TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 115 – March/April 2012

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

Special points of interest for Primary Care

- Rivaroxaban (Xarelto®)

SMC advice:

- Aztreonam (Cayston®)
- Eculizumab (Soliris®)
- Emtricitabine, tenofovir, rilpivirine (Eviplera®)
- Lapatinib (Tyverb®)
- Midazolam (Buccolam®)
- Nevirapine (Viramune ®)
- Panitumumab (Vectibix®)
- Pemetrexed (Alimta®)
- Prednisone (Lodotra®)
- Rilpivirine (Edurant®)
- Rivaroxaban (Xarelto®)
- Saxagliptin (Onglyza®)
- Tapentadol (Palexia®)
- Tocilizumab (RoActemra®)

Inside this issue :

Specialist list - Dementia

The Dementia specialist formulary list has been finalised with a link to the Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's Disease - Shared Care Agreement (Angus & Dundee).

There are also links to advice on Rationalisation of Antipsychotics in people with Dementia with the Good Practice Guide for initiation of treatment and Good Practice Guide for reduction and cessation of treatment

Click here for the Dementia specialist formulary list.

Guidelines and Protocols

VSL#3 Local Treatment Protocol

A local treatment protocol has been developed for VSL#3. This is a food supplement indicated for the treatment of pouchitis in patients with chronic, frequently-recurring pouchitis where remission is unresponsive to antibiotics, or in patients who have had six or more episodes of pouchitis in conjunction with assessment of quality of life using The McMaster Inflammatory Bowel Disease Questionnaire.

Local recommendation

GPs may prescribe under the direction of a gastroenterology specialist.

Click here for protocol.

Drug Safety Updates

Please follow link - Volume 5, Issue 8, March 2012

Prescribing Changes

Rivaroxaban (Xarelto®)

Rivaroxaban for treatment of Atrial Fibrillation (AF) – local advice

A further new oral anticoagulant, rivaroxaban (Xarelto®) is available for the treatment of non-valvular atrial fibrillation. Rivaroxaban has been accepted by the Scottish Medicines Consortium (SMC) – restricted to patients who have poor INR control on warfarin, or with allergy to or intolerable side effects from coumarin anticoagulants. (click here for formulary link). This positioning is in-line with the NHS Health Improvement Scotland (HIS) consensus statement on prevention of stroke and systemic embolism in adult patients with non-valvular AF - click here

Locally, rivaroxaban is considered as the first-choice of the newer oral anticoagulants – this is due to potential advantages in relation to dosing frequency, stability in compliance aids and less dependency on renal excretion. Dabigatran remains as a further formulary option. Rivaroxaban may also be considered where there are logistical difficulties in receiving warfarin therapy.

Rivaroxaban for treatment of deep vein thrombosis (DVT) – local advice

Rivaroxaban has also been recommended by SMC for the treatment of DVT, and the prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.

Locally it is recommended as the first choice oral anticoagulant for treatment of the first presentation of an uncomplicated, confirmed DVT for a duration of 3-6 months. It is **not** recommended for treatment of recurrent DVT, PE or in patients with an eGFR<30mL/minute.

DVT protocols will need to be updated and agreed before local practice is changed.

Following confirmation of DVT, primary care will require information to confirm the ongoing dosage and duration of treatment. The initial supply of rivaroxaban may be issued from secondary care or according to local arrangements.

General information

Please note that dose reduction is necessary if GFR is <50mL/min – see SPC for details.

Local guidelines for management of patients on rivaroxaban (covering conversion to or from parenteral anticoagulants, conversion to or from warfarin, management of bleeding and discontinuation of therapy) are available on the NHS Tayside anticoagulant service website - click here

Key drug interactions include: systemic ketoconazole, itraconazole, voriconazole, posoconazole and HIV protease inhibitors - which are contraindicated. Refer to SPC for further details.

Mycophenolate mofetil generic switch

The patent for mycophenolate mofetil (Cellcept®) expired at the beginning of November 2010 and a large number of generic products have since appeared on the market. As there is no real evidence to suggest that different mycophenolate mofetil formulations are not interchangeable, it has now been agreed that it can be prescribed generically. Recently the decision was made in the main transplant units in Edinburgh and Glasgow to change from routine use of Cellcept® to the less expensive generic alternatives. As a result, secondary care in NHS Tayside will no longer stock Cellcept® and will only stock the branded generic Myfenax®. Patients seen in hospital will therefore be commenced on or switched to generic mycophenolate mofetil and the Myfenax® generic brand will be supplied unless they bring in their own medication.

Mycophenolate mofetil (now on Part 7 of the Scottish Drug Tariff) can therefore be prescribed generically in primary care for all patients. However those **patients on the enteric coated version of mycophenolic acid, Myfortic® must not be switched**, and must be maintained on the Myfortic® brand.

No additional monitoring is required following the switch to generic mycophenolate mofetil. Follow up will be carried out at the Renal Transplant Clinic as usual or by the relevant secondary care specialists. Patients should however be advised to be alert to any new health problems and to inform as appropriate, either the Renal unit, transplant team, hospital specialist or their GP of any unexplained adverse effects. Further correspondence and guidance from the Renal unit will be sent to General Practices and Renal patients. The Renal and Rheumatology specialist formulary lists will be updated accordingly.

There has been consultation with all specialties that initiate treatment with mycophenolate mofetil and all of these have agreed that it may now be prescribed generically. Please note that previous advice issued on the prescribing of tacrolimus and ciclosporin still applies (including prescribing these by brand name). See Tayside Prescriber Issue 117, September 2010.

Medicine	Indication	Local recommendation category	Comments and useful links
Aztreonam lysine 75mg powder and solvent for nebuliser solution (Cayston®) (753/12) - *Full submission*	The suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older.	**Not recommended**	***SMC advice***
Eculizumab (Soliris®)300 mg concentrate for solution for infusion (767/12) - *Non submission*	Treatment of patients with atypical haemolytic uremic syndrome (aHUS).	**Not recommended**	***SMC advice***
Emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) (759/12) - *Abbreviated submission*	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml	**HOSPITAL ONLY** (HIV Clinic)	***SMC advice*** ***SPC link***
Lapatinib (Tyverb®) 250 mg film-coated tablets (768/12) - *Non submission*	Treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy.	**Not recommended**	***SMC advice***
Midazolam, 5mg/mL, oromucosal solution (Buccolam®) (757/12) - *Full submission*	Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years).	**Pending* specialist feedback**	***SMC advice***
Nevirapine 50mg, 100mg, 400mg prolonged release tablets (Viramune prolonged release tablets®) (760/12) - *Abbreviated submission*	In combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets.	**HOSPITAL ONLY** (HIV Clinic)	***SMC advice*** ***SPC link (50mg)*** ***SPC link (100mg)*** ***SPC link (400mg)***
Panitumumab (Vectibix®) 20 mg/mL concentrate for solution for infusion (769/12) - *Non submission*	Treatment of patients with wild-type KRAS metastatic colorectal cancer (mCRC) in first-line in combination with FOLFOX; in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan).	**Not recommended**	***SMC advice***
Pemetrexed (Alimta®) 100 mg / 500mg powder for concentrate for solution for infusion (770/12) - *Non submission*	Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.	**Not recommended**	***SMC advice***
Prednisone (Lodotra®) 1mg, 2mg and 5 mg modified-release tablets (771/12) - *Non submission*	Treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness.	**Not recommended**	***SMC advice***
Rilpivirine 25mg film-coated tablet (Edurant®) (758/12) - *Full submission*	Rilpivirine in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL.	**HOSPITAL ONLY** (HIV Clinic)	***SMC advice*** ***SPC link***
Rivaroxaban 15 and 20mg film-coated tablets (Xarelto®) (755/12) - *Full submission*	Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.	**Formulary - first-line** GPs may prescribe under direction of secondary care (NW Medical Assessment Area, PRI Medical Admissions, Angus DVT Service) Restricted to treatment of first presentation of uncomplicated confirmed DVT, for duration of 3-6 months.	***SMC advice*** ***SPC link (15mg)*** ***SPC link (20mg)*** DVT protocols to be updated. Not recommended for the treatment of recurrent DVT, treatment of PE or in patients with GFR<30mL/min

SMC Advice issued in February 2012 - continued….

Medicine	Indication	Local recommendation category	Comments and useful links
Rivaroxaban 15 and 20mg film-coated tablets (Xarelto®) (756/12) *- Full submission*	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.	**Formulary - first-line new oral anticoagulant** Restricted to patients who have poor INR control on warfarin or with allergy to, or intolerable side effects from coumarin anti-coagulants.	***SMC advice*** ***SPC link (15mg)*** ***SPC link (20mg)*** **Guidance on Management of Patients on Rivaroxiban** Rivaroxaban may also be considered where there are logistical difficulties in receiving warfarin therapy
Saxagliptin (Onglyza®) 2.5 mg and 5 mg film-coated tablets (772/12) *- Non submission*	Adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	**Not recommended**	***SMC advice***
Tapentadol (Palexia®) 50 mg film-coated tablets (773/12) *- Non submission*	Relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.	**Not recommended**	***SMC advice***
Tocilizumab, 20mg/mL concentrate for solution for infusion (RoActemra®) (754/12) *- Full submission*	Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate.	**HOSPITAL ONLY** (Paediatric Rheumatology Clinic) Supplied via a Patient Access Scheme (PAS) (simple discount).	***SMC advice*** ***SPC link***

* '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
Botulinum toxin type A, 50 and 100 LD_{50} units powder for solution for injection (Xeomin®) (731/11)	Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults.	**HOSPITAL ONLY** - Centre for Brain Injury Rehabilitation	***SMC advice*** ***SPC link (50 units)*** ***SPC link (100 units)***

'Local processes exist to allow consideration of prescribing outwith SMC advice or outwith NHS Tayside formulary. Details are available in the NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary (including Individual Patient Treatment Requests)'

Tayside Area Formulary (TAF) Updates - Mar/Apr 2012

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Dementia	*Dementia specialist formulary list added.*
	Renal	*Mycophenolate mofetil now listed as generic on both specialist lists.*
	Rheumatology	
2.8	Oral anticoagulants	*Rivaroxaban▼ * added to formulary as first-line new oral anticoagulant for both SMC recently approved indications (see page 2 and 4 of this supplement). Rivaroxaban▼ * also added to formulary as first-line choice for prophylaxis of venous thromboembolism (VTE) in adults undergoing elective hip or knee replacement surgery. Link inserted to local guidelines for management of patients on rivaroxaban.*
3.1	Bronchodilators	*Removal of black triangles for salmeterol aerosol inhalation, formoterol aerosol inhalation (Atimos Modulite®)*, Fostair® (beclometasone / formoterol)* aerosol inhalation. Budesonide aerosol inhalation removed as discontinued (budesonide as Easyhaler® * and Turbohaler® remain).*
3.2	Inhaled corticosteroids	
3 - Respiratory guidance notes	Guidance on inhaler devices 12 years+	*Reference to NebuChamber® removed as discontinued.*
	Chronic Obstructive Pulmonary Disease (COPD) guidelines	*Further detail on oral steroid and antibiotics for treatment of exacerbation in the community added. Advice on advance supply of oral steroids/antibiotics for COPD exacerbation added.*
4.1	Hypnotics and anxiolytics	*Advice on avoiding use of hypnotics or anxiolytics in elderly patients added. Links to PRODIGY (formerly CKS) guidance updated. Addition of clomethiazole capsules to formulary and Dementia specialist formulary list. Further detail on lorazepam doses and link to guideline The Management of Delirium in Adult and Older In-Patients inserted.*
4.2	Antipsychotics in older patients	*Further advice on antipsychotics in elderly patients added. New sub-section added 'Antipsychotics in older people with dementia'. New indications added within this section for risperidone▼ and haloperidol. New indication for quetiapine added within this section and quetiapine added to Dementia specialist formulary list. Links to advice on rationalisation of antipsychotics in people with dementia added - Good Practice Guide for initiation of treatment and Good Practice Guide for reduction and cessation of treatment.*
4.3	Antidepressant drugs	*Fluoxetine now first choice SSRI due to recent safety advice on citalopram (and escitalopram non-formulary). Trazodone added to formulary and Dementia specialist formulary list. Dose information for venlafaxine added.*
4.11	Drugs for Dementia	*Link inserted to Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's Disease - Shared Care Agreement (Angus & Dundee). Cholinesterase inhibitors - donepezil, galantamine, and rivastigmine, and memantine added to formulary and Dementia specialist formulary list. Links to advice on rationalisation of antipsychotics in people with dementia also added in section 4.2.*
9.6	Vitamin D	*Adcal-D3 caplets have replaced Adcal-D3 chewable tablets.*

* 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.

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