Fife Formulary Changes
Section 3 – Respiratory

Key changes to section 3 (Respiratory) include the following –

- **2 preferred inhaler devices**
  
  The choice of inhaler device should be dependent on the patient’s ability to use the device.
  
  Preferred devices are: metered dose inhaler (MDI) and dry powder inhaler (DPI) (Easyhaler® device when available). Where a patient is able to use an MDI, the MDI remains the preferred inhaler device.
  
  Formulary layout is amended through-out the section to enable inhaler selection according to preferred device.

- **Reduction in choice of Long-acting Beta2-agonist (LABA) to 2 options:**
  
  MDI - salmeterol
  
  DPI - Easyhaler® formoterol

- **Change in second choice long-acting antimuscarinics (LAMA)**
  
  First choice LAMA is still tiotropium (as Handihaler® device and capsules)
  
  Second choice is now aclidinium as its twice daily dosing may be appropriate in some patients who do not experience 24 hour symptom relief from once daily LAMAs.

- **Single agent inhaled corticosteroids (ICS)**
  
  First choice is beclometasone, with second budesonide. Both are available as MDI and DPI (as Easyhaler®).
  
  Fluticasone (Flixotide®) proprionate is no longer formulary choice.

- **ICS/LABA combination inhalers**
  
  Due to the variation in licensed indication and age restrictions, this section of the formulary has been separated into COPD, Asthma (adults), Asthma (adolescents), Asthma (children aged 5-12 years) and Asthma (children less than 5 years), with regard to MDI and DPI selection.
  
  Good practice points are provided throughout the formulary section including the requirement for steroid cards, dependent on dose of inhaler.

- **Antihistamines**
  
  Two additional sedating antihistamines are now considered formulary choices - hydroxyzine and promethazine.

- **Cough suppressants**
  
  Pholcodine is now the only formulary cough suppressant. Codeine is now regarded as non-formulary.
Guidance Documents
The following respiratory guidance documents have recently been reviewed and updated by the Respiratory MCN and approved for use in NHS Fife by the ADTC –

Respiratory Guidance
- Appendix 3A: Guidance on stepwise management of asthma – Appendix updated. No significant changes to previous version.
- Appendix 3B: Choosing preferred asthma inhaler in adults – Appendix updated. Step-wise approach to the management of asthma in adult patients reflecting Fife Formulary choices.
- Appendix 3C: Choosing preferred asthma inhaler devices for adolescents (aged 12-18 years) – Appendix updated. Step-wise approach to the management of asthma in patients aged 12-18 reflecting Fife Formulary choices.
- Appendix 3D: Choosing preferred asthma inhaler devices for children (aged 5-12 years) - Appendix updated. Step-wise approach to the management of asthma in patients aged 5-12 reflecting Fife Formulary choices.
- Appendix 3E: Choosing preferred asthma inhaler devices for children less than 5 years – New Appendix. Step-wise approach to the management of asthma in children aged less than 5 years reflecting Fife Formulary choices.
- Appendix 3F: Guidance on Management of COPD – Appendix updated to reflect Fife Formulary changes.

All NHS Fife ADTC approved guidance documents can be accessed / downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ or via the Fife Formulary/ADTC Quicklink on the NHS Fife intranet homepage.

Yellow Card Reporting
The latest annual report from the Yellow Card Centre covering the period April 2013 – March 2014 has been issued with the following key points reported for NHS Fife -

- The Yellow Card reporting rate for suspected adverse drug reactions from NHS Fife increased significantly in 2012/13 (78 reports) as compared to 2012/13 (58 reports). 18 reports were for vaccines, 6 of which were included in the new vaccines schedule in 2013/14.
- Reporting rate per 100,000 population was slightly lower (21) than the Scottish average reporting rate per 100,000 population (22).
- 35% of the reports received were submitted from healthcare professionals working within hospitals with Victoria Hospital, Whyteman’s Brae Hospital and Queen Margaret Hospital contributing 44%, 22% and 19% of these reports respectively.
- Hospital doctors, GPs and patients were the top 3 reporting groups.
- Reports for serious suspected reactions were higher (65%) than the Scottish average (58%).
- Reports for Black Triangle medicines were lower (10%) than the Scottish average (19%).
- Reports relating to paediatric patients were slightly lower (17%) than the Scottish average (18%).
- There were no herbal reports.

Healthcare professionals are reminded to report via the Yellow Card Scheme www.yellowcard.gov.uk all suspected serious reactions for all medicines (including prescription only, over the counter and herbal preparations) and any suspected reactions for medicines under intensive monitoring, i.e. Black Triangle ▼ medicines. Patients should also be encouraged and supported by healthcare professionals to complete Yellow Card reports for suspected ADRs. Patient specific information on the Yellow Card Scheme and reporting of suspected side effects can be found on the YCC Scotland website at: http://www.yccscotland.scot.nhs.uk/Patients/Pages/default.aspx

The Yellow Card Centre in collaboration with NES have produced six new e-learning modules. These modules have been developed for continuing professional development for all healthcare professionals.


The modules cover the following areas:
1. Module 1 – Basic principles of ADRs
2. Module 2 - Categorisation
3. Module 3 – Drug allergy classification
4. Module 4 – Diagnosis, interpretation and management of ADRs
5. Module 5 – Avoiding ADRs
6. Module 6 – Pharmacovigilance

Staff are also reminded that they can register to receive the monthly Drug Safety Update from the MHRA which helps to keep healthcare professionals up-to-date on key medicines safety information and advice. To subscribe go to http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm
# SMC Recommendations

## Medicines accepted for use by SMC

[www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory/SMC_Advice_Directory/](http://www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory/SMC_Advice_Directory/)

**Formulary Choices** - Products that are recommended within Fife and should be used in the majority of patients.

**Restricted Use** - Products that have been approved by the SMC for a limited indication or for a niche group of patients. Appropriate for them to be prescribed for patient groups that have been approved by the SMC / Fife ADTC.

**Not Preferred** - Products that have been approved by the SMC but agreed in Fife that suitable Formulary choices are already available. These products should only be used when Formulary products have been ineffective, not tolerated or are contra-indicated.

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication Assessed</th>
<th>Fife ADTC Decision &amp; Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saxagliptin, 2.5mg and 5mg, film-coated tablets (Onglyza®)</td>
<td>In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.</td>
<td>Included on the Fife Formulary for this indication.</td>
</tr>
<tr>
<td>Aflibercept, 40mg/mL solution for injection (Eylea®)</td>
<td>For adults for the treatment of visual impairment due to diabetic macular oedema (DMO).</td>
<td>Included on the Fife Formulary for this indication.</td>
</tr>
<tr>
<td>Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)</td>
<td>In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.</td>
<td>Included on the Fife Formulary.</td>
</tr>
<tr>
<td>Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)</td>
<td><strong>SMC restriction:</strong> use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.</td>
<td>Restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis. suspects use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.</td>
</tr>
<tr>
<td>Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)</td>
<td><strong>SMC restriction:</strong> treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.</td>
<td>Hospital use only.</td>
</tr>
<tr>
<td>Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)</td>
<td>For medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea.</td>
<td>Included on the Fife Formulary.</td>
</tr>
<tr>
<td>Brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza®)</td>
<td>Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.</td>
<td>Not included on the Fife Formulary because clinicians do not support Formulary inclusion.</td>
</tr>
<tr>
<td>Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®)</td>
<td>The treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.</td>
<td>Not included pending protocol.</td>
</tr>
<tr>
<td>Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)</td>
<td>Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).</td>
<td>Not included pending protocol.</td>
</tr>
</tbody>
</table>

### Notes
- **Not included** pending protocol.
- Await formulary submission by SCAN and Lothian Formulary Committee decision.
- **Included on the Fife Formulary** for this indication.
- **Alternative to** ranibizumab (Lucentis®)
- **Hospital use only.**
- **Preferred formulary options are** mifepristone and misoprostol as separate ingredients.
- **For restricted use for early medical discharge termination of pregnancy patients.**
- **Individual components are both listed on the Fife Formulary.**
## SMC Recommendations
### Medicines accepted for use by SMC

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obinutuzumab 1,000mg concentrate for solution</td>
<td>In combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy.</td>
<td>Included on the Fife Formulary. Hospital use only.</td>
</tr>
<tr>
<td>Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules</td>
<td>In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.</td>
<td>Included on the Fife Formulary. Hospital use only.</td>
</tr>
<tr>
<td>Cholecalciferol 25,000 international units oral solution</td>
<td>The prevention and treatment of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.</td>
<td>Included on the Fife Formulary.</td>
</tr>
<tr>
<td>Clindamycin 1% / tretinoin 0.025% gel (Treclin®)</td>
<td>The topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.</td>
<td>Included on the Fife Formulary as a 2nd line treatment option. For use in patients where monotherapy (with clindamycin or tretinoin) has been ineffective.</td>
</tr>
<tr>
<td>Dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg film-coated tablets (Triumeq®)</td>
<td>The treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg.</td>
<td>Included on the Fife Formulary. To be prescribed in line with BHIVA guidelines and SMC advice. Hospital use only.</td>
</tr>
<tr>
<td>Umeclidinium, 55 micrograms, powder for inhalation (Incruse®)</td>
<td>As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).</td>
<td>Not included on the Fife Formulary as clinicians do not support Formulary inclusion. Not preferred. Fife Formulary options are LAMA 1st choice Tiotropium 2nd choice Aclidinium</td>
</tr>
<tr>
<td>Indacaterol maleate 143micrograms (equivalent to 110microgram indacaterol) with glycopyrronium bromide 63micrograms (equivalent to 50microgram glycopyrronium) inhalation powder hard capsules (Ultibro® Breezhaler® 85microgram/43microgram [delivered dose])</td>
<td>Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).</td>
<td>Not included on the Fife Formulary as clinicians do not support Formulary inclusion. Not preferred. Fife Formulary options are individual products LAMA 1st choice Tiotropium 2nd choice Aclidinium LABA Salmeterol (MDI) Formoterol (DPI)</td>
</tr>
</tbody>
</table>
SMC Recommendations
Medicines accepted for use by SMC

**Pemetrexed, 100mg & 500mg, powder for concentrate for solution for infusion (Alimta®)**
Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.

**Not included** on the Fife Formulary pending protocol.
Await SCAN formulary submission and decision by the Lothian Formulary Committee.

**Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)**
Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients with World Health Organisation (WHO) functional class II to III with
• inoperable CTEPH,
• persistent or recurrent CTEPH after surgical treatment,
to improve exercise capacity.

**SMC restriction:** for patients in whom a PDE5 inhibitor is inappropriate, not tolerated, or ineffective.

**Not included** on the Fife Formulary as clinicians do not support Formulary inclusion.
Tertiary centre use only.

**Misoprostol 200 microgram, vaginal delivery system (Mysodelle®)**
Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.

**Included on the Fife Formulary.**
Hospital use only.
Alternative to dinoprostone products.

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**SMC Advice - Deferred Formulary Decisions**

**Misoprostol 200 microgram, vaginal delivery system (Mysodelle®)**
Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.

**Included on the Fife Formulary.**
Hospital use only.
Alternative to dinoprostone products.

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**Summary of Approved Lothian Formulary Committee Decisions for SCAN**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Indication Assessed</th>
<th>Place in therapy</th>
<th>Lothian formulary Committee Decision</th>
<th>Add to Fife Formulary Yes / No Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Afatinib (Giotrif®)</strong></td>
<td>As monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s).</td>
<td>Afatinib to be used in a restricted group of patients with specific EGFR mutations (exon 19 deletion). Afatinib will replace erlotinib in this specific group of patients which represents approximately 50% of all EGFR positive patients. Evidence shows that afatinib is the first TKI molecule to show an overall survival advantage compared to chemotherapy in this specific patient group.</td>
<td>Approved. Specialist use only for patients with the exon 19 deletion.</td>
<td>Yes Hospital use only. Patients likely to be treated in Fife.</td>
</tr>
</tbody>
</table>
**Medicines not recommended by SMC**
(Require the submission and approval of an IPTR before prescribing)

www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory/SMC_Advice_Directory/

**Denosumab (Prolia®)** - Osteoporosis in men at increased risk of fractures

**Pertuzumab (Perjeta®)** - For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

**Telavancin hydrochloride (Vibativ®)** - Treatment of adults with nosocomial pneumonia including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

**Voriconazole (Vfend®)** - Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients.

**Tocilizumab (RoActemra®)** - Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

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**Dates for 2015 ADTC Meetings**

<table>
<thead>
<tr>
<th>ADTC meeting</th>
<th>Deadline for submission of papers and agenda items</th>
</tr>
</thead>
<tbody>
<tr>
<td>15th April</td>
<td>30th March</td>
</tr>
<tr>
<td>17th June</td>
<td>1st June</td>
</tr>
<tr>
<td>19th August</td>
<td>3rd August</td>
</tr>
<tr>
<td>21st October</td>
<td>5th October</td>
</tr>
<tr>
<td>16th December</td>
<td>30th November</td>
</tr>
</tbody>
</table>

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Contact Ishtiaq Mohammed, Clinical Effectiveness Pharmacist on 01592 226915 for advice on making a formulary submission or for clarification on the process for approval of guidance documents.

The information provided in this bulletin is correct at the time of publishing but is subject to change as new clinical information becomes available.

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If you require this newsletter in alternative formats please call 01592 226915