TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 110 – October 2011

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

Special points of interest for Primary Care

- Chronic Pain Specialist List

SMC advice:

- Abatacept (Orencia®)
- Azacitidine (Vidaza®)
- Dabigatran (Pradaxa®)
- Golimumab (Simponi®)
- Tenofovir (Viread®)
- Methotrexate (Metoject®)
- Mifamurtide (Mepact®)
- Tapentadol (Palexia® SR)

Inside this issue :

Specialist list - Chronic Pain

Click here for a link to the Chronic Pain specialist formulary list.

Ketamine oral solution, ketamine infusion and lidocaine infusion have been included as medicines that may be prescribed by Hospital Specialists only. Other medicines that may be prescribed in General Practice under the direction of the Chronic Pain team include: hydromorphone m/r capsules; lidocaine plaster for localised neuropathic pain if standard therapies fail / are not tolerated; methadone tablets; and tapentadol prolonged-release tablets where morphine sulphate is not tolerated due to gastrointestinal (GI) adverse effects.

Fentanyl patch, oxycodone oral preparations (restricted use), lidocaine plaster for neuropathic pain associated with post-herpetic neuralgia (PHN) (restricted use), capsaicin cream for PHN, and duloxetine for diabetic neuropathy (restricted use) have been added to the main formulary, and may be initiated in General Practice. Guidance on prescribing of strong opioids is under development and will be accessible from the chronic pain specialist list once completed.

Guidelines and Protocols

Ketamine Oral Solution

A local treatment protocol has been finalised for ketamine oral solution (unlicensed) in Chronic Pain.

It is approved for Hospital Specialist Use only under the direction of the Chronic Pain team for the treatment of complex neuropathic pain, unresponsive to standard treatment.

Ketamine oral solution may only be prescribed by GPs under the direction of a Palliative Care specialist– see Ketamine in Palliative Care.

Key Points from local treatment protocol

Initiation of ketamine oral solution for chronic pain is usually done in hospital, either as a day-case admission or as an inpatient.

Starting dose: 5mg to 10mg four times daily, may be increased in 5mg to 10mg increments.

Usual dose range - 10mg to 60mg four times daily.

Reduce dose if converting from SC or IV ketamine to oral ketamine.

Monitor blood pressure, heart rate and respiratory rate at start of treatment.

Drug Safety Updates

Please follow link - Volume 5, Issue 3, October 2011

Dronedarone- safety review

A Europe-wide review by the EU Committee for Medicinal Products for Human Use (CHMP) on the risks and benefits of treatment with dronedarone, has concluded that the benefits of treatment continue to outweigh the risks for the maintenance of sinus rhythm after successful cardioversion in a limited population of patients with paroxysmal or persistent atrial fibrillation; however, in light of safety concerns dronedarone should only be prescribed after other treatment options have been considered.

Prescribers of dronedarone should refer to the October Drug Safety Update - see above link. The local protocol and local recommendation category for dronedarone will be updated shortly in light of the recent EU review.

Prescribing Changes

Individual Patient Treatment Requests (IPTRs) approved in secondary care

It was recently agreed by the Area Drug and Therapeutics Committee that prescribing for non-formulary / IPTR requests approved in secondary care could be passed to primary care under the following circumstances:

- the medicine is prescribed for a condition that is commonly treated in primary care and where no additional monitoring is required by the GP
- the medicine has been prescribed for at least 6 months in secondary care to establish tolerability and benefit of treatment
- an individual treatment plan has been developed where appropriate

The requirement for funding transfer to accompany prescribing should be considered on a case-by-case basis.

All requests for medicines not recommended by SMC should proceed to IPTR.

Tapentadol prolonged– release tablets (Palexia®SR▼)

Tapentadol is a new strong opioid analgesic with a dual mechanism of action (mu-opioid receptor agonist and noradrenaline reuptake inhibitor). In prolonged-release form, it has been accepted for restricted use by SMC and has been added to the Chronic Pain specialist formulary list. The local recommendation for tapentadol prolonged-release is that **GPs may prescribe under the direction of the Pain Clinic for patients unable to tolerate morphine sulphate MR due to GI adverse effects.** The SMC has not yet received a submission for tapentadol immediate-release tablets and they are therefore not recommended for use (unless an IPTR has been approved). There are only 2 immediate-release tablet strengths available, and these do not allow for an appropriate breakthrough dose at total daily doses of tapentadol below 300mg.

Adverse effects of tapentadol are similar to those of other opioid analgesics, however the incidence of GI adverse effects (constipation, nausea, vomiting) with tapentadol prolonged-release has been found to be lower than with oxycodone modified-release. There is a lack of comparative data with tapentadol and opioid analgesics other than oxycodone. There are no published data at present on the use of tapentadol in cancer pain.

Tapentadol is a schedule 2 controlled drug. Tramadol and tapentadol have similar names and doses - therefore there is a potential risk of confusion between the two different analgesics.

Switching between tapentadol prolonged-release and other strong opioids; and the choice of opioid for breakthrough pain if required (while on tapentadol prolonged-release); should only be undertaken on specialist advice.

The Chronic Pain team is currently developing guidance on prescribing of strong opioids that will hopefully provide clearer guidance on the use of tapentadol and it's place in relation to other strong opioids.

Medicine	Indication	Local recommendation category	Comments and useful links
Abatacept 250mg powder for concentrate for solution for infusion (Orencia®) (719/11) *- Full 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 tumour necrosis factor (TNF)-alpha inhibitor.	**Not recommended**	***SMC advice***
Azacitidine 100mg powder for suspension for injection (Vidaza®) (589/09) *- Re-submission*	Treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).	**Pending* OHMMG decision**	***SMC advice***
Dabigatran etexilate 110mg and 150mg hard capsules (Pradaxa®) (672/11) *- Full submission*	For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more of the following risk factors: • previous stroke, transient ischaemic attack, or systemic embolism • left ventricular ejection fraction <40% • symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2 • age ≥75 years • age ≥65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension	**Pending* national consensus statement and local specialist feedback**	***SMC advice*** ***NHS HIS press release***
Golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) (721/11) *- Full submission*	Treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.	**Pending* specialist feedback**	***SMC advice***
Tenofovir disoproxil (as fumarate), 245mg, film-coated tablet (Viread®) (720/11) *- Full submission*	Treatment of chronic hepatitis B in adults with decompensated liver disease.	**HOSPITAL ONLY** (Hepatitis clinic)	***SMC advice*** ***SPC link*** Also licensed and recommended locally for use in compensated disease.

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

OHMMG - Oncology and Haematology Medicines Management Group

Updates from previous SMC Advice

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Memantine (Ebixa®) (57/03)	Moderate to severe Alzheimer's Disease (AD).	GPs may prescribe under the direction of Psychiatry of Old Age (Angus & Dundee) **HOSPITAL ONLY** (Psychiatry of Old Age) (Perth & Kinross) Restricted to patients with moderate AD who are intolerant of or have a contraindication to cholinesterase inhibitors, or who have severe AD.	***NICE MTA*** ***SPC link*** ***Alzheimer's Disease Shared Care Protocol*** (Angus and Dundee) Initial 6-9 months memantine prescribed from POA (Angus and Dundee)
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.	**HOSPITAL ONLY** (Paediatric rheumatology clinic) May be administered in primary care.	***SMC advice*** ***SPC link*** ***Parenteral Methotrexate Policy*** Monitoring in general practice is covered under the Near Patient Testing Local Enhanced Scheme (LES). Prescribe by brand name.
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.	**HOSPITAL ONLY** (Paediatric Department - under the direction of tertiary centre) Supplied via a Patient Access Scheme (PAS).	***SMC advice*** ***SPC link***
Tapentadol, 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR) (654/10) *- Resubmission*	The management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.	GPs may prescribe under the direction of the pain clinic. Restricted to patients unable to tolerate morphine sulphate MR due to GI adverse effects. **Chronic pain specialist list**.	***SMC advice*** ***SPC link (50mg)*** ***SPC link (100mg)*** ***SPC link (150mg)*** ***SPC link (200mg)*** ***SPC link (250mg)*** This recommendation does not cover immediate release tapentadol tablets.

Tayside Area Formulary (TAF) Updates - October 2011

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Chronic Pain	*Chronic Pain specialist formulary list added.*
	Palliative Care	*Addition of links to Tayside Palliative Care Community Pharmacy Network information from the Palliative Care specialist formulary list.*
4.7	Analgesics	*Tramadol m/r capsules added for restricted use under step 2. Paracetamol intravenous infusion (Perfalgan®▼)* added to formulary (hospital only) under step 3. Fentanyl patches* and oxycodone capsules, m/r tablets* and oral solution added under step 3. Links to the 'Approximate Equivalent Opioid Doses' table inserted.* *Link to British Pain Society guidance inserted for information on the role of opioids in chronic non-malignant pain.* *Tapentadol prolonged-release tablets (Palexia® SR ▼)*, hydromorphone modified-release capsules (Palladone®SR) and methadone tablets added to formulary (all restricted use) and Chronic Pain specialist formulary list.*
4.7.3	Neuropathic Pain	*New section. Lidocaine 5% medicated plasters (Versatis®)* for post-herpetic neuralgia (PHN) and restricted use in localised neuropathic pain (unlicensed use 'off-label') added to formulary and Chronic Pain specialist list. Link to lidocaine plaster Local treatment protocol inserted.* *Capsaicin 0.075% Cream (Axsain®) for PHN and Duloxetine (Cymbalta®▼)* for diabetic neuropathy (restricted use) added to formulary.* *Ketamine oral solution 50mg/5mL (unlicensed) added to formulary for restricted use under the direction of Palliative Care specialists and as Hospital only for complex neuropathic pain by the Pain clinic (added to Chronic Pain specialist list). Link to local protocol for ketamine oral solution inserted. Ketamine infusion (unlicensed use 'off-label') and lidocaine infusion (unlicensed use 'off-label') added to formulary and Chronic Pain specialist formulary list (hospital only) for acute pain in patients with chronic pain and neuropathic pain in complex patients on specialist advice.*
4 - Central Nervous system Guidelines - Pain guidance notes	Management of Neuropathic Pain	*Link to new algorithm for PHN inserted. Guidance notes on duloxetine, lidocaine plasters, capsaicin cream, opioid analgesics, ketamine oral solution, ketamine infusion and lidocaine infusion added.*
	Approximate Equivalent Opioid Doses	*New strengths of oxycodone m/r tablets added.*
	Tapentadol Dose Conversion Chart	*New chart developed for tapentadol with approximate dose conversions to morphine and oxycodone.*
13.5 and Dermatology Guidance Notes - Management of Psoriasis	Calcipotriol	*Calcipotriol cream removed as discontinued.*
		Reference to calcipotriol cream removed as discontinued.

*** SMC accepted medicine**

SMC Briefing Note:

CLICK HERE for September 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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