TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 128 – June / July 2013

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

Special points of interest for Primary Care

- **Strontium**
- **Calcium & Vitamin D**
- **Forceval**

SMC advice:

- Canakinumab (Ilaris®)
- Canakinumab (Ilaris®) - Arthritis
- Everolimus (Votubia®)
- Fluocinolone acetonide (Iluvien®)
- Ivacaftor (Kalydeco®)
- Linaclotide (Constella®)
- Pegylated interferon alpha-2a (Pegasys®)
- Saxagliptin plus metformin (Komboglyze®)

Inside this issue :

Specialist lists - progress

The oncology & haematology (non chemo drugs) specialist list has been agreed at the Medicines Advisory Group (MAG). The Tayside Area Formulary is currently being updated to reflect the changes, and should be live by next month.

The gynaecology specialist list is underway, and will be presented to MAG in August.

Guidelines and Protocols

Rivaroxaban for Pulmonary Embolism

Tayside-wide guidance on the Assessment & Management of Acute PTE has been published. This guidance contains information relating to:

- Investigations and diagnostic advice with specific information relating to pregnant patients
- Clinical management
- Patient counselling requirements

Rivaroxaban is now the first line treatment for PE (and DVT).

The SPC has recently been updated with regards to dosing in renal impairment. There is now no requirement to reduce the dose to 15mg after the first 21 days in those with an eGFR 30-49mls/min, unless the risk of bleeding outweighs the risk of further PE or DVT. **If prescribed for AF the dose should still be reduced to15mg daily in patients with eGFR of 30-49mls/min.**

Locally, we have restricted the use of the new oral anticoagulants (rivaroxaban and apixaban) to those patients with eGFR>30mls/min. **Please note that this is different to what is contained in the SPC.**

There are certain groups of patients in whom rivaroxaban is contraindicated and warfarin should be used instead. These include:

- Patients who require anticoagulation for longer than 12months
- Patients with eGFR<30mls/min
- Patients with active cancer or who are having chemotherapy
- Intravenous drug users
- Pregnant patients
- Patients with hepatic disease associated with coagulopathy
- Patients on interacting drugs, such as azole anti-mycotics, rifampicin, NNRTIs or protease inhibitors. See BNF or individual SPCs for further information.

Drug Safety Updates

Please follow links - Volume 6, Issue 11, June 2013 and Volume 6, Issue 12, July 2013

Drug Safety Updates

Strontium - new restrictions & contraindications

A review of available safety data for strontium has raised concern about its cardiovascular safety due to increased risk of serious cardiac disorders, including MI compared with placebo. The European Medicine Agency is currently evaluating the benefits & risks of strontium. Further information can be found in Drug Safety Update: Volume 6, Issue 9, April 2013

Local Practice

Strontium is no longer recommended as a 2nd line agent for severe osteoporosis in elderly female patients unable to tolerate bisphosphonates. It has now been moved to a 3rd line agent in patients who cannot be given denosumab or annual zoledronic acid and added to the Endocrinology & Medicines for the Elderly (MFE) specialist lists.

Prescribing of strontium in Tayside should be under the direction of MFE or the Bone Clinic.

Strontium is restricted to use in women with severe osteoporosis at high risk of fracture (SMC not recommended for men at increased risk of fracture).

- Contraindications: ischaemic heart disease, peripheral arterial disease; cerebrovascular disease; a history of these conditions; or in patients with uncontrolled hypertension.
- Caution: Patients with; hypertension, hyperlipidaemia, diabetes mellitus, smoking & any other risk factor for cardiovascular events.

Prescribing Changes

Forceval® capsules supply problem

There is currently a supply problem with Forceval® capsules. Valupak Multivitamin and Mineral tablets have been placed on the formulary, and should be prescribed instead of Forceval® at a dose of one tablet daily. **Forceval® dispersible tablets should not be used as an alternative.** These are restricted to those patients who are unable to swallow solid dosage forms or have a feeding tube in place, and are significantly more expensive than Forceval® capsules or Valupak Multivitamin and Mineral tablets.

Calcium and vitamin D formulary changes

Calceos® chewable tablets and Adcal D3® caplets have been removed from the formulary, and Accrete D3® film coated tablets have been added.

Certain orthopaedic wards will continue to use Calceos® until TTO packs of Accrete D3® are available.

Please note that Accrete D3® tablets contain gelatin and are not suitable for those with allergies to peanuts or soya. Adcal D_3® caplets do not contain gelatin and can be taken by those with allergies to peanuts or soya. Please note that such prescribing is non-formulary, and should only be undertaken in the small number of patients with the above allergies / intolerances.

Combivent® nebules switch to salbutamol and ipratropium

As part of a cost-saving initiative, NHS Tayside is recommending that Combivent® nebules are replaced with the individual agents-salbutamol nebules (2.5mg in 2.5mLs) and ipratropium nebules (500micrograms in 2mLs). These two nebules can be combined in the same nebuliser chamber for simultaneous administration.

Current stocks of Combivent® nebules should be used up, after which time all stock lists will be amended, removing Combivent® and adding salbutamol and ipratropium nebules.

Information Technology

Mental Health - information for patients

The web-site that provides patient information leaflets on medicines for mental health (formerly the UKPPG leaflets) is now available on NHS inform.

The link is available within the Mental Health zone, through the Accessing Help / Medicines section of the zone.

The link is www.nhsinform.co.uk/mentalhealth

Medicine	Indication	Local recommendation category	Comments and useful links
Canakinumab (Ilaris®) 150 mg powder for solution for injection (882/13) - *Non-submission*	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above including: – Muckle-Wells Syndrome (MWS) – Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) – Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.	**Not recommended**	***SMC advice***
Canakinumab (Ilaris®) 150 mg powder for solution for injection (883/13) - *Non-submission*	Symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are cotra-indicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.	**Not recommended**	***SMC advice***
Everolimus (Votubia®) 10mg tablets (884/13) - *Non-submission*	Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.	**Not recommended**	***SMC advice***
Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) (864/13) - *Full submission*	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.	**Not recommended**	***SMC advice***
Ivacaftor 150mg film-coated tablets (Kalydeco®) (827/12) - *Resubmission*	Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a *G551D* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	**Not recommended**	***SMC advice***
Linaclotide hard capsules, 290 micrograms (Constella®) (869/13) - *Full submission*	Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. **SMC restriction:** linaclotide is restricted for use in patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options.	**Non formulary - protocol pending**	***SMC advice*** ***SPC link***
Pegylated interferon alpha-2a, 90, 135 and 180microgram pre-filled syringe, 135 and 180microgram pre-filled pen (Pegasys®) (871/13) - *Abbreviated submission*	In combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). **SMC restriction:** prescribing by specialist in paediatric infectious disease or paediatric gastroenterology.	**Hospital Only - Paediatric Gastroenterology**	***SMC advice*** ***SPC link***

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

Medicine	Indication	Local recommendation category	Comments and useful links
Saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets (Komboglyze®) (870/13) - *Abbreviated submission*	Adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. **SMC restriction:** use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate.	**Formulary** **Restriction:** in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate.	*SMC advice* *SPC link*

'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 - June/July

TAF Section	Drug(s)/topic	Changes
1.5	Treatment of inflammatory bowel disease	Sulfasalazine moved from core formulary to GPs under direction of GI (added to GI specialist list).
6.1	Drugs used in diabetes	Saxagliptin and metformin combination tablets added to the formulary.
6.6	Drugs affecting bone metabolism	Strontium ranelate added to the Medicines for the Elderly and Endocrine specialist lists (removed from core formulary).
9.2	Fluids and electrolytes	Dioralyte® sachets used at double the normal concentration (10 sachets in 1L of water) have been added to formulary and gastrointestinal specialist list for use in those with intestinal failure and high output stomas (unlicensed 'off label' use).
9.6	Vitamins	Valupak Multivitamin and Mineral tablets added to formulary. Forceval® capsules removed from formulary. Calceos® and Adcal D3® removed from formulary. Accrete D3® added to the formulary.
11.3	Anti-infective preparations	Propamidine isethanoate 0.1%, chlorhexidine digluconate 0.02% (unlicensed), hexamidine 0.1% (unlicensed), polihexanide 0.02% (unlicensed), amphotericin 0.15% (unlicensed), miconazole 1% (unlicensed) eye drops all added to the formulary and ophthalmology specialist list. Ganciclovir 0.15% eye gel added to the formulary and ophthalmology specialist list. Aciclovir 3% eye ointment moved to the ophthalmology specialist list from the core formulary.
11.8.1	Tear substitutes	Hypromellose eye drops and liquid paraffin (Lacrilube®) eye ointment removed from formulary. Carbomer eye drops now 1st choice. Carmellose sodium (Optive® and Optive Plus®), Liquid paraffin (VitA-POS®), Sodium hyaluronate (Hylo-Tear®, Hylo-Forte® and Clinitas® UDV) and carmellose sodium (Celuvisc® UDV) added to the formulary. Acetylcysteine / hypromellose (Ilube®), ciclosporin (unlicensed) and sodium chloride (unlicensed) eye drops added to the ophthalmology specialist list and formulary.
Wound Management Formulary	Formulary dressings	Mepilex 5x5cm added. Biatain adhesive, 7.5cm x 7.5cm and 15cm x 15cm added.

SMC Briefing Notes:

Click here for June Briefing Note

Click here for July 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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