NHS Fife ADTC Paperwork

Revised versions of ADTC submissions forms for the use of medicines are now available to be downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/.

The revised forms have been made simpler to complete and also help to highlight the key bits of information required by the ADTC before they can make a recommendation in relation to the submission.

<table>
<thead>
<tr>
<th>Submission Form</th>
<th>When should they be completed?</th>
<th>Who can complete a submission form?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request to add a medicine to the Fife Formulary</td>
<td>If a prescriber wishes to add to / amend current Fife Formulary choices</td>
<td>Consultant, GP, senior nurse or senior pharmacist. Where possible, each submission should also be supported by a senior pharmacist.</td>
</tr>
<tr>
<td>Request to use an unlicensed medicine in an individual or group of patients</td>
<td>If a prescriber wishes to prescribe a medicine which does not have a medicines license within the UK e.g. drugs imported from abroad, discontinued drugs. There is no need to complete a submission form for the off-label use of medicines.</td>
<td>Consultant, GP, senior nurse or senior pharmacist. Where possible, each submission should also be supported by a senior pharmacist. The submission should also have the support of the relevant clinical director, general manager or management accountant.</td>
</tr>
<tr>
<td>Individual Patient Treatment Request Forms</td>
<td>To request the use of a medicine in an individual patient in the following circumstances: 1. A medicine that has not been approved by the Scottish Medicines Consortium (SMC), NHS QIS or Fife ADTC. Including medicines that have not been approved due to a non-submission. 2. A medicine that has not yet been assessed by the SMC. 3. For a licensed indication that has not been approved by the SMC, NHS QIS or Fife ADTC. The prescriber should provide evidence of the exceptional nature of the patient compared to the general population.</td>
<td>Consultant, GP, senior nurse or senior pharmacist. Where possible, each submission should also be supported by a senior pharmacist. The submission should also have the support of the relevant clinical director, general manager or management accountant.</td>
</tr>
</tbody>
</table>

Supply of Unlicensed Melatonin

In October 2008, NHS Fife Area Drug and Therapeutics Committee agreed to supporting the use of unlicensed non-medicinal melatonin products e.g. Bio-Melatonin®, Life Extension® and Kidnap®, in preference to the off-label use of Circadin® (only licensed for short-term insomnia in those aged over 55 years of age) in reducing sleep onset latency in children with neuro-developmental disorders and to treat insomnia in patients with dementia. It should be noted that Bio-Melatonin® is the NHS Fife preferred unlicensed product as it is licensed within the EU and its manufacture meets Good Manufacturing Policy standards. Additionally, Bio-Melatonin® can be ordered without the need to complete further paperwork. The other products are imported from the US and are regarded as food supplements rather than medicines and are not manufactured to the same standards.

Recently there have been reports of difficulty in obtaining unlicensed melatonin products due to changes in the information required by the “Specials” supplier. A newly revised request form to be completed by all prescribers prescribing EU unlicensed melatonin products has been issued to all GP practices and pharmacies in Fife. This form needs to be completed if requesting any melatonin product apart from Circadin® or Bio-Melatonin®. Each prescriber should complete a copy of the form and forward to the pharmacy for ordering.

Further copies of the form can be downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Unlicensed Medicines on the left hand side of the Home page.

Key Messages:
- Bio-Melatonin® 3mg tablets are the preferred unlicensed melatonin product for use in NHS Fife.
- Due to individual “special” needs if an alternative unlicensed product is required then a request form needs to be completed by the prescriber and submitted to the pharmacy.
### Medicines accepted for use by SMC

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication assessed</th>
<th>Fife ADTC decisions &amp; comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eslicarbazepine acetate 800mg tablet (Zebinix®)</td>
<td>Adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.</td>
<td>Decision deferred whilst awaiting comments from local specialists.</td>
</tr>
<tr>
<td>Denosumab, 60mg solution for injection in a pre-filled syringe (Prolia®)</td>
<td>Treatment of osteoporosis in postmenopausal women at increased risk of fractures.</td>
<td>Decision deferred while awaiting comments from local specialist.</td>
</tr>
<tr>
<td>Etonogestrel implant 68mg (Nexplanon®)</td>
<td>Contraception.</td>
<td>Add to formulary. Replaces Implanon®.</td>
</tr>
<tr>
<td>Atazanavir 150, 200 and 300mg capsules (Reyataz®)</td>
<td>Treatment of paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products.</td>
<td>New indication noted. Specialist use only.</td>
</tr>
<tr>
<td>Oxycodone hydrochloride 50mg/ml injection (OxyNorm®)</td>
<td>Treatment of moderate to severe pain in patients with cancer.</td>
<td>Add to restricted list. New formulation noted. Restricted to use in cancer patients with moderate to severe pain who require a high dose of oxycodone via a syringe pump. Specialist use only.</td>
</tr>
<tr>
<td>Tacrolimus granules for Oral Suspension (Modigraf®)</td>
<td>• Prophylaxis of transplant rejection in adult and paediatric, kidney, liver or heart allograft recipients. • Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult and paediatric patients.</td>
<td>Add to restricted list. New formulation noted. Restricted to use in patients where small changes (less than 0.5mg) in dosing increments are required (e.g. in paediatric patients) or seriously ill patients who are unable to swallow tacrolimus capsules. Specialist initiation only.</td>
</tr>
<tr>
<td>Moxifloxacin intravenous, 400mg/250mL, solution for infusion (Avelox®)</td>
<td>Treatment of community acquired pneumonia (CAP). It should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents.</td>
<td>Not preferred in NHS Fife. See local guidance on management of Community Acquired Pneumonia (CAP).</td>
</tr>
</tbody>
</table>

### Medicines Not Recommended by SMC

**Glucosamine sulphate (Glusartel®)** is not recommended for relief of symptoms in mild to moderate osteoarthritis (OA) of the knee.

**Eculizumab (Soliris®)** is not recommended for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH).

**Sevelamer carbonate (Renvela®)** is not recommended for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.

**Trabectedin (Yondelis®)** is not recommended for the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.

**Canakinumab (Ilaris®) 150 mg/ml, powder for solution for injection intended is not recommended for Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg.**

**Amifampridine (Firdapse®)** is not recommended for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults.

**Docetaxel (Taxotere®)** in combination with doxorubicin and cyclophosphamide is not recommended for adjuvant treatment of patients with operable node-negative breast cancer.

**Dexamethasone intravitreal implant (Ozurdex®)** is not recommended for the treatment of adult patients with macular oedema following either branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).
Medicines Not Recommended by SMC continued….

Gefitinib (Iressa®) is not recommended for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).

Prucalopride (Resolor®) is not recommended for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

Ranolazine (Ranexa®) is not recommended as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta blockers and/or calcium antagonists).

Denosumab (Prolia®) is not recommended for bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.

Diclofenac 4% spray gel (Mobigel Spray ®) is not recommended for the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures.

Fondaparinux sodium (Arixtra ®) is not recommended for the treatment of acute symptomatic spontaneous superficial-vein thrombosis of the lower limbs without concomitant deep-vein thrombosis.

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Management and Treatment of Thrush (Candidiasis) During Breastfeeding

A new NHS Fife guidance document has been approved for the management of thrush during breastfeeding. The guidance document was produced by Gina Graham, NHS Fife Breastfeeding Support Co-ordinator and has been approved by the ADTC. The incidence of candidiasis of the breast appears to be increasing, possibly because of the increased use of antibiotics in pregnancy and the intrapartum period. Recent antibiotics and / or nipple trauma appear to be linked with an increased susceptibility to candida in the breast which flourishes in the moist environment and high humidity provided by breast pads.

If topical symptoms of nipple thrush or symptoms of thrush in the baby (oral or in nappy area) are not appropriately treated, or the mother is prescribed antibiotics on the assumption that breast pain is associated with infection, ductal thrush may develop where the associated breast pain may be felt deep within the breast, is often described as intense and often leads to the early cessation of breastfeeding.

Breastfeeding rates in many areas of Fife are low and complications in breastfeeding are rarely encountered by many practitioners. Huge variations in practices have been identified across Fife with many cases being inappropriately managed, mainly by not treating mother and baby concurrently.

Key points from the guidance

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 and the use of fluconazole in breastfeeding mothers (off-label uses).

Copies of the guidance have been distributed to all staff members via e-mail. Further copies can be downloaded from the ADTC website [www.fifeadtc.scot.nhs.uk/](http://www.fifeadtc.scot.nhs.uk/) by clicking on the link for Guidance documents / Formulary Appendices (Appendix 1.2A).

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Distribution of ADTC Bulletins, Fife Guidelines and Revised Formulary Sections

The ADTC have agreed that all future copies of the ADTC bulletin, updated formulary sections and copies of approved guidance documents will be sent out to NHS Fife staff via e-mail.

Copies of the documents can also be downloaded from the ADTC website [www.fifeadtc.scot.nhs.uk/](http://www.fifeadtc.scot.nhs.uk/).

Anyone who does not have access to e-mail or the internet and who still require paper copies of the documents can request a copy by contacting Sandra Macdonald on (01592) 226915.
NHS Fife e-Formulary for EMIS and Vision practices

By the end of March 2011, it is hoped that all GP practices that are currently using EMIS or Vision practice prescribing systems will have had the NHS Fife version of the electronic formulary (e-Formulary) loaded onto their systems.

This will help ensure that when a GP is about to prescribe a medication for the first time or as an acute prescription the system will help flag up if a medicine is recommended in the Fife Formulary or not. This should help to improve compliance with the Fife Formulary and also ultimately ensure that NHS Fife is using the most cost-effective medicines for the majority of their patients.

Practices that will be migrating to EMIS / Vision systems in the future will have the formulary loaded onto their prescribing systems shortly after the migration has taken place.

For the EMIS system further work is currently being undertaken to introduce default dosing instructions and quantities for formulary approved drugs. There will also be the possibility to prescribe by disease state by the use of synonyms.

It is hoped that future developments in Vision will also allow prescribing by disease state and allow the pre-population of dosage instructions for formulary drugs.

SIGN 121 - Diagnosis and Management of Psoriasis and Psoriatic Arthritis in Adults

SIGN have recently issued a guideline document on the Diagnosis and Management of Psoriasis and Psoriatic Arthritis in Adults (SIGN 121, October 2010).

In terms of treatment in primary care the key summary points from the guidance are -

- Short term intermittent use of potent topical steroids or a combined potent steroid plus calcipotriol ointment is recommended to gain rapid improvement in plaque psoriasis.
- For long term topical treatment a vitamin D analogue e.g. calcipotriol is recommended.
- If a vitamin D analogue is ineffective or not tolerated then coal tar, tazarotene or short contact dithranol should be considered.
- Short term intermittent use of potent topical steroids or a combination of a potent steroid and a vitamin D analogue should be considered in scalp psoriasis.
- Moderate potency topical steroids are recommended for short term use in facial or flexural psoriasis. If ineffective, then intermittent use of vitamin D analogues or tacrolimus ointment should be considered.

Refer to chapter 13 of the Fife Formulary for local choices in the treatment of psoriasis.

Dates for 2011 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>20th April</td>
<td>4th April</td>
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<tr>
<td>15th June</td>
<td>30th May</td>
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<tr>
<td>10th August</td>
<td>25th July</td>
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<tr>
<td>12th October</td>
<td>26th September</td>
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<tr>
<td>21st December</td>
<td>5th December</td>
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</tbody>
</table>

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 telephone 01592 226915

Produced By: Ishtiaq Mohammed, Clinical Effectiveness Pharmacist
All comments welcome - email: sandra.macdonald@nhs.net  or visit our website: www.fifeadtc.scot.nhs.uk