Formulary Changes

Updated Musculoskeletal Formulary Section

The revised musculoskeletal section of the formulary (Section 10) has been approved by the ADTC.

Key changes to the section include –

• Addition of internet links to relevant SIGN and NICE guidance.
• Emphasis on gastrointestinal (GI), cardiovascular and renal risk due to the prescribing of anti-inflammatory drugs. Increased clarity on the choice of NSAID in these high risk groups. Naproxen is now the preferred NSAID choice in patients over 45 or those with underlying cardiovascular disease. Diclofenac should only be considered in patients under 45 who do not have underlying cardiovascular disease. Patients at risk of GI events should be prescribed a formulary NSAID + a PPI (omeprazole or lansoprazole).
• The coxibs (celecoxib, etoricoxib) are no longer included in the formulary and should only be considered along with other non-formulary NSAIDs in patients where at least 2 formulary NSAID choices have been ineffective or not tolerated.
• Due to differences in bioavailability different brands of ciclosporin and tacrolimus should be prescribed by brand name. The NHS Fife preferred choice for ciclosporin is Neoral® and for tacrolimus, depending on the dose, it is Advagraf® or Prograf®.
• Febuxostat (Adenuric®) is restricted to specialist initiation only, for the management of chronic gout.
• Due to limited benefits in osteoarthritis, glucosamine products are not recommended for prescribing on the NHS.
• Due to safety concerns, quinine tablets should only be prescribed for leg cramps when non-pharmacological interventions have not worked. Ongoing prescribing of quinine should be reviewed every 3 months.
• Topical NSAIDs – piroxicam is now the 1st line choice and ibuprofen 1% gel the 2nd line choice. Diclofenac gel 1%, ketoprofen gel. Novelat® and rubefacient preparations are all non-formulary.
• Capsaicin cream 0.075% is restricted to specialist initiation only, in the treatment of neuropathic pain.

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

Copies of the section have been distributed to all staff via e-mail. Copies of the formulary section 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 link on the NHS Fife intranet homepage.

Pentasa® Preferred Mesalazine Brand for the Treatment of Ulcerative Colitis

Pentasa® has been approved as the formulary choice mesalazine product for the treatment of ulcerative colitis. All new patients requiring mesalazine should be prescribed Pentasa®. Patients currently stabilised on alternative brands do not need to be switched but a switch to Pentasa® may be considered if symptoms relapse.

Due to differences in bioavailability and release profiles it is recommended that mesalazine products should be prescribed by brand name only. Previously NHS Fife has not stated which brand should be prescribed. Asacol®, currently the most commonly prescribed brand, is approximately 35% more expensive than the equivalent formulation of Pentasa®. Pentasa® is available as tablets, sachets, enema and suppositories and in a range of strengths allowing flexibility in dosing and minimising tablet burden.

Currently 8% of prescriptions in primary care are still prescribed by the generic name. It is important that these patients are reviewed and their prescriptions altered to the brand that they are currently being dispensed. All prescriptions for mesalazine products should always state the brand that should be dispensed.

Adcal-D3® Range Formulary Choice for Calcium & Vitamin D Preparations

The ADTC have approved the addition of Adcal-D3® caplets to the Fife Formulary.

Adcal-D3® caplets are easy-to-swallow and do not need to be chewed. The alternative caplet formulation - Calcichew-D3® caplets are more expensive and contain soya (avoid in patients with peanut allergy) and gelatine so are not suitable for all patients.

Adcal-D3® now consists of 3 formulations - caplets, chewable tablets and effervescent tablets and should be suitable for the majority of patients. The Adcal-D3® range has been approved as the Fife Formulary choice for calcium & vitamin D products.

The Calcichew-D3® range, Calfovit® and Calceos® are now all considered to be non-formulary and should not be initiated in new patients.
## 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 decisions &amp; comments</th>
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<tbody>
<tr>
<td>Ticagrelor film-coated tablets (Brilique®)</td>
<td>Coadministered with aspirin, for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (unstable angina, non ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]), including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).</td>
<td>Not preferred. Fife Formulary choice for this indication is aspirin and clopidogrel.</td>
</tr>
<tr>
<td>Azacitidine 100mg powder for suspension for injection (Vidaza®)</td>
<td>Treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).</td>
<td>Add to restricted list. Specialist, hospital use only. Advise contingent on the continuing availability of the Patient Access Scheme.</td>
</tr>
<tr>
<td>Dabigatran etexilate 110mg and 150mg hard capsules (Pradaxa®)</td>
<td>Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with or more of the following risk factors: • previous stroke, transient ischaemic attack, or systemic embolism • left ventricular ejection fraction &lt;40% • symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2 • age ≥75 years • age ≥65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension</td>
<td>Decision deferred whilst awaiting National Consensus Statement and local discussions.</td>
</tr>
<tr>
<td>Tenofovir disoproxil (as fumarate), 245mg, film-coated tablet (Viread®)</td>
<td>Treatment of chronic hepatitis B in adults with compensated liver disease.</td>
<td>Decision deferred. Awaiting feedback from specialists.</td>
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<tr>
<td>Golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®)</td>
<td>Treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy. Restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines for anti-TNF agents in adults with ankylosing spondylitis. Golimumab is restricted to use at a dose of 50mg only.</td>
<td>Decision deferred. Awaiting feedback from specialists.</td>
</tr>
<tr>
<td>Adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Joven®)</td>
<td>Emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise-induced anaphylaxis.</td>
<td>Not preferred. Current formulary choices are Epipen 150mcg, 300mcg and Anapen 500mcg.</td>
</tr>
<tr>
<td>Bocceprevir 200mg capsule (Vircirel®) Treatment experienced patients</td>
<td>Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alpha and ribavirin, in adult patients with compensated liver disease who have failed previous therapy.</td>
<td>Decision deferred, awaiting feedback from specialists.</td>
</tr>
<tr>
<td>Bocceprevir 200mg capsule (Vircirel®) Treatment naïve patients</td>
<td>Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon ribavirin, in adult patients with compensated liver disease who are previously untreated.</td>
<td>Decision deferred, awaiting feedback from specialists.</td>
</tr>
<tr>
<td>Botulinum toxin type A, 50 and 100 LD50 units powder for solution for injection (Xeomin®)</td>
<td>Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults.</td>
<td>Not preferred. Fife formulary choice is BOTOX®. Must prescribe botulinum toxin products by brand name.</td>
</tr>
<tr>
<td>Flurbiprofen 0.5% / salicylic acid 10% cutaneous solution (Actikerall®)</td>
<td>Topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratoses (grade 1/II) in immunocompetent adult patients.</td>
<td>Add to restricted list. For use in patients with ≤10 isolated lesions of actinic keratoses where cryotherapy is unsuitable.</td>
</tr>
<tr>
<td>Olmesartan medoxomil/amlopidine besilate/hydrochlorothiazide 20mg/5mg/12.5mg, 40mg/5mg/12.5mg, 40mg/10mg/12.5mg, 40mg/5mg/25mg, 40mg/10mg/25mg film-coated tablets (Sevikar HCT®)</td>
<td>Substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlopidine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlopidine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlopidine).</td>
<td>Not preferred. Olmesartan is not a formulary choice in Fife. Losartan is the Fife Formulary choice Angiotensin Receptor Blocker for hypertension.</td>
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</table>
Medicines not recommended by SMC

These products should not be prescribed for the indication stated within NHS Fife without submission and approval of an Individual Patient Treatment Request Form (IPTFR).

Abatacept (Orencia®) is not recommended 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 antirheumatic drugs including methotrexate or a tumour necrosis factor (TNF) alpha inhibitor. Health benefits compared to cost not proven.

Eribulin (Halaven®) is not recommended for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Health benefits compared to cost not proven.

Rosuvastatin (Crestor®) is not recommended for the prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors. Health benefits compared to cost not proven.

Bromfenac (Yellox ®) eye drops are not recommended for the treatment of postoperative ocular inflammation following cataract extraction in adults. Non-submission by license holder.

Conestat alfa (Rucenost ®) is not recommended for the treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. Non-submission by license holder.

Infliximab (Remicade®) is not recommended for the treatment of moderately active Crohn’s disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. Non-submission by license holder.

Quetiapine (Serquel XL®) is not recommended as add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had suboptimal response to antidepressant monotherapy. Non-submission by license holder.

Rosuvastatin ‘Not Recommended’ for the Primary Prevention of Cardiovascular Disease

Rosuvastatin has not been recommended by the Scottish Medicines Consortium (SMC) for the prevention of major cardiovascular events in patients who are considered high risk of a first cardiovascular event. In the submission, the SMC were asked to consider the use of rosvastatin as a 2nd line treatment option in patients for whom simvastatin is contra-indicated or not tolerated. The SMC did not approve the use of rosvastatin due to a lack of robust economic benefits.

Local Advice

NHS Fife cholesterol guidelines (Appendix 2F of the Fife Formulary) state in primary prevention the preferred drug is simvastatin 40mg. In patients who are unable to tolerate simvastatin 40mg step down to simvastatin 20mg or switch to pravastatin 40mg. Other statins or lipid lowering agents are not recommended for primary prevention.

Key Messages

- Simvastatin 40mg is the 1st line statin for primary prevention.
- Simvastatin 20mg or pravastatin 40mg should be considered in patients unable to tolerate simvastatin 40mg.
- Rosuvastatin should NOT be prescribed for primary prevention.

References

1. SMC advice (725/11), October 2011. www.scottishmedicines.org.uk/SMC_Advice/Advice/725_11_rosuvastatin_Crestor/rosuvastatin_Crestor

NICE Clinical Guidance 127 – Clinical Management of Primary Hypertension in Adults – Follow Local Guidance

NICE have recently produced an updated guidance document on the management of patients with primary hypertension. Important changes from previous guidance include:

• Using ambulatory or home blood pressure monitoring to confirm the diagnosis of hypertension.
• A calcium-channel blocker (CCB) is recommended as first choice step 1 antihypertensive drug for people aged over 55 years and black people of any age. An ACE inhibitor remains the recommendation for those under the age of 55.
• An ACE inhibitor in combination with a calcium channel blocker is recommended for people of any age at step 2 drug treatment.
• Chlortalidone or Indapamide are now recommended as the preferred thiazide diuretics in new patients instead of bendroflumethiazide. Thiazide diuretics are only recommended at step 1 or step 2 in patients unable to tolerate a CCB or where a CCB is contraindicated or in addition to an ACE inhibitor and a CCB at step 3.
• Spironolactone 25 mg once daily is recommended as the first choice additional treatment if the person’s blood potassium level is 4.5 mmol/L or less) at step 4.

It should be noted the NICE Clinical Guidance has no formal status in Scotland and there is no requirement to follow the guidance.

NHS Fife guidance on hypertension (Appendix 2A of the Fife Formulary) was recently reviewed and updated in April 2011. The prescribing subgroup of the vascular MCN has been tasked with reviewing the local guidance to take into account changes in the NICE guidance. Until that review is complete the current local Fife guidance should be continued to be followed.

References

Guidance

Updated Fife Formulary Appendices – Respiratory Section

Further to the approval of the updated respiratory formulary section, the associated formulary appendices have been reviewed and updated by the Respiratory MCGN. There are now 5 respiratory appendices relating to the treatment of asthma and COPD.

• Appendix A – Stepwise management of patients with asthma – This appendix has been reviewed and updated to reflect the changes in the latest SIGN/BTS Guidelines for Management of Asthma. The key change in this appendix is that children aged 5-12 years should refered to a paediatrician for a review at Steps 4 and 5.

• Appendix B – Choosing asthma inhaler devices for adults - Updated appendix highlighting the preferred inhaler devices in adults and when alternatives to MDI’s should be considered.

• Appendix C – Choosing asthma inhaler devices for children aged 5-12 years - New appendix highlighting the preferred inhaler devices in children and when alternatives to MDI’s should be considered.

• Appendix D – Inhaled corticosteroids for children – Updated appendix highlighting the range of inhaled corticosteroid products available approved in the Fife Formulary to be prescribed to children; the age range that they can be prescribed for, maximum doses and additional guidance notes.

• Appendix E – Management of COPD – Updated guidance to take into account advice in NICE Clinical Guideline 101 – COPD. Other changes include a reminder that mucolytics should be prescribed for an initial 4 week trial and should not be prescribed routinely to prevent exacerbations; patients with Stage 3 COPD should have annual oximetry.

A copy of the appendices has been emailed out to all GP practices, secondary care settings and community pharmacies. Further copies can be accessed/downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ or the Fife Formulary link on the NHS Fife intranet homepage by clicking on the link for Guidance documents/formulary appendices and then Fife wide guidance.

NHS Fife Guidance of the Acute Management of Parkinson’s Patients

A guidance document on the acute management of Parkinson’s patients has been developed by the Fife Parkinson’s Disease specialist team and has been approved for use in NHS Fife by the Clinical Governance department and the Fife ADTC.

The guidance provides advice on the initial management of patients when they are admitted to a hospital setting especially if there is noone available from the Specialist PD team, i.e. in the evening or at weekends. The specialist team should be alerted to the patient’s admission a.s.a.p., but the guidance provides interim advice until the team can review the patient. All too often people with Parkinson’s have their medication omitted or given at incorrect times when in hospital. This has a detrimental impact on their care and recovery. It can mean the difference between a 2 day stay or a 2-3 week stay. Patients who do not receive their medications are at greater risk of aspiration and fractures.

The guidance is aimed at hospital wards and community hospitals but may be of interest to others. Copies of the guidance can be accessed/downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ or the Fife Formulary link on the NHS Fife intranet homepage by clicking on the link for Guidance documents/formulary appendices and then Fife wide guidance.

Updated Guidance for the Management and Treatment of Thrush (Candidiasis) in Breastfeeding (Formulary Appendix 12A)

A revised version of the guidance has been approved by the ADTC. The revised version contains background information on other potential causes of breast pain, certain sections have been reworded to give greater clarity and links to internet sites for further information have now been added.

A copy of the guidance has been emailed out to all GP practices, secondary care settings and community pharmacies. Further copies can be accessed/downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ or the Fife Formulary link on the NHS Fife intranet homepage by clicking on the link for Guidance documents/formulary appendices and then Fife wide guidance.

Dates for 2011/2012 ADTC Meetings

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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 telephone 01592 226915

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