IN THIS ISSUE:

Formulary Changes

Chapter 6 - Endocrine System
Chapter 6 of the Fife formulary (Endocrine System) has recently been reviewed and updated.

Key Changes to this chapter include the following –

Diabetes
- Insulins - A new section on the use of insulin in Type 2 Diabetes has been included. Due to significant cost differences and lack of evidence of clinical advantages with insulin analogues, preferred 1st choice insulins are human insulins with insulin analogues 2nd choice. The majority of type 2 diabetes patients newly prescribed insulin should now be initiated on human insulins.

- Oral Glucose Tolerance Test – Patients requiring an oral glucose tolerance test should be prescribed Rapilose® which is significantly cheaper than prescribing glucose powder.

- Blood Glucose and Ketone Test Strips – A new section with preferred blood glucose and ketone test strips has been included. The Fife Formulary choices are:
  - Blood glucose strips
    - Type 1 Diabetes - Glucomen® LX Sensor Strips
    - Type 2 Diabetes - 1st choice Glucomen® GM Strips 2nd choice Trueyou® Strips
    - Ketone Strips – Glucomen® LX Strips

- As part of the medicines management component of the QOF contract it is proposed that practices will be asked to review patients on alternative test strips and switch to the formulary choices.

HRT
- Climaval® has been included in the Fife Formulary as a 2nd choice oestrogen only tablet formulation.

- The following products are no longer formulary choices – Prempak-C®, Premarin® and the Femseven® Patch.

Osteoporosis
- Denosumab (Prolia®) is now a second choice agent for the treatment of osteoporosis after oral bisphosphonates.

- Strontium (Protelos®) - Due to recent safety concerns strontium is no longer a formulary choice and is now only recommended in severe osteoporosis when all other treatment options have been tried/ or considered inappropriate. (See BNF for cautions and contraindications)

- Specific drug choices for the treatment of post-menopausal women, men and steroid induced osteoporosis are included.

Gluten Free Food Formulary
Formulary choices for gluten free foods (GFF) have been agreed and approved in NHS Fife to coincide with an additional Community Pharmacy Service which will be introduced in Fife from April 2014 enabling patients to obtain gluten free foods directly from their chosen local pharmacy. The service will run as a pilot until 31 March 2015.

The purpose of the GFF formulary is to standardise the range of products available to patients needing a GF diet and at the same time offer a range of products to select from and the flexibility to choose different products from month to month. The GFF formulary offers dietary staples but excludes sweet biscuits and cake mixes.

It is expected that all patients in receipt of GFF products (either through the new pharmacy service or continuing through their general practice) will have products prescribed in line with the GFF formulary choices.

Further information on the community pharmacy service and the GFF formulary has been sent out to all practices and community pharmacies in Fife. Further information can also be found in the latest edition of the Fife Prescribing Update (Issue 46, March 14) http://intranet.fife.scot.nhs.uk/uploadfiles/publications/FPU%2046.pdf
Formulary Changes

Chapter 14 – Immunological Products and Vaccines

Chapter 14 of the Fife Formulary has been reviewed and updated.

Points to note in this chapter include the following –

- Electronic links to relevant sections in the Green Book, the childhood immunisation schedule and travel advice websites have been included. An electronic link is also provided to national guidelines on the use of immunoglobulins.
- List of travel vaccines prescribable on the NHS or those that require private prescriptions.
- Medicines for prophylactic use e.g. ciprofloxacin, oral rehydration salts should not be prescribed on the NHS.
- Patients requiring regular medication for stable pre-existing conditions can be supplied with a maximum of 3 months treatment. If patients are to be abroad for an extended period then the patient should be provided with a list of their regular medication and be advised to make arrangements to get further supplies from health care providers at their destination.

Oral Rehydration Salts

The Fife Formulary choice oral rehydration salt for the management of dehydration Electrolyte® has recently been discontinued by the manufacturer. The Fife Formulary choice is now Dioralyte®.

Emergency Contraception

Upostelle® has replaced Levonelle® as the preferred levonorgestrel based emergency contraceptive for up to 72 hours after unprotected sexual intercourse. Upostelle® is bioequivalent to Levonelle® and is 15% cheaper.

Preservative Free Timolol Eye Drops

Tiopex®, a once daily eye gel, is now the preferred preservative free (P/F) formulation of timolol in NHS Fife. Tiopex® is significantly cheaper than the alternative P/F formulation of Timoptic® drops.

Reminder - P/F formulations of eye preparations should be reserved for use in patients with known sensitivity to the preservative as P/F products are significantly more expensive than standard formulations.

Naloxone 1mg/ml Injection (Prenoxad®)

Prenoxad® has been added to the Fife Formulary for emergency use in the home or other non-medical setting for the complete or partial reversal of respiratory depression due to a suspected opioid overdose. Adequate training on the use of Prenoxad® to patients or their support network is required therefore Prenoxad® is only approved for use on the recommendation of a specialist once training has been provided to the patient/support network. Prenoxad® is not approved for initiation in primary care.

Wound Formulary and Wound Management Guidelines 2014

The wound formulary has been updated to reflect recent changes to woundcare products which are available on national contract and via the Area Distribution Centre in Fife.

The formulary contains information in the following areas –

- How to assess different wound types
- Selection of wound dressings
- Management of bacterial infection in wounds
- Wound cleansing guidelines
- Monographs for wound dressings – which include information on 1st and 2nd line Fife Formulary woundcare products, a description of the dressings and how they work, indications for the different dressing types and method of use.

- There is also a summary table at the end of each monograph highlighting the pack sizes that are available and the costs of the different products
- Information on specialised dressing and therapies
- Assessment chart and sheet for wound management
- A woundcare products conversion chart is also included – The chart highlights the 1st and 2nd line choice dressings for woundcare products and for ease of reference it lists a range of dressings that are non-formulary so that the appropriate formulary products can be prescribed.

The revised wound formulary can be accessed via the ADTC website and print versions are expected to be distributed over the next couple of months.

The Fife Formulary can be accessed / downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Fife Formulary or via the Fife Formulary Quicklinks on the NHS Fife intranet homepage.

SIGN 136 – Management of Chronic Pain

www.sign.ac.uk/guidelines/fulltext/136/index.html

New guidance on managing chronic pain has been published by SIGN. It covers best practice in the assessment and management of adults with chronic non-malignant pain in non-specialist settings.

The guidance includes: self management, pharmacological, psychological, physical, complementary and dietary therapies. It also includes treatment pathways for patients with neuropathic pain and using strong opioids in chronic pain.

In terms of medicines the guideline makes recommendations on the use of non-opioid analgesics (both oral and topical formulations), the use of opioid analgesics, gabapentin, pregabalin, carbamazepine and the use of antidepressants in the management of pain.

A new chronic pain management website for use by health care professionals and the public has also been launched http://chronicpainscotland.org/
The annual report from the Yellow Card Centre highlighting adverse events reports submitted from NHS Fife has recently been issued.

**A summary of the key points from the annual report are –**

- There has been a steady rate of decline in the reporting trend across Scotland from 2008 onwards.
- The reporting rate for suspected adverse drug reactions from NHS Fife decreased slightly in 2012/13 (58 reports compared to 61 reports in 2011/12). A decreasing trend is evident since 2008.
- Reporting rate per 100,000 population was the same (16) as the Scottish average.
- Reports for serious suspected reactions were marginally lower (53%) than the Scottish average (56%).
- Reports for Black Triangle medicines were lower (29%) than the Scottish average (37%).
- Reports relating to paediatric patients were higher in Fife (19%) than the Scottish average (12%).

**Key messages to all staff –**

- All healthcare professionals are requested to report via the Yellow Card Scheme [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).
- All suspected serious reactions for all medicines.
- Any suspected reactions for medicines under intensive monitoring i.e. Black Triangle medicines.
- Any adverse events due to incorrect prescribing or incorrect administration of a medicine that results in harm to a patient should be reported via the Yellow Card Scheme.
- Patients should be encouraged and supported to complete Yellow Card reports for suspected ADRs.

**Guidance Documents**

The following guidance documents have been approved for use by the ADTC -

**Updated**

**Appendix 6A - Guidance on Diagnosis and Management of Osteoporosis**
The guidance cover the following areas - a pathway for the management of patients with a fracture or significant risk factors; a list of standard investigations that should be performed prior to treatment; treatment options in line with Fife Formulary choices; information on the likely duration of bisphosphonate therapy and when patients should be reviewed.

**Updated**

**Appendix 6B - Guidance on the Management of Menopause in Primary Care**
The comprehensive guidance provides advice in the following areas – Diagnosis of the menopause; indications for the use of HRT; general prescribing information; safety and potential side-effects of HRT; advice on starting and stopping HRT; possible alternatives to HRT; advice on contraception in the perimenopause; links to other useful resources.

**Updated**

**Appendix 12A – Guidance for the Management and Treatment of Thrush (Candidiasis) in Breastfeeding**
The guidance document contains information relating to the following areas –

- Signs / symptoms suggestive of thrush.
- Actions to be taken by health professionals if a patient presents with symptoms.
- Treatment for thrush in both babies and the breastfeeding mother.
- Guidance on the use of miconazole oral gel in babies aged less than 4 months, nystatin in babies less than 4 weeks and the use of fluconazole in breastfeeding mothers (all off-label uses).

Clinicians should note a recent change in the licensed dose for miconazole gel – The license dose for use in infants from 4-24 month is now 1.25ml four times daily and in children aged 2 years and older 2.5ml four times daily.

**Updated**

**Guidance Antimicrobial Prescribing IV to Oral Switch Therapy (IVOST) and Restricted Antimicrobial List for Ward-based Prescribing**

Updated versions of the above guidance documents, which are relevant to the acute services division, are now available.

Copies of all the above guidance documents can be accessed/downloaded from the ADTC website [www.fifeadtc.scot.nhs.uk](http://www.fifeadtc.scot.nhs.uk) by clicking on the link for Fife Formulary or via the Fife Formulary Quicklinks on the NHS Fife intranet homepage.
### SMC Recommendations
**Medicines accepted for use by SMC**

**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>Bortezomib 3.5mg powder for solution for injection (Velcade®)</td>
<td>In combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation. SMC restriction: use as triple therapy in combination with dexamethasone and thalidomide.</td>
<td>Included on the Fife Formulary as a triple combination induction therapy. To be used in combination with thalidomide + dexamethasone. Hospital use only.</td>
</tr>
<tr>
<td>Tocilizumab, 20mg/mL concentrate for infusion (RoActemra®)</td>
<td>In combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate. Tocilizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate.</td>
<td>Included on the Fife Formulary for the treatment of systemic juvenile idiopathic polyarthritis. 3rd choice after failure with etanercept and infliximab. May be used 2nd line in patients unable to use infliximab. Hospital use only.</td>
</tr>
<tr>
<td>Trastuzumab, 600mg/5mL solution for injection (Herceptin®)</td>
<td>Treatment of adult patients with HER2 positive metastatic breast cancer and early breast cancer in a range of settings. SMC restriction: Subcutaneous trastuzumab injection is accepted for use in line with previous SMC advice for intravenous trastuzumab.</td>
<td>Not included pending protocol. Await Lothian Formulary Committee decision following SCAN submission.</td>
</tr>
<tr>
<td>Saxagliptin plus metformin, 2.5mg / 850mg and 2.5mg / 1000mg film-coated tablets (Komboglyze®)</td>
<td>In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus when the maximally tolerated dose of both metformin and the sulphonylurea does not provide adequate glycaemic control.</td>
<td>Not included on the Fife Formulary because NHS Fife decision is that the medicine does not represent sufficient added benefit to comparator medicines to treat the condition in question. Both metformin and saxagliptin (2nd choice gliptin) are included in the Fife Formulary as single agents.</td>
</tr>
<tr>
<td>Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®)</td>
<td>Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. SMC restriction: only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery) and; retreatment would take place only if the patient had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32.</td>
<td>Add to restricted list. Restricted to use by trained specialists after failure with both laser and ranibizumab. To be used only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery). Hospital use only.</td>
</tr>
<tr>
<td>Levonorgestrel 1500microgram tablet (Upostelle®)</td>
<td>Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.</td>
<td>Included on the Fife Formulary. Replaces Levonelle®.</td>
</tr>
<tr>
<td>Timolol, 1mg/g eye gel for single-dose container (Tiopex®)</td>
<td>Reduction of the elevated intraocular pressure in patients with: - ocular hypertension, chronic open angle glaucoma. SMC restriction to use in patients who have proven sensitivity to preservatives.</td>
<td>Included on the Fife Formulary. Specialist initiation only. Preferred preservative free timolol formulation. Replaces Timoptol p/f drops. P/F formulations of timolol should only be used in patients with known sensitivity to benzalkonium chloride.</td>
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Summary of Approved Lothian Formulary Committee Decisions for SCAN Medicines January 2014

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Indication Assessed</th>
<th>Place in Therapy</th>
<th>Lothian Formulary Committee Decision</th>
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</thead>
<tbody>
<tr>
<td>Axitinib, 1mg and 5mg, film-coated tablets (Inlyta®)</td>
<td>Treatment of adult patients with advanced renal cell carcinoma after failure of prior treatment with sunitinib or a cytokine.</td>
<td>2nd line after failure of one line of tyrosine kinase inhibitor or cytokine irrespective of the choice of first line TKI.</td>
<td>Included on the Additional List. Only approved for use after failure with sunitinib. 2nd line use after pazopanib would be an off-label use and is not currently approved.</td>
</tr>
<tr>
<td>Enzalutamid 40mg soft capsules (Xtandi®)</td>
<td>Treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy.</td>
<td>2nd line after docetaxel chemotherapy in men with ECOG performance status 0-2.</td>
<td>Approved. Included on the Additional List. Specialist hospital use only.</td>
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Medicines not recommended by SMC
www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory/SMC_Advice_Directory/

Require the submission and approval of an IPTR before prescribing

Golimumab (Simponi®) is not recommended for treatment of moderately to severely active ulcerative colitis in adult patients 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.

Fentanyl citrate (Breakyl®) is not recommended for treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.

Colestilan (BindRen®) is not recommended for treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.

Lomitapide (Lojuxta®) is not recommended as adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein apheresis in adult patients with homozygous familial hypercholesterolaemia.

Dates for 2014 ADTC Meetings

<table>
<thead>
<tr>
<th>ADTC meeting</th>
<th>Deadline for submission of papers and agenda items</th>
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<tbody>
<tr>
<td>16 April</td>
<td>31 March</td>
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<td>18 June</td>
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<td>20 August</td>
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<td>15 October</td>
<td>29 September</td>
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<td>17 December</td>
<td>01 December</td>
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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.

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

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