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Tayside DTC Supplement No 107 – June/July 2011

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

Special points of interest for **Primary Care**

Palliative Care and Rheumatology specialist

SMC advice:

- Ferric carboxymaltose (Ferinject®)
- Filgrastim (Zarzio®)
- Omalizumab (Xolair®)
- Tapentadol (Palexia® SR)
- Triptorelin ((Decapeptyl SR®) 22.5mg



Specialist lists - Palliative Care

The Palliative Care specialist formulary list has been developed providing a list of medicines and their indications which are commonly used by or recommended by palliative care specialists. Unlike other specialist formulary lists it does not have links to formulary sections for each medicine.

The Palliative care specialist list includes medicines which may be prescribed in General Practice under specialist direction, some of which are likely to be familiar to non-specialists, such as hyoscine butylbromide injection for excess respiratory tract secretions in the last days of life. Other medicines in the list may be less familiar such as ketamine oral solution and ketamine injection (both third line in pain management).

The list includes links to guidance from the NHS Scotland Palliative Care Guidelines, local guidance from the formulary section Analgesic Prescribing Guidelines for the Management of Cancer Pain, the local policy for <u>lust In Case Boxes in primary care</u> and the local guideline - <u>Liverpool Care</u> Pathway (LCP) for the Dying Patient.



Specialist lists - Rheumatology

The Rheumatology specialist formulary list has been finalised with links to local guidance including monitoring guidance for DMARDs and biologics and a link to the Rheumatology Services website. The Rheumatology Services website includes links to referral guidance and links to local, national and international guidance.

The Rheumatology specialist list includes hospital only biologics, DMARDs that may be prescribed in general practice under specialist direction and febuxostat (also under specialist direction).

The Gastroenterology, Chronic Pain, Stroke and Urology specialist lists are in development.



Drug Safety Updates

Thalidomide and thromboembolism

Patients treated with thalidomide have an increased risk of arterial thromboembolism, including myocardial infarction and cerebrovascular events, in addition to the established risk of venous thromboembolism. The risk appears to be greatest during the first 5 months of therapy. Healthcare professionals are advised to consider venous and arterial thrombotic risk and the need for thromboprophylaxis in the evaluation of patients suitable for treatment with thalidomide. A careful assessment of the individual patient's underlying risk factors should be undertaken before prescribing thromboprophylaxis. For further information see Drug Safety Update, Volume 4, Issue 12, July 2011

Other side effects of thalidomide include, nerve damage, dizziness, drowsiness, constipation, severe skin reactions, neutropenia and severe life-threatening birth defects. All patients receiving thalidomide must be counselled on potential adverse effects and provided with pregnancy prevention advice (males and females). For further information see Information for Patients Taking Thalidomide Celgene™.

Patients, prescribers and supplying pharmacies must comply with a pregnancy prevention programme. Every prescription for thalidomide must be accompanied by a complete Prescription Authorisation Form. For further information see Thalidomide Celgene Information Pack.

Inside this issue: Specialist lists -Palliative Care Specialist lists -Rheumatology 1-2 **Drug Safety Updates** SMC Advice issued in June 2 2 Updates from previous **SMC** Advice 3 TAF Updates **SMC** Briefing Note 4 Forthcoming SMC Advice



Drug Safety Updates continued

Please follow links -

<u>Drug Safety Update, Volume 4, Issue 11, June 2011</u>
<u>Drug Safety Update Volume 4, Issue 12, July 2011</u>

SMC Advice issued in June 2011

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Ferric carboxymaltose 50mg iron/mL solution for injection/infusion (Ferinject®) (463/08) - 2nd re-submission	Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.	HOSPITAL ONLY (renal clinic) Renal specialist list Restricted to intravenous infusion in pre-dialysis CKD patients.	SMC advice SPC link
Filgrastim, 30 million units (300 micrograms) 0.5mL, 48 million units (480 micrograms) 0.5mL, solution for injection or infusion in pre-filled syringe (Zarzio®) (704/11)	See SMC summary advice.	Pending* OHMMG decision	SMC advice
Omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe (708/11) - Abbreviated submission	Adults, adolescents (12 years of age and older) and children (6 to <12 years of age) with convincing IgE (immunoglobulin E) mediated asthma.	HOSPITAL ONLY (adult chest/rhinology and paediatric asthma clinics). Respiratory specialist list Restricted to patients uncontrolled on optimised BTS Step 5 therapy including chronic systemic steroids.	SMC advice SPC link Protocol (6-11 years) Protocol (12+ years)
Tapentadol, 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR) (654/10) - Re-submission	Management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.	Pending* specialist feedback	SMC advice
Triptorelin (Decapeptyl SR®) 22.5mg powder and solvent for suspension for injection(705/11) - Abbreviated submission	 Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration. Treatment of metastatic prostate cancer. 	GPs may prescribe under the direction of the urology/oncology clinic. Formulary	SMC advice SPC link Initiate triptorelin treatment with the I 1.25mg 3-monthly inj before moving to the 22.5mg 6-monthly inj. Note that triptorelin 22.5mg is not licensed for adjuvant or neo-adjuvant use. A general practice minor surgery fee is available for the administration of triptorelin.

 $[\]ensuremath{^*}$ 'pending' means that no local recommendation to support use is in place at the current time

OHMMG - Oncology and Haematology Medicines Management Group

Updates from previous SMC Advice (2007 - 2011)

Medicine	Indication	Local recommendation category	Comments and useful links
Buprenorphine/naloxone 2mg / 0.5mg, 8/2mg sublingual tablet (Suboxone®) (355/07) - Full submission	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment.	Not recommended	SMC advice



Tayside Area Formulary (TAF) Updates - July 2011

TAF Section	Drug(s)/topic	Changes	
Specialist formulary lists and formulary	Palliative Care	Palliative Care specialist formulary list added.	
development	Rheumatology	Rheumatology specialist formulary list added.	
2.12	Statins	5mg strength of rosuvastatin added to formulary as lower starting dose recommended in elderly, patients of Asian origin & patients with moderate renal impairment.	
2.12	Ezetimibe	Information on restricted use of ezetimibe (in combination with a statin for patients who have failed to reach target cholesterol levels with optimised doses of statin alone) clarified further - patients should have tried both a lipophilic (simvastatin/atorvastatin) and a hydrophilic (rosuvastatin /pravastatin) statin and concordance with treatment should be considered.	
3	Respiratory system guidelines	Addition of a new section on long-term macrolide antibiotics to guidance notes. Information on long-term macrolides added to COPD guidelines. Links to patient information leaflets (PILs) for inhaler devices and spacer devices added to inhaler device guidance.	
3.2	Inhaled corticosteroids	Addition of a note on stepping down inhaled corticosteroids in controlled asthma at start of section. Link to inhaler device guidance added.	
3.4	Omalizumab*	Formulary updated to include new formulation as prefilled syringe and new 75mg strength (prefilled syringes replace previous formulation of powder for reconstitution with solvent).	
6.6	Bisphosphonates	Information on atypical stress fractures updated. Recommendation on bisphosphonate holidays added and link to <u>local guidance</u> (NHS Tayside Staffnet intranet link only) inserted.	
8.3.4.2	Triptorelin*	Formulary updated to include new 22.5mg 6-monthly injection, for use after treatment has been initiated with the 11.25mg 3-monthly injection.	
9.1	Parenteral iron	Addition of ferric carboxymaltose injection (Ferinject®▼)* to formulary and Renal specialist formulary list for intravenous infusion in pre-dialysis Chronic Kidney Disease (CKD) patients.	
10.1	Drugs used in rheumatic diseases and gout	Link to NHS Tayside Rheumatology Services website (NHS Tayside Staffnet intranet link only) and SIGN guideline no. 123 Management of early rheumatoid arthritis added.	
	NSAIDs	Naproxen now first choice NSAID in rheumatological disease. Additional safety information on use of NSAIDs in elderly and renal impairment, and concurrent use of NSAIDs with ACE inhibitors or Angiotensin-II receptor antagonists and diuretics added. Information on NSAIDs and association with an increased risk of thrombotic events added.	
	Corticosteroids	Information on use of corticosteroids in rheumatic disease added including links to local recommendations for diagnosis and management of polymyalgia rheumatica and giant cell arteritis (NHS Tayside Staffnet intranet links only). Link to RCP guidelines for Glucocorticoid-induced osteoporosis inserted. Link to local guidance for Management of Flare of Rheumatoid Arthritis (NHS Tayside Staffnet intranet link only). Methylprednisolone acetate (Depo-Medrone®) now first choice systemic corticosteroid injection.	
	DMARDs	Methotrexate and/or Sulfasalazine now first choice DMARDs for rheumatoid arthritis (RA). Oral methotrexate 2.5mg tablets and sulfasalazine e/c tablets added to formulary and Rheumatology specialist list. Methotrexate injection (Metoject®)* (hospital only— note: may be administered in primary care) added to formulary and Rheumatology specialist list. Other DMARDs added to formulary and Rheumatology specialist list: azathioprine, ciclosporin, cyclophosphamide, hydroxychloroquine sulphate, leflunomide, minocycline, mycophenolate mofetil, penicillamine, and sodium aurothiomalate.	
	Cytokine modulators	Section on cytokine modulators (TNF-alpha inhibitors (antagonists)) added. Certolizumab pegol (Cimzia® ▼)* (hospital-only) now first choice TNF-alpha antagonist for RA when response to DMARDs including methotrexate is inadequate. Adalimumab (Humira® ▼)*, etanercept (Enbrel® ▼)*, infliximab (Remicade®), rituximab (MabThera®)* and tocilizumab (RoActemra® ▼)* (all hospital-only) added to formulary and Rheumatology specialist list.	
	Drugs used for the treatment of gout	Febuxostat (Adenuric [®] ▼)* added to Rheumatology specialist list for management of chronic hyperuricaemia in gout where allopurinol is inadequate, not tolerated or contraindicated.	
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^{*} SMC accepted medicine

And Finally.....

SMC Briefing Note:
CLICK HERE for June 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.

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