>Not Included</th>
<th>Fife Formulary Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SMC Advice</strong></td>
<td><strong>Formulary Decisions</strong></td>
<td><strong>metformin (Vipdomet)</strong></td>
<td><strong>Not preferred.</strong></td>
</tr>
<tr>
<td>Controlled on their maximal tolerated dose of metformin and pioglitazone.</td>
<td>Alogliptin/metformin is licensed for use in triple combination therapy with pioglitazone or as add-on to insulin. The manufacturer’s submission related only to the use of alogliptin/ metformin in dual therapy, therefore SMC cannot recommend the use of alogliptin/ metformin in triple therapy with either pioglitazone or insulin.</td>
<td>Not included on the Fife Formulary as clinicians do not support formulary inclusion.</td>
<td>Fife Formulary choice NOAC for this indication is rivaroxaban.</td>
</tr>
<tr>
<td>Alogliptin/metformin is licensed for use in triple combination therapy with pioglitazone or as add-on to insulin. The manufacturer’s submission related only to the use of alogliptin/ metformin in dual therapy, therefore SMC cannot recommend the use of alogliptin/ metformin in triple therapy with either pioglitazone or insulin.</td>
<td>Dabigatran etexilate was non-inferior to a vitamin K antagonist for recurrent symptomatic venous thromboembolism events (VTE) and death related to VTE in three phase III studies (two in the treatment of DVT/PE and one in the prevention of recurrent DVT/PE). The economic case was based on evidence relating to a maximum of 18</td>
<td>Not included on the Fife Formulary as clinicians do not support formulary inclusion.</td>
<td>Fife Formulary choice NOAC for this indication is rivaroxaban.</td>
</tr>
<tr>
<td><strong>SMC Restriction</strong>: to use in patients for whom this fixed dose combination of alogliptin and metformin is an appropriate choice of therapy and only when the addition of a sulphonylurea to metformin monotherapy is not appropriate.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For patients in whom dual combination therapy with metformin and alogliptin is appropriate it has the potential to reduce the pill burden at no additional cost.</td>
<td></td>
<td></td>
<td></td>
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### Septembe 2014 921/13

**azelastine hydrochloride 137micrograms plus fluticasone propionate 50micrograms per actuation nasal spray (Dymista® nasal spray)**

**Meda Pharmaceuticals**

**Product Update**

**Indication under review**: for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

**This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Dymista®. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.**

### Septembe 2014 955/14

**dabigatran etexilate, 110mg, 150mg capsules (Pradaxa®)**

**Boehringer Ingelheim Ltd**

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

**Comparator Medicines**: Rivaroxaban, or LMWH plus warfarin

**dabigatran etexilate (Pradaxa®)** is accepted for use within NHS Scotland.

**Indication under review**: treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Dabigatran etexilate was non-inferior to a vitamin K antagonist for recurrent symptomatic venous thromboembolism events (VTE) and death related to VTE in three phase III studies (two in the treatment of DVT/PE and one in the prevention of recurrent DVT/PE). The economic case was based on evidence relating to a maximum of 18
## SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>Date</th>
<th>medication</th>
<th>Indication under review</th>
<th>SMC restriction: to use in the following situations:</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septemb  er 2014 993/14</td>
<td>empagliflozin 10mg and 25mg tablet (Jardiance®) Boehringer Ingelheim / Eli Lilly</td>
<td>Treatment of type 2 diabetes to improve glycaemic control in adults or combination therapy: in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.</td>
<td>As monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Comparator Medicines: A variety of anti-diabetic medicines can be used in combination with metformin as dual- or triple-therapy and as add-on to insulin. These include sulphonylureas, dipeptidyl-peptidase-4 (DPP-4) inhibitors, TDZ, SGLT-2 inhibitors and glucagon-like peptide-1 (GLP-1) agonists. Empagliflozin was superior to placebo for glycaemic control in combination with various anti-diabetic medicines (metformin; metformin plus sulphonylurea; thiazolidinedione ± metformin; and insulin) and it was non-inferior to a sulphonylurea in combination with metformin. Empagliflozin is also indicated as monotherapy in patients who cannot tolerate metformin. SMC cannot recommend the use of empagliflozin as monotherapy as the company's submission did not include evidence of cost-effectiveness in this setting.</td>
<td>Not included on the Fife Formulary as clinicians do not support formulary inclusion.</td>
</tr>
<tr>
<td>Septemb  er 2014 990/14</td>
<td>trastuzumab emtansine, 100mg and 160mg powder for concentrate for solution for infusion (Kadcyla®) Roche Products Ltd</td>
<td>Indication under review: as a single agent, for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy.</td>
<td>Trastuzumab emtansine (Kadcyla®) is not recommended for use within NHS Scotland. In a randomised phase III open-label study, trastuzumab emtansine (Kadcyla®) conferred a median six months additional survival benefit compared with an active comparator. The submitting company’s justification of the treatment’s cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</td>
<td>Not included on the Fife Formulary as clinicians do not support formulary inclusion.</td>
</tr>
</tbody>
</table>

Not preferred. Fife Formulary ‘gliclizin’ is dапagliflozin. (Restricted to use with insulin only). [http://www.fifeadt.sco t.nhs.uk/formulary/6- endocrine.aspx](http://www.fifeadt.sco t.nhs.uk/formulary/6- endocrine.aspx)

SMC empagliflozin (Jardiance)

SMC trastuzumab emtansine (Kadcyla)