TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 114 – February 2012

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

Special points of interest for Primary Care

- Aliskiren
- Sevelamer carbonate (Renvela®) - Renal specialist list update

SMC advice:

- Dexamethasone (Ozurdex®)
- Entecavir (Baraclude®)
- Erlotinib (Tarceva®)
- Exenatide (Bydureon®)
- Fentanyl (Instanyl®)
- Linagliptin (Trajenta®)
- Ranolazine (Ranexa®)

Inside this issue :

Specialist list Update - Renal

The Renal Specialist Formulary list has been updated with sevelamer carbonate (Renvela®) now the first-choice non-calcium based phosphate-binding agent for hyperphosphataemia in new patients on haemodialysis or peritoneal dialysis and patients with Chronic Kidney Disease not on dialysis with a serum phosphate concentration of 1.78mmol/L or more. Sevelamer hydrochloride (Renagel®) remains on the Renal specialist list for existing patients on haemodialysis or peritoneal dialysis.

Links to the Renal Department Electrolyte replacement guidelines , updated Guidelines for the Management of Bone Metabolism and Disease in Chronic Kidney Disease and the NHS Tayside Adult Empirical Treatment of Infection Guidelines for Renal Patients have also been added to the specialist list.

Click here for a link to the Renal specialist list.

Prescribing Changes

Aliskiren— review by European Medicines Agency (EMA)

A recent safety warning from the MHRA has highlighted concerns regarding the use of aliskiren in addition to an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) in diabetic patients. CLICK HERE for MHRA information. A recent EMA press release recommends that aliskiren should be contraindicated in patients with diabetes or renal impairment (Chronic Kidney Disease (CKD) stage 3A or higher (eGFR< 60mL/min)) who take ACE inhibitors or ARBs. For all other patients receiving aliskiren in combination with an ACE inhibitor or ARB, the balance of benefits and risks of continuing treatment should be considered carefully.

Aliskiren is not recommended by SMC but may be prescribed locally via the Individual Patient Treatment Request (IPTR) form by the Cardiovascular Risk Clinic in patients unable to achieve BP control with a variety of anti-hypertensives. Specialists are concerned that practices may dis-continue aliskiren without contacting the relevant clinic.

The following are local points further to the EMA advice:

- All patients taking aliskiren and also taking ACE inhibitors or ARBs with diabetes or renal impairment (CKD stage 3A or higher) and under the care of the Cardiovascular Risk Clinic will automatically be reviewed at their next clinic appointment
- Any patients taking aliskiren and ACE inhibitors or ARBs with diabetes or renal impairment (CKD stage 3A or higher) who are not under the care of the Cardiovascular Risk Clinic should be identified by practices and referred to the Cardiovascular Risk Clinic for assessment
- GPs should not discontinue aliskiren in patients without prior discussion with the appropriate secondary care physician

Drug Safety Updates

Please follow link - Volume 5, Issue 7, February 2012

Medicine	Indication	Local recommendation category	Comments and useful links
Dexamethasone (Ozurdex®) 0.7 mg intravitreal implant (751/11) - *Non submission*	Treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.	**Not recommended**	***SMC advice***
Entecavir, 0.5mg and 1mg film-coated tablets and 0.05 mg/mL oral solution (Baraclude®) (747/11) - *Full submission*	Treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease.	**Not recommended**	***SMC advice***
Erlotinib 25, 100 and 150mg film-coated tablets (Tarceva®) (749/11) - *Full submission*	First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.	***Pending OHMMG decision**	***SMC advice***
Exenatide 2mg powder and solvent for prolonged-release suspension for injection (Bydureon®) (748/11) - *Full submission*	Treatment of type 2 diabetes mellitus in combination with: - metformin - sulphonylurea - thiazolidinedione - metformin and sulphonylurea - metformin and thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.	***Pending specialist feedback**	***SMC advice***
Fentanyl 50, 100, 200 microgram single dose nasal spray (Instanyl®) (750/11) - *Abbreviated submission*	For the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.	***Pending specialist feedback**	***SMC advice***
Linagliptin, 5mg film-coated tablet (Trajenta®) (746/11) - *Full submission*	The treatment of type 2 diabetes mellitus to improve glycaemic control in adults: As monotherapy: in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contra-indicated due to renal impairment. As combination therapy: in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control; in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.	***Pending specialist feedback**	***SMC advice***
Ranolazine, 375mg, 500mg and 750mg prolonged-release tablets (Ranexa®) (565/09) - *2nd Resubmission*	As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists).	**Not recommended**	***SMC advice***

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

OHMMG - Oncology and Haematology Medicines Management Group

Tayside Area Formulary (TAF) Updates - Feb 2012

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Renal	***Sevelamer carbonate (Renvela®)* now first-choice non-calcium based phosphate-binding agent for hyperphosphataemia in new patients on haemodialysis or peritoneal dialysis and patients with CKD not on dialysis with serum phosphate concentration of 1.78mmol/L or more. Sevelamer hydrochloride (Renagel®) remains on specialist list for existing patients on haemodialysis or peritoneal dialysis. Links to the Renal Department Electrolyte replacement guidelines , updated Guidelines for the Management of Bone Metabolism and Disease in Chronic Kidney Disease and the NHS Tayside Adult Empirical Treatment of Infection Guidelines for Renal Patients added.***
9.2	Fluids and electrolytes	***Links added to the Renal Department Electrolyte replacement guidelines inserted.***
9.5	Phosphate-binding agents	***Updated advice on sevelamer carbonate (Renvela®)* and sevelamer hydrochloride (Renagel®) added as above. Link to the updated Guidelines for the Management of Bone Metabolism and Disease in Chronic Kidney Disease inserted.***
9.6	Vitamin D	***Link to the updated Guidelines for the Management of Bone Metabolism and Disease in Chronic Kidney Disease inserted.***

* SMC accepted medicine

SMC Briefing Note:

Click here for January 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.