TAYSIDE PRESCRIBER

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Produced by Tayside New Medicines Implementation Panel (NMIP)

In this issue:

Improved Long-Term Planning for High Cost New Medicines

The SMC is to set up a national timetable for new, high clinical impact, and high cost medicines. The aim of this arrangement is to help Boards to plan for the financial impact of high cost medicines in advance, thereby facilitating access to treatments simultaneously across Scotland once approved by the SMC. The timetable will be in place by Spring 2004.

SMC Advice issued in December 2003

Salmeterol/fluticasone (Seretide Accuhaler®) – chronic obstructive pulmonary disease

SMC recommendation

Advice: following a full submission.
Salmeterol/fluticasone (Seretide Accuhaler®) is accepted for use within NHS Scotland for the treatment of patients with severe chronic obstructive pulmonary disease. It is the first of two long-acting β_2-agonist/corticosteroid combination inhaler preparations considered by SMC and licensed for the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD). The individual components have been available for many years and the combination product offers ease of administration and additional convenience. The combination appears to improve lung function to a greater extent than either of the individual constituents given alone. Comparative data with other combination products is limited at the present time.

➢➢➢ **Tayside recommendation**

Not currently recommended – pending formulary decision

Points for consideration:

- Although widely prescribed, none of the single inhaled corticosteroid preparations currently available is licensed specifically for use in the treatment of COPD.
- No comparative efficacy data versus generic beclometasone co-prescribed with a long-acting beta$_2$ agonist are available.
- Seretide is marginally less expensive than salmeterol and fluticasone given as single preparations.
- The combination inhaler Symbicort (formoterol/budesonide) is also licensed for use in COPD but has not been evaluated by the SMC.
- Recent draft NICE guidelines recommend that inhaled corticosteroids should be prescribed for patients with an FEV_1 ≤50% predicted who are having two or more exacerbations requiring

treatment with antibiotics or oral corticosteroids in a 12-month period. The aim of this is to reduce exacerbation rates, ease breathlessness and slow the rate of decline in health status, not to improve lung function per se.

- Further advice on the management of COPD is available in the Respiratory Guidance Notes within the Tayside Area Prescribing Guide (TAPG).
- **The place of Seretide in the management of COPD, and in relation to tiotropium, will be addressed by the Formulary Committee. Prescribers are advised to await the outcome of the formulary decision.**

Testosterone gel (Testogel®) – hypogonadism

SMC recommendation

Advice: following a full submission.
Testosterone (Testogel®), replacement therapy for adult male hypogonadism is accepted for restricted use within NHS Scotland. It offers an alternative to testosterone patches for those patients requiring a transdermal delivery system. Testosterone gel is at least as effective as testosterone patches and costs less, so is a cost-effective transdermal treatment for this condition.

➢➢➢**Tayside recommendation**

Recommended for use within specialist treatment pathways

Points for consideration:

- Fewer application-site reactions have been reported with testosterone gel compared to testosterone patches.
- No comparative efficacy and safety data versus non-transdermal testosterone replacement therapies (e.g. oral, depot injection, implant) are available.
- Testosterone gel is available in 5g sachets. The dose should be adjusted in 2.5g steps, which may present practical problems in the measurement of half a sachet of the gel.
- Patients must take precautions to prevent testosterone transfer to other persons in contact with skin areas treated with Testogel.

The following recommendation relates to a HOSPITAL ONLY medicine

Adalimumab (Humira®) – rheumatoid arthritis (RA)

SMC recommendation

Advice: following a full submission.
Adalimumab (Humira®) is accepted for restricted use within NHS Scotland for the treatment of rheumatoid arthritis (RA). It should be initiated only by specialist physicians experienced in the diagnosis and treatment of RA, and used in accordance with British Society Rheumatology (BSR) guidelines for prescribing TNF-α blockers in adults [which have been endorsed by the National Institute of Clinical Excellence (NICE) and QIS]. The BSR have established a Biologics Registry and details of patients treated with TNF-antagonists including adalimumab should be entered into this database. Adalimumab is the third TNF-antagonist licensed for the treatment of rheumatoid arthritis (RA).

➢➢➢**Tayside recommendation**

Recommended for use within specialist treatment pathways

Points for consideration:

- Adalimumab is the first anti-TNF α antibody that is entirely humanised.
- Adalimumab shows improvement in the signs and symptoms and radiological progression of RA in patients with active RA who have shown an inadequate response to DMARDs (disease modifying anti-rheumatic drugs). It appears to have similar efficacy to other TNF-antagonists (etanercept, infliximab).
- To ensure maximum efficacy, adalimumab should be given in combination with methotrexate, although it can be given as monotherapy in cases of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
- Clinical studies show that adalimumab has a similar adverse-effect profile to other TNF-antagonists. In common with etanercept, it does not appear to produce the severe administration reactions associated with infliximab.
- At an average annual cost of £9,295 per patient, adalimumab is the same price as etanercept.
- The frequency of adalimumab administration is less than etanercept and more than infliximab during maintenance therapy.
- Adalimumab has the advantage of being available as a pre-filled syringe suitable for self-administration by the patient.
- Adalimumab appears as cost-effective as other currently available TNF-antagonists.
- **Adalimumab is recommended locally as a further option to existing TNF-antagonists used in the treatment of RA.**
- Refer to the British Society Rheumatology (BSR) "Guidelines for prescribing TNF-α blockers in adults with RA" and the NICE "Guidance on the use of etanercept and infliximab for the treatment of RA" for more information on the use of TNF antagonists in RA.

Deferred Advice

Advice on teriparatide (Forsteo®) has been deferred to January 2004.

Erratum –DTC Supplement Sept 2003, Issue No.31. The cost of olopatadine eye drops should read 175p per ml versus 14.6p per ml for sodium cromoglicate.

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