



Tayside DTC Supplement No 103 – February / March 2011

Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

Special points of interest for Primary Care

- Improved access to palliative care guidelines
- Topiramate for migraine prophylaxis

SMC advice:

- Capsaicin, 179mg cutaneous patch (Qutenza®)
- Eslicarbazepine acetate 800mg tablet (Zebinix®)
- Prilocaine hydrochloride 2% hyperbaric solution for injection (Prilotekal®)

Inside this issue :

Specialist lists - progress	1
Guidelines & Protocols	1-2
Drug Safety Updates	2
SMC Advice - Review of MAG process	2
SMC Advice issued in February 2011	3-4
Updates from previous SMC Advice	4
TAF Updates	5
SMC Briefing Note	5
Forthcoming SMC	5



Specialist lists - Respiratory

The respiratory specialist list has been finalised with links to the relevant shared care agreements / new treatment protocols. The list includes medicines for nebulisation -colistimethate sodium, tobramycin and dornase alfa. Other medicines include N-acetylcysteine tablets, azathioprine tablets and omalizumab injection. [Click here](#) for link.



Guidelines and Protocols

NHS Scotland Palliative Care Guidelines

A link to the NHS Scotland Palliative Care Guidelines has been inserted on the home page of the Tayside Area Formulary (left hand menu bar underneath 'SECTIONS'). This provides a wealth of information on pain management, symptom management and subcutaneous medication as well as other important issues. [Click here](#) for link.

Dronedarone Protocol - update & amended advice

This supersedes the advice given in DTC supplement no. 99.

The NHS Tayside dronedarone protocol, [click here](#) for link, has been updated as follows, to incorporate further information from the Scottish Medicines Consortium and safety advice from the [MHRA Drug Safety Update- February 2011](#)

SMC advice: dronedarone is accepted for restricted use for the prevention of recurrence of atrial fibrillation in patients for whom beta-blockers, class Ic anti-arrhythmic drugs and amiodarone are contra-indicated, ineffective or not tolerated. Treatment should be initiated on specialist advice only.

Dronedarone appears less effective than amiodarone in reducing atrial fibrillation recurrence but has the potential for improved tolerability compared to comparator medicines.

Monitoring- treatment safety: patients should be advised to immediately report any symptoms of potential liver injury (such as sustained new onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine or itching) or symptoms of heart failure (such as weight gain, dependent oedema or increased dyspnoea) to their GP.

Measure LFT's monthly for the first 6 months of treatment, then at months 9 and 12, then every 6 months thereafter. If ALT levels are ≥ 3 times the upper limit of normal, treatment with dronedarone should be withdrawn immediately and the specialist initiating treatment contacted for further advice. Appropriate investigation and close observation of patients should continue until normalisation of ALT levels.

Due to the increased monitoring requirements described above, the Medicines Advisory Group have agreed that a **shared care protocol** for the use of dronedarone should be prepared. In the interim, the existing arrangements for the prescribing and monitoring of dronedarone should continue.



Guidelines and Protocols continued

Topiramate Protocol - update

The local protocol for the use of topiramate in the prophylaxis of migraine has been updated. For this indication topiramate is reserved for patients who have not responded to, cannot tolerate, or have contra-indications to established migraine prophylactic treatments (i.e. beta-blockers or tricyclic antidepressants). More detail has been included on dose titration and response to treatment. The patient should be informed prior to initiating treatment of possible side effects including mood disturbances, depression, suicidal ideation and potential weight loss. Topiramate may reduce the efficacy of the oral contraceptive pill and an alternative migraine prophylactic agent should be considered in these patients. Treatment should be initiated by the Neurology Clinic. [Click here](#) for protocol. The protocol is also available from section 4.3.4 Antimigraine drugs of the Tayside Area Formulary.

Review of local processing of SMC accepted advice

The current local new medicines process involves challenging timelines for clinicians to respond with local information on the proposed use of new treatments that have recently been accepted by the Scottish Medicines Consortium. This information is essential for the Medicines Advisory Group (MAG) when considering the place of new medicines in local treatment pathways and agreeing local recommendations on use.

The following revisions to the local new medicines process aim to address this issue:

- Time period for submission of the form '*Information to Support Local Introduction*' by clinicians to be extended to 3 months - [click here](#) to access.
- Monthly reminder requests to be issued until the 3-month period is reached.
- All new medicines to be given a local interim status of '**Pending Specialist Feedback**' until local information is available and discussed at MAG.
- Local recommendation status will automatically move to '**Not recommended in absence of clinician demand**' after 3 months if a completed local introduction form has not been submitted.
- Subsequent to this, specialists can submit a completed local introduction form and MAG will review the local recommendation.
- NB - 'Pending specialist feedback' means that no local recommendation to support use of the new medicine in NHS Tayside is available at the current time. Clinicians are expected to wait until this is in place before prescribing.



Drug Safety Updates

Please follow link - [Drug Safety Update, Volume 4, Issue 6, January 2011](#)

Medicine	Indication	Local recommendation category	Comments and useful links
Capsaicin, 179mg, cutaneous patch (Qutenza®) (673/11) - Full submission	Peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.	HOSPITAL ONLY Restricted to use under the supervision of a pain specialist. SMC restriction: use of this product is restricted to the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments. Treatment should be under the supervision of a specialist in pain management.	SMC advice SPC link Evidence was presented for patients with PHN only. Capsaicin patch significantly reduced pain scores compared to a low-concentration control patch in three clinical studies. The manufacturer did not submit data on the use of capsaicin patch in other neuropathies, therefore SMC cannot recommend its use in
Colesevelam 625mg film-coated tablets (Cholestagel®) (690/11) - Non-submission	In combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hyper-cholesterolaemia.	Not recommended	SMC advice
Fenticonazole 2% vaginal cream and 200mg/600mg vaginal capsules (Ginoxin®) (691/11) - Non-submission	Treatment of vulvovaginal candidiasis.	Not recommended	SMC advice
Filgrastim 12 million units (120microgram) / 0.2mL, 30 million units (300microgram) / 0.5mL, 48 million units (480microgram) / 0.5mL solution for injection/infusion in pre-filled syringe (Nivestim®) (671/11) - Full submission	The reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia; The mobilisation of peripheral blood progenitor cells (PBPC); In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9/l$ and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events; The treatment of persistent neutropenia (ANC less than or equal to $1.0 \times 10^9/l$) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.	Pending* OHMMG decision	SMC advice
Golimumab, 50mg, solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (Simponi®) (674/11) - Full submission	Active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.	Not recommended	SMC advice

SMC Advice issued in February 2011 - continued.....

Medicine	Indication	Local recommendation category	Comments and useful links
Ivabradine 5mg and 7.5 mg film coated tablets (Procoralan [®]) (689/11) - Non-submission	Symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm, in combination with beta-blockers, in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.	Not recommended	SMC advice
Miconazole, 50mg, MucoAdhesive buccal tablet (Loramyc [®]) (517/08) - Resubmission	Oropharyngeal candidiasis (OPC) in immunocompromised patients.	Not recommended	SMC advice
Rituximab 100mg in 10mL, 500mg in 50mL, concentrate for solution for infusion (MabThera [®]) (675/11) - Full submission	Follicular lymphoma patients responding to induction therapy.	Pending* OHMMG decision SMC restriction: for maintenance treatment in follicular lymphoma patients who have responded to induction with rituximab plus chemotherapy. Rituximab significantly increased progression free survival following a response to induction therapy in patients with previously untreated follicular lymphoma compared with observation alone. Longer follow up is required to establish benefit in overall survival.	SMC advice
Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin [®]) (623/10) - Resubmission	In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.	Not recommended	SMC advice

* 'pending' means that no local recommendation to support use is in place at the current time

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Eslicarbazepine acetate 800mg tablet (Zebinix [®]) (592/09) - Resubmission	As adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.	GPs may prescribe under the direction of Neurology/ Epilepsy clinic Supplied via a Patient Access Scheme (PAS) (simple discount). Restricted to patients with highly refractory epilepsy.	SMC advice SPC link
Degarelix (Firmagon [®]) (560/09) - Re-submission	Gonadotropin-releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer.	Pending* OHMMG decision	SMC advice
Prilocaine hydrochloride 2% hyperbaric solution for injection (Prilotekal [®]) (665/10) - Full submission	Spinal anaesthesia.	HOSPITAL ONLY SMC restriction: for use in spinal anaesthesia in ambulatory surgery settings such as day surgery units.	SMC advice SPC link



Tayside Area Formulary (TAF) Updates - Feb/Mar 2011

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development		<i>Link to Respiratory specialist list added.</i>
Appendices - Specialist formulary lists	Respiratory	<i>Respiratory specialist list added.</i>
3	Respiratory system Guidelines	<i>New sections added on Adult Cystic Fibrosis and Idiopathic Pulmonary Fibrosis with links to relevant formulary sections. Link to BTS Interstitial Lung Disease Guideline within the Idiopathic Pulmonary Fibrosis section and link to information leaflet on intravenous antibiotic therapy within the Adult Cystic Fibrosis section.</i> <i>Link to NHS Tayside Respiratory MCN Adult Asthma Pathway (NHS Tayside Staffnet intranet link only) added to the following sections: Notes on Managing Chronic Asthma, Emergency Management of Acute Asthma in Adults & Children over 12 years and Managing Chronic Asthma in Adults and Children over 12 years.</i>
3	Introduction	<i>Link to NHS Tayside Respiratory MCN Adult Asthma Pathway (NHS Tayside Staffnet intranet link only) inserted.</i>
3.4	Antihistamines and allergic emergencies	<i>Omalizumab ▼ * (hospital only) added to formulary and Respiratory specialist formulary list for use in accordance with the omalizumab▼ local treatment protocol.</i>
3.7	Mucolytics	<i>Dornase alfa nebuliser solution added to formulary and Respiratory specialist list for use in adult cystic fibrosis in accordance with shared care agreement. N-acetylcysteine (unlicensed - in accordance with shared care agreement) and azathioprine added to formulary and Respiratory specialist list both for use in combination with prednisolone for idiopathic pulmonary fibrosis.</i>
16	Primary Care Anti-infective Advisory Notes	<i>New section on Adult Cystic Fibrosis Nebulised Antibiotics featuring link to shared care agreement for nebulised tobramycin. Shared care agreement for nebulised colistin (colistimethate sodium) is under development and will be linked to once available.</i>

* SMC accepted medicine

SMC Briefing Note:
[Click here](#) for February Briefing Note

[Forthcoming SMC Advice](#)

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutics Committee.

Please direct any queries to either:

Karen Harkness
Principal Pharmacist - Clinical Effectiveness
email: kharkness@nhs.net

or

Claire James
Senior Pharmacist - Clinical Effectiveness
email: clairejames@nhs.net

Local implementation of SMC recommendations is taken forward by the Tayside Medicines Governance Unit. This bulletin is based on evidence available to the Tayside Medicines Governance Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use.

[CLICK HERE](#) for access to the Medicines Governance section of the Pharmacy Staffnet site.