TAYSIDE PRESCRIBER

Tayside D&TC Supplement No. 33

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Produced by Tayside New Medicines Implementation Panel (NMIP)

In this issue:

Scottish Medicines Consortium (SMC) & NMIP Terminology

The SMC has changed the way that it presents advice on the use of new medicines. In future, the following three categories of recommendations will be used:

- accepted for use (replaces recommended for general use)
- accepted for restricted use (replaces recommended for general use)
- not recommended

All who quote or refer to SMC advice are now required to quote all of the guidance in full.

In future, the D&TC Supplement to the Tayside Prescriber will quote the full SMC advice for each new medicine followed by a local Tayside NMIP recommendation and any points for consideration. NMIP will categorise new medicines accepted by the SMC into those appropriate for consideration by the formulary committee and those appropriate for use within specialist treatment pathways.

SMC Advice issued in November 2003

Mometasone inhaler (Asmanex®) – asthma

SMC recommendation

Advice: following a full submission.
Accepted for restricted use within NHS Scotland.
Mometasone is the fourth inhaled steroid licensed for treatment of asthma. It is available as a dry powder inhaler. It has a similar efficacy and adverse event profile to other currently available inhaled steroids. It is suitable for use as a second line agent following treatment failure on first line inhaled steroids.

➢➢➢ **Tayside recommendation**

Not currently recommended – pending formulary decision

Points for consideration:

- Mometasone appears roughly equivalent to twice the dose of CFC beclometasone (BDP).
- The recent SIGN/BTS "British guideline on the management of asthma" states that the relative safety of mometasone is not fully established.
- Mometasone is not licensed for use in children under 12 years.
- No data are currently available on the use of mometasone in combination with long-acting beta$_2$ agonists.
- Mometasone is considerably more expensive than BDP-CFC (28 days of BDP 400mcg twice daily costs £9.23 versus £17.15-£20.72 for mometasone 400mcg daily).
- BDP is currently the most cost-effective inhaled steroid.
- All three alternative inhaled steroids: BDP, budesonide and fluticasone are included in the Tayside Area Prescribing Guide (TAPG).
- Further advice on the management of asthma is available in the Respiratory Guidance Notes within the TAPG.
- **The place of mometasone in the management of asthma will be addressed by the Formulary Committee. Prescribers are advised to await the outcome of the formulary decision.**

Olmesartan (Olmetec®) – hypertension

SMC recommendation

Advice: following a full submission.
Accepted for restricted use within NHS Scotland.
Olmesartan has been shown to be at least as effective as other angiotensin II receptor antagonists (AIIAs) for the treatment of hypertension. It may be considered for use, along with other AIIAs, as an alternative in patients unable to tolerate an ACE inhibitor.

➢➢➢Tayside recommendation

Not currently recommended – pending formulary decision

Points for consideration:

- Olmesartan is priced competitively versus other AIIAs.
- ACE inhibitors are associated with a stronger evidence base than AIIAs in cardiovascular disease, and are less expensive.
- Evidence based guidelines recommend that AIIAs are reserved for patients unable to tolerate ACE inhibitors.
- Losartan and valsartan are currently recommended within the TAPG as the AIIAs of choice locally.
- Further advice on the management of hypertension is available in the Cardiovascular Guidance Notes within the TAPG.
- **The place of olmesartan in relation to other AIIAs in the management of hypertension will be addressed by the Formulary Committee. Prescribers are advised to await the outcome of the formulary decision.**

Pimecrolimus 1% cream (Elidel®) – atopic dermatitis (AD)

SMC recommendation

Advice: following a resubmission.
Not recommended for use within NHS Scotland.
Pimecrolimus cream is the first topical immunomodulator for the treatment of signs and symptoms of mild-to-moderate atopic dermatitis. There is no evidence that it has clinical advantage in terms of efficacy or safety when compared with the alternative treatments, which include mild-to-moderately potent topical corticosteroids. The economic case for using this expensive preparation is unproven.

➢➢➢**Tayside recommendation**

Not recommended

Points for consideration:

- Pimecrolimus cream is not stocked by the hospital pharmacy.

Sertraline (Lustral®) – post-traumatic stress disorder (PTSD)

SMC recommendation

Advice: following a full submission.
Not recommended for use within NHS Scotland.
Sertraline has demonstrated some benefit in treating post-traumatic stress disorder (PTSD) in two of four 12-week double blind treatment studies, and in extension studies for up to 64 weeks. The product licence restricts its use to women only; a narrower indication than for the other drug currently licensed for treating PTSD, and against which no comparative trials have been conducted. The manufacturer submitted no evidence to demonstrate the cost-effectiveness of their drug.

➢➢➢**Tayside recommendation**

Not recommended

Points for consideration:

- Sertraline is also licensed for the treatment of depression; this SMC/Tayside recommendation applies only to the PTSD indication.
- Paroxetine is also licensed for treating PTSD, and may be used in both men and women.

The following recommendations relate to HOSPITAL ONLY medicines

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

SMC recommendation

Advice: following a full submission.
Not recommended for use within NHS Scotland.
Clostridium botulinum toxin A (Botox®) produces a localised reduction in muscle tone in patients with post-stroke hand and wrist spasticity and may improve disability. However, the place in therapy was not clearly defined nor was the economic case proven.

➢➢➢**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. This SMC/Tayside recommendation applies only to the indication of post-stroke hand and wrist spasticity.
- Other drug therapies for post-stroke spasticity include oral antispasmodic drugs, eg baclofen, tizanidine, diazepam and dantrolene. These also reduce muscle tone but can cause generalised weakness.
- "Guidelines for the use of botulinum toxin in the management of adult spasticity" produced by the Royal College of Physicians' emphasise physical therapy as the mainstay of treatment.

Interferon beta 1a liquid (Avonex®) – multiple sclerosis

SMC recommendation

Advice: following an abbreviated submission.
Accepted for restricted use within NHS Scotland.
Avonex is a liquid formulation which replaces a powder formulation of the same strength that requires reconstitution. It is supplied at the same price. This product is used for the treatment of selected ambulatory patients with relapsing-remitting multiple sclerosis under the provisions of a risk-sharing scheme between the Scottish Executive and the manufacturer.

➢➢➢**Tayside recommendation**

Recommended for use within specialist treatment pathways

Methyl aminolevulinate 160mg/g cream (Metvix®) – actinic keratoses (AK) basal cell carcinoma (BCC)

Actinic keratoses

SMC recommendation

Advice: following a resubmission.
Accepted for use within NHS Scotland.
The evidence of efficacy for Metvix for the treatment of thin or non-hyperkeratotic and non-pigmented actinic keratosis on the face and scalp is not strong. The health economic evidence is incomplete, though it suggests similar costs to the alternative treatment (cryotherapy). However, Metvix appears to have a place for treatment of those patients when other therapies are considered less appropriate and should be delivered by a dermatologist experienced in this therapy.

➢➢➢**Tayside recommendation**

Recommended for use within specialist treatment pathways

Points for consideration:

- Methyl aminolevulinate is a topical photosensitiser for use in photodynamic therapy (PDT).
- Methyl aminolevulinate photodynamic treatment (MAL-PDT) shows similar rates of lesion clearance to cryotherapy in patients with AK lesions on the face/scalp.
- There is no data to assess the efficacy and tolerability of MAL-PDT relative to other topical treatments used in AK.
- MAL is an alternative to 5-aminolaevulinic acid (ALA) – the unmethylated form of MAL, which although currently unlicensed in the UK is used on a named patient basis.

- "Guidelines for topical PDT" produced by the British Association of Dermatologists states that PDT may prove advantageous where size, site or number of lesions limits efficacy and/or acceptability of conventional therapies.

Basal cell carcinoma

SMC recommendation

Advice: following a resubmission.
Accepted for restricted use within NHS Scotland.
Methyl aminolevulinate cream (Metvix®) appears to be effective for the treatment of basal cell carcinoma in those patients in whom standard treatment with surgery or cryotherapy is contraindicated. Its use should be restricted to specialist dermatologists and to superficial lesions where penetration is most effective.

➢➢➢Tayside recommendation

Recommended for use within specialist treatment pathways

Points for consideration:

- Topical PDT has lower penetration in nodular BCC where lesions are of greater thickness.
- "Guidelines for the management of BCC" produced by the British Association of Dermatologists recommends excision for most lesions, except primary, superficial lesions at low-risk sites where topical PDT is considered a fair choice second-line to surgical techniques.

Failure of manufacturer to submit to SMC

The SMC process requires manufacturers to submit an application to the SMC. The following recommendation has been made in the absence of a submission.

Ketotifen eye drops (Zaditen)® - seasonal allergic conjunctivitis (SAC)

SMC recommendation

Advice: In the absence of a submission to the SMC from the licence holder.
Ketotifen hydrogen fumarate (Zaditen Eye Drops) is not recommended for use within NHS Scotland for the symptomatic treatment of seasonal allergic conjunctivitis.

➢➢➢Tayside recommendation

Not recommended

Points for consideration:

- Sodium cromoglicate 2% is an alternative eye drop included in the TAPG.
- Ketotifen eye drops are not stocked by the hospital pharmacy.

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