TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 129 – August/September 2013

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

Special points of interest for Primary Care

- **Linaclotide**
- **Diclofenac**
- **Adrenaline auto-injectors**
- **Calcium polystyrene sulphonate**

SMC advice:

July 2013:

- Adalimumab (Humira®) - single use
- Adalimumab (Humira®)
- Aflibercept (Zaltrap®)
- Everolimus (Afinitor®)
- Latanoprost (Monopost®)
- Nomegestrol acetate/estradiol (Zoely®)

August 2013:

- Abatacept (Orencia®)
- Argatroban (Exembol®)
- Calcium polystyrene sulphonate (Sorbisterit®)
- Chloroprocaine hydrochloride (Ampres®)
- Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil (Stribild®)
- Pirfenidone (Esbriet®)
- Ursodeoxycholic acid (Ursofalk®)

Inside this issue :

Specialist lists - progress

The Obstetrics & Gynaecology specialist formulary list is due to be presented at the Medicines Advisory Group (MAG) in September.

Work has started on the Parkinson's disease specialist formulary list.

The Oncology & Haematology (non chemo drugs) specialist formulary list is due to be published in the next few weeks on the Tayside Area Formulary (TAF) website.

Guidelines and Protocols

Linaclotide Protocol

Linaclotide is licensed for the symptomatic treatment of moderate to severe irritable bowel syndrome (IBS), with constipation, in adults.

The SMC have accepted it for restricted use in patients who have not responded adequately to or cannot tolerate all other suitable treatment options.

The term "All other suitable treatment options" is not clearly defined.

Prior to linaclotide, treatment options included antispasmodics and laxatives as first line with tricyclic antidepressants (TCAs) and SSRIs as unlicensed second line options.

Current guidance deals with IBS in general, whereas this protocol applies to IBS with constipation only.

In NHS Tayside linaclotide is **restricted** to use in patients who have poor response to treatment with a bulk forming laxative plus or minus an antispasmodic following treatment for 3 to 6 months.

CLICK HERE for the protocol.

Drug Safety Updates

Please follow link - Volume 7, Issue 1, August 2013

Drug Safety Updates

Diclofenac: new contraindications

As result of a European wide review on cardiac safety for diclofenac the drug is now contra-indicated in patients with ischaemic heart disease, peripheral arterial disease, cerebrovascular disease and congestive heart failure. This advice relates to tablets, capsules, suppositories & injection. Further information can be found in Drug Safety Update Volume 6, Issue 11, June 2013. Click Here for a summary and key messages for patients.

Oral diclofenac will be removed from the Tayside Area Formulary. Formulary first line choices of NSAID are ibuprofen and naproxen. Diclofenac intramuscular injection & suppositories will remain on the formulary for ureteric colic. Diclofenac intramuscular injection & suppositories should not be given for more than 2 days. Use of diclofenac in a patient with a contra-indication is outside the marketing authorisation and risk of use rests with the prescriber.

The decision to prescribe any NSAID should be based on an assessment of a patient's individual risk factors, including any history of cardiovascular or gastrointestinal illness. Advice on initiating treatment with an NSAID is included within the NICE Clinical Knowledge Summaries topic - NSAIDs - Prescribing issues.

Prescribing Changes

Lisdexamfetamine

Lisdexamfetamine (Elvanse® or Vyvanse®) has been licensed as a prescription only medicine (POM) for use in attention deficit hyperactivity disorder (ADHD). Although it has not yet been classified as a controlled drug, the Home Office is recommending that it be treated as a Schedule 2 CD pending formal classification. Emergency supply, in the absence of a prescription, is not recommended.

Adrenaline auto-injectors - EpiPen®

Jext® is currently the Tayside Area Formulary first choice adrenaline auto-injector. A decision has been made to revert back to EpiPen® as formulary 1st choice.

EpiPen® (£26.45) is now slightly cheaper than Jext® (£28.77) (MIMS August 2013). It also has a self-sheathing needle, good training material and an expiry reminder service in the form of an email which is comparable to Jext® .

Jext® has an expiry of 2 years and EpiPen® has an expiry of 18months.

There has been very poor uptake of Jext® prescribing, with the majority of prescriptions still being for EpiPen®. Clinical areas who prescribe adrenaline auto-injectors favoured a change back to EpiPen®, mainly due to patient and prescriber preference.

Adrenaline for self-administration must be prescribed by brand name to ensure that the patient receives the same device that they have been taught to use. Patients should not be switched between brands of adrenaline auto-injector without thorough training and education.

EpiPen® and EpiPen® Jr use the same administration technique as they always have, but have a new design which was made available from September 2012. There may still be patients with EpiPen® devices featuring the old design. Stocks of the device with the old design have been gradually phased out. For further information see the EpiPen® manufacturer's website.

Calcium polystyrene sulphonate - Sorbisterit®

Calcium polystyrene sulphonate (Sorbisterit®) has been approved by SMC for the treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment. Calcium polystyrene sulphonate may be used to remove excess potassium in mild hyperkalaemia or in moderate hyperkalaemia when there are no ECG changes. Sorbisterit® provides an alternative to Calcium Resonium® at a lower cost. The dose of Sorbisterit® and Calcium Resonium® differ as the strength of the active ingredient varies slightly. Neither products should be taken with fruit juice due to high potassium content. Sorbisterit® must be taken with or just after food. Sorbisterit® is now the Tayside Area Formulary choice of calcium polystyrene sulphonate powder, replacing Calcium Resonium®, the previous formulary choice.

Medicine	Indication	Local recommendation category	Comments and useful links
Adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) (880/13) *- Abbreviated submission*	Treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corti-costeroid, and an immunomodulator, or who are intolerant to or have contra-indications for such therapies. **SMC restriction:** prescribing by specialists in paediatric gastroenterology.	**Hospital Only** Paediatric Gastroenterology	***SMC advice*** ***SPC link***
Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8ml solution for injection vial for paediatric use (Humira®) (881/13) *- Abbreviated submission*	In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 2 years. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations.	**Hospital Only** Paediatric Rheumatology	***SMC advice*** ***SPC link***
Aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) (878/13) *- Full submission*	In combination with irinotecan/ 5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.	**Not recommended**	***SMC advice***
Everolimus, 5mg and 10mg tablets (Afinitor®) (872/13) *- Full submission*	Treatment of hormone receptor-positive, human epidermal growth factor type 2 (HER2)/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.	**Not recommended**	***SMC advice***
Latanoprost 50microgram/mL preservative-free single-dose eye-drops (Monopost®) (879/13) *- Abbreviated submission*	For the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. **SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	**GPs under the direction of ophthalmology** **Restricted to patients who require benzalkonium chloride free preparation** Ophthalmology Specialist List	***SMC advice*** ***SPC link*** ***Replaces tafluprost for patients who require a benzalkonium chloride free preparation***
Nomegestrol acetate/estradiol (Zoely®) 2.5 mg/1.5 mg film-coated tablets (898/13) *- Non-submission*	Oral contraception.	**Not recommended**	***SMC advice***

'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)'

Medicine	Indication	Local recommendation category	Comments and useful links
Abatacept 125mg/mL solution for subcutaneous injection in a pre-filled syringe (Orencia®) (888/13) *- Abbreviated submission*	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.	**Hospital Only** **Rheumatology Specialist List** 4th line agent When response to DMARDs (including at least one TNF-alpha inhibitor) inadequate. Supplied via a Patient Access Scheme (PAS)	***SMC advice*** ***SPC link***
Argatroban, 100mg/ml, concentrate for solution for infusion (Exembol®) (812/12) *- Resubmission*	Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.	**Hospital Only** **Renal Specialist List** 2nd line	***SMC advice*** ***SPC link*** *For use in patients with renal failure only* *1st choice danaparoid*
Calcium polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®) (890/13) *- Abbreviated submission*	Treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.	**Formulary**	***SMC advice*** ***SPC link*** *Replaces Calcium Resonium®*
Chloroprocaine hydrochloride, 10mg/mL, solution for injection (Ampres®) (885/13) *- Full submission*	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.	**Not Recommended**	***SMC advice***
Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®) (887/13) *- Full submission*	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®.	**Non-Formulary** Supplied via a Patient Access Scheme (PAS)	***SMC advice*** ***SPC link*** *Alternatives preferred; Atripla®, Eviplera®, raltegravir.*
Pirfenidone 267mg capsule (Esbriet®) (835/13) *- Resubmission*	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). **SMC restriction:** For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%.	**Pending* specialist feedback** Supplied via a Patient Access Scheme (PAS)	***SMC advice*** ***SPC link***
Ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) (889/13) *- Abbreviated submission*	For the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.	**Non-Formulary** Non drug techniques preferred **Formulary**	***SMC advice*** ***SPC link*** *Additional strength*

* '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
Colistimethate sodium dry powder for Inhalation, hard capsules, 1.66 million units/capsule (Colobreathe®) NICE TA 276; March 2013	Treatment for chronic pseudomonas lung infection in cystic fibrosis patients who would benefit from continued colistimethate sodium treatment but cannot take it in its nebulised form & would otherwise be offered tobramycin treatment (more expensive).	**Non-formulary** Protocol under development Supplied via a Patient Access Scheme	NICE TA 276
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.	**Formulary** Restricted to use in patients with poor response to laxatives +/- antispasmodics after 3 to 6 month trial	***SMC advice*** ***SPC link*** CLICK HERE *for protocol.* *More expensive than standard treatments.* *Review linaclotide response after 1 month.*

Tayside Area Formulary (TAF) Updates - Aug/Sep 2013

TAF Section	Drug(s)/topic	Changes
1.6	Laxatives	Linaclotide▼ added to the formulary – see SMC advice (page.4) for indication. Link to local protocol added.
1.9	Drugs affecting biliary composition and flow	Ursodeoxycholic acid 500mg film-coated tablets added to the formulary. See page. 4 for indication. Dissolution of gallstones indication removed from formulary for ursodeoxycholic acid as non-drug techniques preferred.
2.8	Heparinoids	Danaparoid (first line) and argatroban (second line) added to formulary and Renal specialist formulary list (hospital only). See page. 4 for indication for argatroban.
3.4	Allergic emergencies	EpiPen® now formulary first choice adrenaline auto-injector. See page. 2 for more information.
7.3	Contraceptives	Etonogestrel/ethinylestradiol vaginal ring (NuvaRing®▼) added to formulary as an alternative route for combined hormonal contraception when non oral route preferred.
7.4.3	Renal colic	Note added: Diclofenac intramuscular injection or suppositories should not be given for more than 2 days. Links to Drug Safety Update Volume 6, Issue 11, June 2013 and CKS topic – NSAIDs – Prescribing issues added.
9.2	Potassium removal	Calcium Resonium® removed from formulary and Renal specialist list. Sorbisterit® now preferred alternative preparation of calcium polystyrene sulphonate. Sorbisterit® added to core formulary. See page.2 for further information.
10.1.1	Non-steroidal anti-inflammatory drugs (NSAIDs)	Removal of diclofenac, naproxen now also first choice. Link to Drug Safety Update Volume 6, Issue 11, June 2013 and CKS topic – NSAIDs – Prescribing issues added. Additional information simplified.
10.1.3	Cytokine modulators	Abatacept (Orencia®▼) 125mg/mL solution for subcutaneous injection (pre-filled syringe) added to formulary and Rheumatology specialist list (hospital only). See page. 4 for indication.
11.6	Prostaglandin analogues	Latanoprost 50microgram/mL preservative-free single-dose eye-drops added to formulary (for prescribing under the direction of ophthalmology) and added to the Ophthalmology specialist formulary list. See SMC advice (page. 3) for indication. Restricted to patients who require a benzalkonium chloride free preparation (replaces tafluprost).
13.6	Co-cyprindiol (Dianette®) tablets	Link added to Drug Safety Update Volume 6, Issue 11, June 2013.

SMC 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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