Formulary Changes - Chapter 1

The gastrointestinal section of the Fife Formulary has been reviewed and updated by a review group consisting of GI consultants, GPs, GI specialist nurses and primary and secondary care pharmacists. The section has been approved for use in NHS Fife by the Area Drugs & Therapeutics Committee (ADTC).

Formulary Section Key Changes

- Formulary choice antacid is now Mucogel®. Maalox® is non-formulary due to it being more expensive than Mucogel®.
- Acidex® is the formulary choice compound alginate preparation. Gaviscon Advance® is now considered 2nd choice and its use should be restricted to use:
  - when Acidex® fails to control symptoms,
  - for the treatment of laryngeal reflux,
  - in patents when salt restriction is imperative.
- Co-phenotrope (Lomotil®) is now considered non-formulary for the management of diarrhoea. Formulary choice is loperamide capsules.
- The Pentasa® range is now the formulary choice aminosalicylate for oral treatment.
- The section on the management of constipation has been reformatted to provide more specific advice and formulary choices for the management of different types of constipation e.g. acute, chronic, drug induced, in palliative care.
- Proctosedyl® is considerably more expensive than Anusol HC® and Scheriproct®. Proctosedyl® and Anugesic HC® are now non-formulary for the management of haemorrhoids.

Ensuring compliance with the formulary choices is one of the ways that NHS Fife can ensure that the most cost-effective products and devices are used for our patients.

NHS Fife Formulary Abbreviated List

An abbreviated version of the Fife Formulary is now available in paper and electronic formats. The abbreviated list provides an easy reference source for all prescribers and clinicians to determine Fife Formulary recommended choices.

The abbreviated list includes the names of medicines specifically recommended as 1st and 2nd choices or those only approved for restricted use within NHS Fife.

Paper versions of the abbreviated list have been distributed to all relevant clinicians. Further paper copies of the abbreviated list can be requested from sandra.macdonald@nhs.net.

An interactive pdf file, suitable for saving to your PC desktop or downloading onto mobile devices e.g. Smart phones, e-readers and tablets, can be accessed from the ADTC website using the following link www.fifeadtc.scot.nhs.uk/formulary/NHS%20Fife%20Formulary%20Abbreviated%20List.pdf

Both the abbreviated list and the full version of the Fife Formulary are updated electronically on a regular basis and can be accessed via the ADTC website at www.fifeadtc.scot.nhs.uk/
Prescribing of Aqueous Cream

A recent MHRA Drug Safety Update article (Drug Safety Update March 2013 vol 6, issue 8 www.mhra.gov.uk/home/groups/dsu/documents/publication/con254819.pdf) reminds prescribers of the risk of skin irritation when using aqueous cream especially in children being treated for eczema. This is thought to be caused by sodium lauryl sulphate, a constituent of aqueous cream.

The NHS Fife Formulary recommends that aqueous cream is only used as a soap substitute and should not be prescribed for use as a general moisturiser in patients with eczema and other dry skin conditions.

Prescribing of Medicines for 'Off-label' Indications

In a recent report from the Scottish Public Services Ombudsman an NHS Fife clinician was criticised for not following the Board’s policy on the use of off-label medicines. The Area Drugs and Therapeutics Committee would like to remind all prescribers of the following considerations and requirements when prescribing a medicine for an off-label use.

Off-label use is defined as - medicines with a UK marketing authorisation, which are prescribed -

- for an unlicensed indication,
- via a different route,
- at a higher/lower dosage,
- in a patient group not covered by the license (i.e. out with the terms of the marketing authorisation).

If a patient is harmed by off-label use of a medicine then the manufacturer is unlikely to be found liable, unless the harm is directly attributable to a defect in the medicine, rather than the way in which it was prescribed. The prescriber would be liable instead.

When prescribing a medicine for off-label use prescribers must –

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its efficacy and safety.
- make a clear, accurate and legible record in the patient’s notes stating the reason for prescribing the medicine for an off-label use.
- ensure that the patient is aware of the off-label use of a medicine and is provided with sufficient information about the off-label use and any queries from the patient are answered.
- ensure the patient has given informed consent by being involved in the decision making process.

For further helpful advice on the prescribing of medicines for off-label use refer to the General Medical Council guidance ‘Good practice in prescribing and managing medicines and devices’ http://www.gmc-uk.org/Prescribing_Guidance__2013__50955425.pdf
### SMC Recommendations

**Medicines accepted for use by SMC**

In this document, we divide the medicines into three categories based on their recommendation levels:

- **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.

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<th>Fife ADTC Decision &amp; Comments</th>
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| **Bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®)**           | Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).  
  **SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chloride. | **Included on the Fife Formulary.**  
  Restricted to use in patients requiring a preservative free prostaglandin analogue due to sensitivity to benzalkonium chloride.  
  Replaces tafluprost (Saflutan®) as the preservative free Formulary option.  
  Specialist initiation only.                                                                                                                                                                                                 |
| **Infliximab 100mg powder for concentrate for solution for infusion**  | Treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.  
  **SMC restriction:** as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory. | **Not included on the Fife Formulary for this indication.**                                                                                                                                                                     |
| **Ingenol mebutate, 150 & 500micrograms/g, gel (Picato®)**             | Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.                                                                                                                                 | **Included on the Fife Formulary as a 3rd line treatment option for patients with small field actinic keratosis (max. 25cm² area).**  
  1st line option for small field AK is Solaraze® (diclofenac 3%)  
  2nd line option 5-FU (Efudix®).  
  Specialist initiation only.                                                                                                                                                                                                 |
| **Rivaroxaban 15mg and 20mg film-coated tablets (Xarelto®)**           | Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults.                                                                                                                                                                  | **Included in the Fife Formulary as 1st line option for the licensed indication.**  
  Anticipated duration for the majority of patients is 6 months.  
  Treatment for up to 12 months may be appropriate for some patients.  
  Specialist initiation only.                                                                                                                                                                                                 |
| **Sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection**         | Reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This resubmission is for the part of the indication relating to routine reversal of neuromuscular blockade.  
  **SMC restriction:** only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/ chest surgery) or where prompt reversal of neuromuscular block is required. | **Included on the Fife Formulary restricted list for use only in the following circumstances –**  
  1. Routine reversal in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/ chest surgery)  
  or  
  2. Where prompt reversal of neuromuscular block is required.  
  Hospital use only.                                                                                                                                                                                                 |
## SMC Recommendations

**Medicines accepted for use by SMC**

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| Abatacept 250mg powder for concentrate for solution for infusion (Orencia®) | In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.  
**SMC restriction:** abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.                                                                 | **Included** on the Fife Formulary restricted list.  
3rd line option after failure with at least 2 of the following agents anti-TNF, tocilizumab or rituximab.  
Hospital use only.                                                                                                                                                                                                                                                                                                                                                                     |
| Adalimumab, 40mg/0.8mL, solution for injection (Humira®)           | Treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).  
To be used only after the failure of at least 2 standard NSAIDs.  
Hospital use only.                                                                                                                                                                                                                                                                                                                                                                     | **Included** on the Fife Formulary for the indication stated.  
Alternative option to ranibizumab.  
Hospital use only.                                                                                                                                                                                                                                                                                                                                                                     |
| Aflibercept 40mg/mL solution for intravitreal injection (Eylea®)      | Treatment of neovascular (wet) age-related macular degeneration in adults.  
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.                                                                                                                                                                                                                                               | **Included** on the Fife Formulary.  
Alternative option to ranibizumab.  
Hospital use only.                                                                                                                                                                                                                                                                                                                                                                     |
| Darunavir oral suspension 100mg/mL (Prezista®)                      | Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.  
**SMC restriction:** to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV.                                                                                                                                                                                                                                                       | **Not Included** on the Fife Formulary for this indication.  
HIV paediatric specialist use only.                                                                                                                                                                                                                                                                                                                                                      |
| Insulin glargine 100units/mL solution for injection in a vial, cartridge, pre-filled pen (Lantus®, Clikstar®, Lantus®Solostar®) | Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.  
**SMC restriction:** patients in whom treatment with an insulin analogue is appropriate.                                                                                                                                                                                                                                                                                                                                             | **Included** on the Fife Formulary for the indication stated.  
Specialist initiation only.                                                                                                                                                                                                                                                                                                                                                          |
| Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)    | Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.  
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilimumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.                                                                                                                                                                               | **Not Included** pending protocol.                                                                                                                                                                                                                                                                                                                                                 |
Medicines not recommended by SMC (Requires approval of an Individual Patient Treatment Request (IPTR) before prescribing)

**Bevacizumab (Avastin®)** is not recommended in combination with carboplatin and gemcitabine for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.

**Botulinum toxin type A (Botox®)** is not recommended for the prophylaxis of headaches in adults with chronic migraine.

**Insulin degludec (Tresiba®)** is not recommended for treatment of diabetes mellitus in adults.

**Axitinib (Inlyta®)** is not recommended for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.

**Ruxolitinib (Jakavi®)** is not recommended for treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocytopenia myelofibrosis.

**Timothy grass pollen allergen (GRAZAX®)** is not recommended for disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis.

**Deferasirox (Exjade®)** is not recommended for treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.

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

Dates for 2013 ADTC Meetings

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All comments welcome - email: Sandra.macdonald@nhs.net
Or visit our website: www.fifeadtc.scot.nhs.uk

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