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SMC Advice Issued February 2004

Fluvastatin XL (Lescol XL[®]) – secondary prevention after PCI

SMC recommendation

Advice: following a full submission.

Fluvastatin is accepted for restricted use within NHS Scotland for the secondary prevention of coronary events after percutaneous coronary angioplasty (PCI). Fluvastatin is best placed for the management of patients previously untreated with a statin.

In Scotland a significant number of patients being considered for coronary angioplasty are likely to have been prescribed a statin for secondary prevention indications prior to referral for PCI and in these patients there is no need to change the statin used. Fluvastatin was found to reduce the risk of a major adverse coronary event in patients post PCI. The reduction in risk was greatest in patients with diabetes mellitus and multivessel disease. The economic model, compared fluvastatin to placebo rather than active treatment, and for this comparison it was cost effective.

Tayside recommendation

Recommended within specialist treatment pathway

Points for consideration:

- Fluvastatin is also licensed for the reduction of elevated cholesterol in patients with primary hypercholesterolaemia, and to slow the progression of coronary atherosclerosis in patients with primary hypercholesterolaemia and concomitant coronary heart disease. The above SMC recommendation relates only to the XL formulation and to use post PCI.
- Fluvastatin is the only statin licensed for use post PCI irrespective of cholesterol level.
- PCI is not undertaken in Tayside, therefore fluvastatin XL should not be initiated locally but may continue to be prescribed following recommendation from a tertiary centre.
- Fluvastatin is one of the least potent statins in terms of lipid lowering reduction per mg.
- Simvastatin and pravastatin are recommended locally in the [Tayside Area Prescribing Guide](#) (TAPG) as the statins of choice for secondary prevention.

Frovatriptan (Migard[®]) – Migraine

SMC recommendation

Advice: following a resubmission.

Frovatriptan (Migard[®]) is accepted for use within NHS Scotland for treatment of the headache phase of migraine attacks with or without aura.

It is the seventh 5-HT₁ agonist to be marketed in the UK for this indication. It is less effective at rapidly relieving migraine when compared with the most commonly prescribed drug in this class, but has a similar duration of effect. It is also less expensive than other 5-HT₁ agonists.

Tayside recommendation

Not currently recommended – pending formulary decision

Points for consideration:

- Although frovatriptan has a longer elimination half-life than other 5-HT₁ agonists, 26 hours compared with 2-6 hours, significant reductions in incidence of migraine recurrence have not been demonstrated in clinical studies.
- Frovatriptan has a similar adverse-event profile to other 5-HT₁ agonists.
- Sumatriptan and zolmitriptan are currently recommended in the [TAPG](#) as the 5-HT₁ agonists of choice locally.
- The place of frovatriptan in relation to other 5-HT₁ agonists used in the treatment of migraine will be addressed by the Formulary Committee. Prescribers are advised to await the formulary decision.
- Frovatriptan is not stocked by the hospital pharmacy.

Travoprost 40mg/ml eye drops (Travatan[®]) – glaucoma

SMC recommendation

Advice: following a full submission

Travoprost (Travatan[®]) 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 travoprost, 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 betablockers 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:

- Travoprost appears to be at least as effective as timolol 0.5% twice daily in reducing IOP. It also shows similar efficacy to other topical ocular prostaglandin analogues (latanoprost, bimatoprost).
- In comparison to timolol, travoprost has, in general, worse ocular tolerability and a limited knowledge on its mechanism of action and on the long-term adverse effects. It appears to have a similar adverse-effect profile to other prostaglandin analogues, which are not associated with the potential cardiovascular and respiratory adverse effects that may follow systemic absorption of beta-blockers.
- Travoprost is priced competitively versus other prostaglandin analogues and has the advantage of not requiring refrigeration.
- A case for the cost-effectiveness of travoprost versus beta-blockers as first-line therapy in glaucoma was not addressed in the manufacturer's submission to the SMC.
- **Travoprost is currently included in the [TAPG](#) as an alternative to latanoprost for second-line treatment of glaucoma.**

Funding of High Cost Secondary Care Elderly New Medicines in TPC

LHCCs are to reserve funds for high cost secondary care elderly new medicines in 2004-05. Following receipt of NMIP documentation in relation to a new medicine, Lead Clinicians should submit funding bids to their LHCC as follows: Dundee via Mr D Lynch, General Manager; Angus via Mr D Gill, Lead Pharmacist; P&K via Dr A McCracken, Prescribing Working Group Chair.

Use of New Medicines Prior to SMC Evaluation/Outwith SMC Advice in Exceptional Cases – revised TPC process

New medicines should not normally be prescribed in NHS Tayside until they have been evaluated by the SMC and are accepted for use in NHS Scotland. If TPC clinicians wish to prescribe a new medicine that has not been evaluated by the SMC or is not recommended by the SMC, they should make a case for exceptional treatment to their Directorate Management Team (DMT) or LHCC as follows:

- Mental health cases – Mental Health DMT
- Care of the elderly secondary care cases – LHCCs (Dundee via Mr D Lynch, General Manager; Angus via Mr D Gill, Lead Pharmacist; P&K via Dr A McCracken, Prescribing Working Group Chair)
- General practice cases – LHCCs (contacts as above)

The DMT or LHCC will then consider whether there are overriding factors that make the decision not to prescribe unreasonable in the particular circumstances. A checklist and guidance notes have been produced by NMIP to facilitate this process – these have been sent to General Managers, Lead Pharmacists and TPC Lead Clinicians and will shortly be available on the DTC website under “New Medicines”, “NMIP Processes”.

Prescribing following the approval of secondary care cases should remain the responsibility of secondary care specialists ie such new medicines should be supplied from hospital.

Formulary Decisions – January 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 January 2004 meeting of the Formulary Committee are summarised below:

| Deferred Medicine | Indication | Formulary Decision |
|--|--------------------------|--------------------|
| Desogestrel (Cerazette [®]) | Contraception | Non-formulary |
| Perindopril/indapamide (Coversyl Plus [®]) | Hypertension | Non-formulary |
| Calcium/colecalciferol (Calfovit D3 [®]) | Calcium/vit D deficiency | Formulary |
| Mirtazepine (Zispin Soltab [®]) | Depression | Formulary |
| Mometasone inhaler (Asmanex [®]) | Asthma | Non-formulary |
| Olmesartan (Olmetec [®]) | Hypertension | Non-formulary |
| Salmeterol/fluticasone (Seretide Acculaer [®]) | COPD | Formulary |
| Levodopa/carbidopa/entacapone (Stalevo [®]) | Parkinson's disease | Specialist pathway |

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”.

Forthcoming SMC Advice

Products for which SMC advice is expected in the next quarter are listed below. Details of expected advice dates are available on the upgraded SMC website (www.scottishmedicines.org) under “Work Programme”.

| Cardiovascular system | Infections |
|---|---|
| Nicotinic acid modified release tablets (Niaspan [®]) | Ertapenem (Invanz [®]) |
| Valsartan/hydrochlorothiazide (Co-Diovan [®]) | Endocrine system |
| Clopidogrel (Plavix [®]) | Somatropin (Norditropin SimpleXx [®]) |
| Cilostazole (Pletal [®]) | Rosiglitazone (Avandia [®]) |
| Respiratory system | Rosiglitazone maleate/metformin (Avandamet [®]) |
| Budesonide/eformoterol (Symbicort Turbohaler [®]) | Malignant disease & immunosuppression |
| Central Nervous System | Temoporfin (Foscan [®]) |
| Quetiapine (Seroquel [®]) | Macrogol (Idrolax [®]) |
| Olanzapine (Zyprexa velotab [®]) | Darbepoetin alfa (Aranesp [®]) |
| Methylphenidate (Equasym XL [®]) | Musculoskeletal & joint diseases |
| Lamotrigine (Lamictal [®]) | Infliximab (Remicade [®]) |
| Botulinum type A neurotoxin (Botox [®]) <i>resubmission</i> | Skin |
| Buprenorphine patch (Transtec [®]) | Clindamycin/benzoyl peroxide (Duac [®]) |
| Aripiprazole (Abilify [®]) | |
| Alteplase (rt-PA) (Actilyse [®]) | |

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/thb/adtc).