TAYSIDE PRESCRIBER

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Produced by Tayside New Medicines Implementation Panel (NMIP)

In this issue:

SMC Advice Issued in May 2004

Botulinum type A neurotoxin (Botox®) – post-stroke hand and wrist spasticity

SMC recommendation

Advice: following a resubmission.
Clostridium botulinum toxin A (Botox®) is not recommended for use within NHS Scotland for the treatment of focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity, associated with stroke in adults.
Botox produces a localised reduction in muscle tone in patients with post-stroke hand and wrist spasticity and improves disability at least up to 12 weeks. However, there is currently very little direct evidence of cost-effectiveness of this approach.

Tayside recommendation

Not recommended

Points for consideration:

- Botox® is also licensed for the treatment of foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, blepharospasm, hemifacial spasm, cervical dystonia, and hyperhidrosis of the axillae. Dysport® is a further botulinum type A neurotoxin. The above SMC advice relates only to Botox® in the indication of post-stroke hand and wrist spasticity

Budesonide/formoterol inhaler (Symbicort Turbohaler®) – severe COPD

SMC recommendation

Advice: following a full submission
Budesonide/formoterol inhaler (Symbicort Turbohaler®) is accepted for use within NHS Scotland for the symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.
It is the second 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 are limited at the present time.

Continued over

Budesonide/formoterol inhaler continued

Tayside recommendation

Recommended within formulary

Points for consideration:

- Symbicort® is also licensed for the treatment of asthma, the above SMC recommendation relates only to the COPD indication.
- Symbicort® reduces exacerbation rates more than formoterol, but not more than budesonide, and increases the time to first exacerbation more than either budesonide or formoterol taken alone.
- No comparative efficacy or safety data exist for Symbicort® versus generic beclometasone co-prescribed with a long-acting β_2-agonist. Similarly, no comparative data versus the alternative combination inhaler, Seretide® (fluticasone/salmeterol), are available.
- Symbicort® is slightly less expensive than budesonide plus formoterol given as single preparations, and is comparable in cost to Seretide Accuhaler®.
- Recent NICE guidelines recommend that long-acting bronchodilators should be used in COPD patients who remain symptomatic despite treatment with short-acting bronchodilators, and in patients who have two or more exacerbations a year. 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.
- A recent review in the Drug & Therapeutics Bulletin concludes that combination inhalers need to be compared with the administration of an inhaled long-acting β_2-agonist plus an inhaled corticosteroid given via separate inhalers in randomised controlled trials. **In the absence of such evidence, it is difficult to justify using long-acting β_2-agonist/corticosteroid combination inhalers as a first choice in managing patients with COPD.**
- Advice on the management of COPD is available in the Respiratory Guidance Notes within the Tayside Area Prescribing Guide (TAPG).

Olanzapine (Zyprexa®) – maintenance treatment of bipolar disorder

SMC recommendation

Advice: following a full submission.

Olanzapine (Zyprexa®) is accepted for use within NHS Scotland for the prevention of recurrence in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

Olanzapine has been shown to be significantly superior to placebo in delaying symptomatic relapse of mania or depression and of mania alone. Apart from weight gain, somnolence and treatment-emergent depression, most significant differences between olanzapine and active competitors favoured olanzapine.

Tayside recommendation

Recommended within specialist treatment pathway

Points for consideration:

- Olanzapine is also licensed in schizophrenia and for the treatment of moderate to severe manic episode, the above SMC recommendation relates only to maintenance treatment in bipolar disorder. The SMC approved olanzapine for restricted use in the acute phase of mania in June 2003.
- Clinical studies involving patients with bipolar disorder show that olanzapine is more effective than lithium in delaying symptomatic relapse into mania and at least as effective as lithium in delaying relapse into depression. Adding olanzapine to lithium or valproate semisodium is more effective than lithium or valproate monotherapy.
- Recent CSM advice advises caution in use of olanzapine in patients with a previous history of stroke or transient ischaemic attack.
- The cost of olanzapine is considerably higher than lithium (£105 for 30 days olanzapine 10mg od versus £1 for lithium at an average dose of 350mg od).
- Savings in reduced hospital inpatient costs are anticipated.
- Further information on the management of patients with bipolar disorder is available within consensus guidelines produced by the British Association of Psychopharmacology.

Continued over

Olanzapine continued

- **The use of olanzapine for maintenance treatment of bipolar disorder should be prescribed on the recommendation of a clinician experienced in managing this complex disorder.**

Temoporfin (Foscan®) – advanced head and neck squamous cell cancer

SMC recommendation

Advice: following a full submission.
Temoporfin (Foscan®) is not recommended for use within NHS Scotland for the palliative treatment of patients with advanced head and neck squamous cell carcinoma failing prior therapies and unsuitable for radiotherapy, surgery or systemic chemotherapy.
It is the first photosensitising drug licensed in the UK for use in photodynamic therapy (PDT) for the treatment of these patients. Its effects in terms of tumour mass reduction and improvement in quality of life were small and were only observed in patients with lesions less than 10mm deep, which were fully illuminated with activating light. The quality of life benefits resulting from palliation, particularly in this subgroup, were marginal and the economic case for its use over other palliative treatments was not made.

Tayside recommendation

Not recommended

Points for consideration:

- Further information on the management of head and neck cancer is available within a consensus document developed by the British Association of Otorhinolaryngologists Head and Neck Surgeons.
- NICE plans to publish a guideline on head and neck cancers in October 2004. The draft consultation document indicates that photodynamic therapy should only be offered in the context of multi-centre clinical trials, unless there is reliable evidence of effectiveness.
- Temoporfin is not stocked by the hospital pharmacy.

Formulary decisions – April 2004

The following SMC recommendations were deferred to the Formulary Committee for consideration of local place in therapy. The Tayside Formulary includes first and second-line treatment options for the majority of conditions seen in both primary and secondary care. Decisions made at the April 2004 meeting of the Formulary Committee are summarised below:

Deferred Medicine	Indication	Formulary Decision
Frovatriptan (Migard®)	Migraine	Non-formulary
Rosiglitazone/metformin (Avandamet®)	Type 2 diabetes	Non-formulary
Clindamycin/benzoyl peroxide (Duac®)	Acne	Non-formulary
Budesonide/formoterol (Symbicort Turbohaler®)	COPD	Formulary

Tayside recommendations in relation to all medicines that have been evaluated by the SMC are available on the DTC website under "New Medicines" and "Recommendations".

The Formulary Committee has also approved the addition of both rosiglitazone and pioglitazone for **combination treatment** in type 2 diabetes mellitus in patients with insufficient glycaemic control despite maximal tolerated doses of oral monotherapy with either metformin or a sulphonylurea:

- in combination with metformin particularly in overweight patients
- in combination with a sulphonylurea only in patients who show intolerance to metformin or for whom metformin is contraindicated.

Refer to the Formulary Committee Minute for background to these decisions.

The 2nd Edition of the Tayside Area Prescribing Guide is currently with the printers and due to be issued in June 2004.

Forthcoming SMC Advice

Products for which SMC advice is expected in the next quarter are listed below.

Gastro-intestinal system
Rabeprazole (Pariet®)
Macrogol (Movicol® Paediatric Plain)
Cardiovascular system
Melagatran/Ximelagatran (Exanta®)
Losartan (Cozaar®)
Valsartan/hydrochlorthiazide (Co-Diovan®)
Central Nervous System
Quetiapine (Seroquel®)
Methylphenidate (Equasym XL®)
Buprenorphine patch (Transtec®)
Aripiprazole (Abilify®)
Aprepitant (Emend®)
Infections
Mycophenolate (Myfortic®)
Ertapenem (Invanz®)
Emtricitabine (Emtriva®)

Endocrine system
Somatropin (Norditropin SimpleXx®)
Ibandronic acid (Bondronat®)
Pioglitazone (Actos®)
Obstetrics, gynaecology & urinary tract disorders
Duloxetine (Yentreve®)
Malignant disease & immunosuppression
Rituximab (MabThera®)
Giladel wafer
Fulvestrant (Faslodex®)
Bortezomib (Velcade®)
Darbepoetin alfa (Aranesp®)
Nutrition & blood
Laronidase (Aldurazyme®)
Musculoskeletal & joint diseases
Lumiracoxib (Prexige®)
Infliximab (Remicade®)
Etanercept (Enbrel®)
Eye
Latanoprost (Xalatan®)

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