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Produced by Tayside New Medicines Implementation Panel (NMIP)

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SMC Advice Issued in July 2004 –part I

Infliximab (Remicade[®]) – ankylosing spondylitis (AS)

SMC recommendation

Advice: following a full submission.

Infliximab (Remicade[®]) is not recommended for use within NHS Scotland for the treatment of ankylosing spondylitis, in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy.

In one relatively small study, it has demonstrated improvements in signs and symptoms, quality of life and physical functioning. However there is no evidence of a decrease in joint damage. The economic case is not demonstrated.

Tayside recommendation

Not recommended

Points for consideration:

- Infliximab is the first tumour necrosis factor (TNF)-antagonist licensed in the UK for the treatment of ankylosing spondylitis (AS). Infliximab is also licensed for the treatment of rheumatoid arthritis and Crohn's disease. The above SMC advice relates only to the AS indication.
- A recent bulletin from the [Canadian Coordinating Office for Health Technology Assessment](#) concludes that unanswered questions remain regarding the optimal dose of infliximab in AS, long-term safety and impact on disease progression.
- The licence for etanercept was extended in January 2004 to cover the treatment of AS. The SMC is currently awaiting a submission from the manufacturer for use in this indication.

Laronidase (Aldurazyme[®]) – mucopolysaccharidosis I (MPS I)

SMC recommendation

Advice: following a full submission.

Laronidase is not recommended for use within NHS Scotland for the treatment of mucopolysaccharidosis I. Laronidase was approved by the EMEA under exceptional circumstances and has been granted orphan drug status. The evidence of its efficacy is therefore limited. No information is presented in the submission to support the therapy being cost-effective and therefore the economic case is not demonstrated.

Continued over

Laronidase continued

Tayside recommendation

Not recommended

Points for consideration:

- Orphan status applies to medicinal products for the diagnoses, prevention or treatment of life-threatening or very rare serious conditions affecting not more than 5 in 10,000 persons in the European Union.
- MPS I is an extremely rare disorder caused by an inherited deficiency in the activity of the lysosomal enzyme alpha-L-iduronidase. Laronidase is a life-long enzyme replacement therapy.
- A randomised controlled study involving patients with the intermediate form of MPS I shows modest improvements in respiratory function and walking distance. Outcome data in relation to the main complications of MPS I are currently unavailable.
- Laronidase is not stocked by the hospital pharmacy.

Latanoprost (Xalatan®) – ocular hypertension/open-angle glaucoma

SMC recommendation

Advice: following a full submission.

Latanoprost (Xalatan®) is accepted for restricted use within NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma. Use of latanoprost, as monotherapy, should be restricted to patients who have contraindications to beta-blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta-blockers when required.

It is one of a number of topical ocular prostaglandin analogue preparations licensed in the UK for this indication. In reducing IOP it is comparable in effect to other drugs in its class.

Tayside recommendation

Recommended for second-line use within formulary

Points for consideration:

- Latanoprost once daily reduces IOP significantly more than timolol 0.5% twice daily. However, this difference has not been shown to be clinically important.
- Latanoprost appears to have a similar adverse-effect profile to the other topical ocular prostaglandin analogues. Prostaglandin analogues are associated with a higher incidence of ocular hyperaemia than beta-blockers and can also cause eyelash changes and iris pigmentation. However, they are not associated with the potential systemic cardiovascular and respiratory adverse effects that may follow systemic absorption of beta-blockers.
- Latanoprost is priced competitively versus other prostaglandin analogues and is considerably more expensive than timolol (£12 per month for latanoprost versus £3 per month for timolol 0.5% bd).
- Latanoprost is included in the [Tayside Area Prescribing Guide \(TAPG\)](#) for second-line treatment of glaucoma.

Movicol Paediatric Plain® – faecal impaction

SMC recommendation

Advice: following an abbreviated submission.

Movicol Paediatric Plain is accepted for use in Scotland as an alternative to Movicol Half for the treatment of paediatric faecal impaction. The new product is a reformulation of an existing paediatric presentation of macrogol to remove flavour and sweetener, and no clinical data have been considered in drafting this recommendation.

Tayside recommendation

Non-formulary

Points for consideration:

- Movicol® contains macrogol 3350, a long-chain polyethylene glycol which acts as an osmotic laxative.
- Movicol Paediatric Plain® is similar in price to the existing Movicol-Half® preparation. *Continued over*

Movicol Paediatric Plain[®] continued

- The Tayside Area Drug Formulary does not currently include paediatric treatments.
- **Movicol-Half[®] is the macrogol laxative recommended locally for the treatment of faecal impaction in children.**

Quetiapine (Seroquel[®]) – manic episodes

SMC recommendation

Advice: following a full submission.

Quetiapine (Seroquel[®]) is accepted for use within NHS Scotland for the treatment of manic episodes associated with bipolar disorder as monotherapy or as adjunct therapy to mood stabilisers.

Active comparators were included in the monotherapy trials but the studies were not designed to show differences between active comparator and quetiapine. It has not been compared to other atypical antipsychotics in this indication.

Economic data suggest that quetiapine (Seroquel[®]) is at least cost neutral, compared to other licensed approaches using atypical antipsychotics in this indication, either as adjunctive therapy or monotherapy.

Tayside recommendation

Recommended within specialist treatment pathway

Points for consideration:

- Quetiapine is the second atypical antipsychotic to be licensed for the acute treatment of mania. Unlike olanzapine, it is not currently licensed for maintenance therapy. Quetiapine is also licensed for the treatment of schizophrenia. The above SMC advice relates only to manic episodes.
- Quetiapine monotherapy appears to show similar reduction in manic symptoms as comparator treatments (haloperidol, lithium). Adding quetiapine to a mood stabiliser (lithium, valproic acid) appears to be more effective than mood stabiliser alone.
- Quetiapine is associated with a lower incidence of extrapyramidal symptoms than haloperidol or lithium.
- Whilst quetiapine is associated with less weight gain than olanzapine, both quetiapine and olanzapine cause more weight gain than typical antipsychotics.
- No comparative safety or efficacy data versus olanzapine are available.
- Quetiapine is a similar price to olanzapine.
- Further information on the management of patients with bipolar disorder is available within [consensus guidelines](#) produced by the British Association of Psychopharmacology.
- A SIGN guideline on the management of bipolar affective disorder in primary and secondary care is due in Autumn 2004.
- **The use of quetiapine in the treatment of manic episodes is restricted to patients under the overall supervision of clinicians experienced in managing bipolar disorder.**

Formulary Update – glitazones

As noted in the [D&TC Supplement Issue 39](#), May 2004, the Formulary Committee has approved the addition of rosiglitazone and pioglitazone to the Prescribing Guide for combination treatment in type 2 diabetes. For current guidance on the use of glitazones in type 2 diabetes please see [NICE guidance 63](#) August 2003.

Local guidance can also be accessed via the [DARTS](#) website.

Change in web-site address

The web address for the D&TC site available on SHOW has changed to:

www.show.scot.nhs.uk/nhstaysideadc - please update if saved as a favourite.

Contact details: Local implementation of SMC recommendations is being taken forward by the Tayside Medicines Unit – contact Jan Jones, Pharmaceutical Prescribing Adviser (jan.jones@tpct.scot.nhs.uk) if you have any queries in relation to the introduction of new drugs within NHS Tayside

This bulletin is based on evidence available to the Tayside Medicines Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use and access to the NHS Tayside Drug and Therapeutics Committee website (www.show.scot.nhs.uk/nhstaysideadc).