



Special points of interest for Primary Care

- Stroke Specialist List
- Ezetimibe Algorithms
- Lidocaine Plaster

SMC advice:

- Alteplase 2mg (Actilyse Cathflo[®])
- Calcium carbonate (Kalcipos-D 500mg/800 IU chewable tablets[®])
- Capecitabine (Xeloda[®])
- Darunavir (Prezista[®])
- Ferric carboxymaltose (Ferinject[®])
- Methotrexate (Metoject[®])
- Retigabine (Trobal[®])

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Specialist lists - Update

The Gastroenterology and Chronic Pain specialist lists are in the process of being finalised and should be added to the Tayside Area Formulary website soon.

The Urology, ENT and Mental Health specialist lists are in development.



Specialist lists - Stroke

The stroke specialist list has been finalised with links to the protocol - [Management of Acute Stroke Presenting within 4^{1/2} Hours of Onset of Symptoms](#) for use of Alteplase injection. There is also a link to the [NHS Tayside Treatment Protocol for stroke patients](#) which includes guidance on antiplatelets, anticoagulants, antihypertensives and lipid lowering.

[Click here](#) for a link to the Stroke Specialist formulary list.



Guidelines and Protocols

Ezetimibe - Algorithms for review of prescribing

Algorithms have been developed to assist with the review of Ezetimibe prescribing for the GMS Quality and Outcomes Framework (QOF) local Meds 6 & 10 indicators 2011/12.

There are 2 algorithms providing a summary of guidance for review of patients prescribed ezetimibe plus a statin (Algorithm A) and patients prescribed ezetimibe without a statin (Algorithm B).

These algorithms have been incorporated into the formulary alongside the entry for ezetimibe in section 2.12.

[Click here](#) for a link to Algorithm A and [click here](#) for a link to Algorithm B.

Lidocaine 5% medicated plaster (Versatis[®])

The Drug & Therapeutics Committee have approved the off-label use of lidocaine plasters in neuropathic pain under the direction of the Pain Clinic.

The initial 4 week trial will be prescribed and supplied by the Pain Clinic, thereafter GPs may prescribe under the direction of the Pain Clinic.

[Click here](#) for link to local treatment protocol.

Refer to [Palliative Care Guidelines](#) for use in palliative care.

Important facts:

- Off-label use. Lidocaine plasters are only licensed in post-herpetic neuralgia (PHN).
- Use in patients who have failed 1st and 2nd line treatment with either amitriptyline, gabapentin or pregabalin.
- The Pain Clinic will review patients at 6 monthly intervals.

Local recommendation

Restricted off-label use by Chronic Pain Team (also approved for off-label use in palliative care) GPs may prescribe under the direction of the Chronic Pain Team (& Palliative care).

Note: GPs may prescribe for PHN (Formulary)



Drug Safety Updates

Please follow links - [Volume 5, Issue 1, August 2011](#)

[Volume 5, Issue 2, September 2011](#)

Pioglitazone: risk of bladder cancer

A Europe-wide review has found a small increased risk of bladder cancer in patients taking the antidiabetic drug pioglitazone. However, the benefits continue to outweigh the risks for those who respond to treatment and in whom there are no identified risk factors for bladder cancer. [Click here](#) for MHRA advice.

The following points should be considered before initiating and during pioglitazone therapy:

- Do not prescribe pioglitazone to patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria.
- Review the safety and efficacy of pioglitazone in individuals after 3 to 6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Stop pioglitazone in patients who do not respond adequately to treatment.
- Assess risk factors for the development of bladder cancer before prescribing pioglitazone i.e. age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region.
- Start elderly patients on the lowest possible dose of pioglitazone and monitor regularly because of the increased risks of bladder cancer and heart failure in the elderly.



Prescribing Changes

High dose antioxidants & zinc in age-related macular degeneration (AMD)

Over-the-counter dietary supplements containing antioxidants and zinc (e.g. l-caps) may have very modest benefit in patients with advanced AMD. However, it is unclear whether they have any additional benefit over a healthy diet rich in lutein (plenty of fresh fruit and vegetables).

The long-term safety and cost-effectiveness of these high dose supplements are unknown, they contain beta-carotene and patients who smoke (or are recent ex-smokers) should not take them due to increased risk of lung cancer.

They are not licensed medicinal products therefore the balance of benefit versus harm has not been formally assessed.

Local ophthalmologists do not recommend that these supplements are prescribed on the NHS, but direct patients to information on 'Nutrition and the Eye' developed by the UK Macular Disease Society. [Click here](#) for the document.

Dabigatran - prevention of stroke

Dabigatran has been accepted for use within NHS Scotland for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with defined risk factors. Please see [SMC advice](#) for further information.

A national Consensus Statement to support patients, general practitioners and hospital specialists in local decision-making around the safe and effective use of dabigatran is expected by the end of October 2011. This will inform the Tayside local implementation strategy for this new medicine. For the majority of patients with good INR control, warfarin is likely to remain the treatment of choice.

[Click here](#) for recent press release.

Introduction of dabigatran, and the other new oral anticoagulants, will need careful planning and guidance. GP's should resist pressure to prescribe these agents until there is clear local consensus and guidance on which patients are eligible and how treatment should be initiated or transferred. In the meantime clinicians should use [the non-formulary request form](#) if there is an exceptional case where this drug is required.

Non-calcium based phosphate binders

Local recommendations for the use of non-calcium based phosphate binders (sevelamer hydrochloride*, sevelamer carbonate and lanthanum carbonate) have been extended to cover the treatment of hyperphosphataemia in patients on haemodialysis or peritoneal dialysis, and patients with chronic kidney disease (CKD) not on dialysis who have a serum-phosphate concentration of 1.78mmol/L or more.

Non-calcium based phosphate binders should be used second-line i.e. in patients unable to take calcium based phosphate binders.

* Note that sevelamer hydrochloride is not licensed for patients with CKD not on dialysis and is therefore not recommended locally for this indication.

Medicine	Indication	Local recommendation category	Comments and useful links
Paliperidone palmitate 50mg, 75mg, 100mg and 150mg prolonged release suspension for injection (Xeplion®) (713/11) - Full submission	Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone.	Not recommended	SMC advice
Prucalopride 1mg and 2mg tablet (Resolor®)(653/10) - Re-submission	Symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.	Not recommended	SMC advice
Ranibizumab, 10mg/mL solution for injection (Lucentis®)(711/11) - Full submission	Treatment of visual impairment due to diabetic macular oedema in adults.	Not recommended	SMC advice
Retigabine, 50mg, 100mg, 200mg, 300mg and 400mg film-coated tablets (Trobalt®) (712/11) - Full submission	Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy.	Pending* specialist feedback	SMC advice
Trabectedin, 0.25 and 1mg powder for concentrate for solution for infusion (Yondelis®)(452/08) - 2nd Re-submission	Treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.	Not recommended	SMC advice

SMC Advice issued in August 2011

Medicine	Indication	Local recommendation category	Comments and useful links
Alteplase 2mg powder and solvent for solution for injection for infusion (Actilyse Cathflo®) (717/11) - Abbreviated submission	Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.	Pending* specialist feedback	SMC advice
Bilastine (Ilasten®)(730/11) - Non-submission	Symptomatic treatment of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria.	Not recommended	SMC advice
Calcium carbonate equivalent to 500mg calcium, cholecalciferol (vitamin D ₃) 800 IU (20 microgram) tablets (Kalcipos-D 500mg/800 IU chewable tablets®)(718/11) - Abbreviated submission	<ul style="list-style-type: none"> — Prevention and treatment of calcium and vitamin D deficiency in the elderly. — Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency. 	Not recommended in Tayside	SMC advice
Capecitabine 150mg, 500mg, tablets (Xeloda®)(716/11) - Full submission	The adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin.	HOSPITAL ONLY (Oncology)	SMC advice SPC link Colorectal Cancer Protocol
Collagenase clostridium histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®)(715/11) - Full submission	Treatment of Dupuytren's contracture in adult patients with a palpable cord.	Not recommended	SMC advice

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

SMC Advice issued in August 2011 continued....

Medicine	Indication	Local recommendation category	Comments and useful links
Darunavir 400mg tablets (Prezista®) (707/11) - Full submission	Darunavir 800mg once daily co-administered with low dose ritonavir (100mg once daily) for the treatment of HIV-1 infection in anti-retroviral therapy experienced adults with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm ³ .	HOSPITAL ONLY (HIV clinic)	SMC advice SPC link
Glucosamine sulphate 1,500mg powder for oral solution (Dolenio®)(729/11) - Non-submission	Symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee.	Not recommended	SMC advice
Glucosamine sulphate 1,500mg powder for oral solution (Glusartel®)(647/10) - Resubmission	Relief of symptoms in mild to moderate osteoarthritis of the knee.	Not recommended	SMC advice
Methotrexate 50mg/mL solution for injection (Metoject®) prefilled syringes 12.5mg, 17.5mg, 22.5mg, 27.5mg and 30mg (724/11) - Abbreviated submission	Polyarthritic forms of severe active juvenile idiopathic arthritis, when the response to non-steroidal anti-inflammatory drugs has been inadequate.	Pending* specialist feedback	SMC advice
Mifamurtide 4mg powder for suspension for infusion (Mepact®)(621/10) - Resubmission	In combination with post-operative multi-agent chemotherapy for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection, in children, adolescents and young adults. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis.	Pending* specialist feedback	SMC advice
Nilotinib 150mg hard capsules (Tasigna®) (709/11) - Full submission	For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.	Pending* OHMMG decision	SMC advice

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

AMG - Antimicrobial Management Group

OHMMG - Oncology and Haematology Medicines Management Group

Updates from previous SMC Advice

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 Main users- Haematology, Renal & General Medicine. Renal specialist list Restricted to administration by intravenous infusion. Excludes patients receiving haemodialysis.	SMC advice SPC link Ferric carboxymaltose was previously restricted to the Renal Clinic (see DTC Supplement No 107). Iron sucrose remains the first-line parenteral iron preparation in haemodialysis patients.
Iron isomaltoside 1000, 100mg/mL solution for injection/infusion (Monofer®) (697/11) - Full submission	Treatment of iron deficiency anaemia in the following conditions: - when oral iron preparations are ineffective or cannot be used; - where there is a clinical need to deliver iron rapidly.	Not recommended in Tayside	SMC advice



Tayside Area Formulary (TAF) Updates - Sept 2011

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Stroke	Stroke specialist formulary list added - Click here
2.2	Indapamide	Indapamide 2.5mg once daily added to formulary for use with perindopril erbumine (if blood pressure target not achieved with perindopril erbumine alone) in patients with a previous stroke or TIA. Link to NHS Tayside Treatment protocol for stroke patients inserted.
2.5	ACE inhibitors	Perindopril erbumine added to formulary as first choice for secondary prevention post-TIA or ischaemic stroke. Link to NHS Tayside Treatment protocol for stroke patients inserted.
2.8	Oral anticoagulants	Link to the NHS Tayside Treatment protocol for stroke patients inserted.
2.9	Oral antiplatelet drugs	Clopidogrel now first choice for secondary prevention in confirmed non-cardioembolic ischaemic stroke/TIA. Aspirin is only indicated in these patients with clopidogrel allergy or intolerance. Aspirin 75mg combined with clopidogrel 75mg for at least one month has been added to the formulary and Stroke specialist formulary list (HOSPITAL ONLY) for those with clinically significant carotid disease post ischaemic stroke or TIA.
2.10	Fibrinolytic drugs	Alteplase added to formulary and Stroke specialist formulary list (hospital only) as first choice for thrombolysis in acute stroke. Link to protocol Management of Acute Stroke Presenting within 4^{1/2} Hours of Onset of Symptoms inserted.
2.12	Statins	Link to NHS Tayside Treatment protocol for Stroke patients added for use of atorvastatin 80mg. Atorvastatin 80mg daily has been added to the Stroke specialist formulary list for ischaemic stroke or TIA directly attributable to significant carotid artery disease or other known significant macrovascular disease.
	Ezetimibe	Algorithms on Ezetimibe prescribing have been developed and a link to these added to the formulary (algorithms are for the review of Ezetimibe prescribing for the GMS QOF Meds 6 & 10 indicators 2011/12).
9.1	Parenteral iron	Ferric carboxymaltose injection (Ferinject®)* (hospital only) is now included in the formulary for use in areas in addition to Renal, such as Haematology & General Medicine.

* SMC accepted medicine

SMC Briefing Note:

[CLICK HERE](#) for July Briefing Note

[CLICK HERE](#) for August 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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