

Tayside D&TC Supplement No. 42

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Produced by Tayside New Medicines Implementation Panel (NMIP)

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SMC Advice Issued in July 2004 – part II

Emtricitabine (Emtriva®) - HIV

SMC recommendation

Advice: following a full submission.

Emtricitabine (Emtriva®) is not recommended for use within NHS Scotland for the treatment of HIV-1 infected adults and children. In combination with other antiretroviral agents it produces a viral response in treatment-naïve patients and those previously stabilised on other antiretrovirals. However, an economic evaluation was not provided, thus the economic case is not demonstrated.

Tayside recommendation

Not recommended

Points for consideration:

- Emtricitabine (FTC) is a further nucleoside reverse transcriptase inhibitor (NRTI), with a resistance profile similar to lamivudine.
- There are no efficacy data to support the use of emtricitabine in patients who have failed on existing antiretroviral regimens and there is no evidence that emtricitabine is associated with advantages in terms of efficacy or safety compared with the majority of NRTIs, including lamivudine.
- The cost of emtricitabine is comparable to other NRTIs.
- Emtricitabine is not stocked by the hospital pharmacy.

Etanercept (Enbrel®) - psoriatic arthritis (PsA)

SMC recommendation

Advice: following a full submission.

Etanercept (Enbrel®) is accepted for use within NHS Scotland for the treatment of active and progressive psoriatic arthritis in adults. It is the first drug to be licensed for this indication and not only improves symptoms of arthritis and psoriasis, but may slow the progression of joint damage (at least over a period of one year).

Tayside recommendation

Recommended within specialist treatment pathway – HOSPITAL ONLY

Points for consideration:

- Etanercept is the first TNF-antagonist licensed in the UK for the treatment of PsA and is indicated for patients who have failed to adequately respond to disease-modifying anti-rheumatic drugs (DMARDs).
- Etanercept is also licensed for the treatment of rheumatoid arthritis and severe ankylosing spondylitis. The above SMC advice relates only to the PsA indication.
- A phase III clinical study in PsA shows significantly more patients achieving 20% improvements in American College of Rheumatology score (ACR₂₀) with etanercept versus placebo (59% vs 15% at three months).
- Use of etanercept is associated with injection-site reactions and increased incidence of infection. TNF-antagonists may initiate autoimmune processes and they have been associated with rare reports of demyelinating disease including multiple sclerosis. There are also concerns that continual inhibition of TNF may increase the risk of cancer, particularly lymphoproliferative malignancies.
- The British Society for Rheumatology is currently developing guidelines on the use of TNF-antagonists in PsA and NICE plans to introduce guidance on the use of etanercept for PsA in October 2005.
- A local protocol for the use of etanercept in PsA has been developed by the Rheumatology Clinic. This recommends that **etanercept is restricted to the Rheumatology Clinic for the treatment of patients with active PsA (excluding pure axial involvement) with ≥3 swollen and ≥3 tender joints on 2 separate occasions at least 1 month apart despite an adequate trial of at least 2 DMARDs.**
- The Medicine & Cardiovascular Clinical Group is currently addressing the funding of etanercept for this indication. Prescribing should not take place until funding is approved.

Olanzapine IM injection (Zyprexa®) – control of agitation and disturbed behaviours

SMC recommendation

Advice: following a full submission.

Olanzapine for intramuscular use is accepted for use within NHS Scotland for the control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. Intramuscular olanzapine has been shown to be at least as clinically and cost-effective as haloperidol or lorazepam in treating agitation and other symptoms associated with acute schizophrenia and bipolar disorder. Both the clinical and the economic case are limited by the entry criteria for trials, which effectively restricted entry to moderately agitated patients and excluded those who were severely agitated. However, the difficulties in conducting research in this clinical situation are recognised.

Tayside recommendation

Not currently recommended – pending specialist treatment pathway

Points for consideration:

- Olanzapine is the first atypical antipsychotic available as a parenteral formulation for acute use.
- Olanzapine IM shows a faster onset of action than haloperidol or lorazepam and is associated with less acute dystonia, extrapyramidal effects and Parkinsonism than haloperidol.
- Although olanzapine IM is more expensive, the increased cost of using olanzapine instead of haloperidol or lorazepam is small.
- Local advice on rapid tranquillisation in the management of acutely disturbed patients is included in the [Psychiatric Guidance Notes](#) within the Tayside Area Prescribing Guide (TAPG).
- A local protocol defining the criteria for use of olanzapine IM is currently under development.

Seretide 50 Evohaler (salmeterol 25mcg/fluticasone 50mcg inhaler) - asthma

SMC recommendation

Advice: following an abbreviated submission.

Seretide 50 Evohaler[®] is accepted for use within NHS Scotland for the regular treatment of asthma where use of a combination of the long-acting beta agonist salmeterol and the inhaled corticosteroid fluticasone is appropriate for a child aged 4-12 years.

The acquisition cost of the combination product is less than for the individual components given by aerosol inhalation and for the combination given by Accuhaler[®].

Tayside recommendation

Non-formulary

Points for consideration:

- Seretide 50 Evohaler[®] and 100 Accuhaler[®] are the only Seretide[®] preparations licensed for use in children aged over 4 years.
- The Tayside Area Drug Formulary does not currently include paediatric treatments.
- **Seretide[®] is recommended locally for consideration in children who require a long-acting beta₂ agonist (ie at step 3 of the [SIGN/BTS asthma guidelines](#)) following evaluation by a paediatrician. The Evohaler[®] preparation through a volumatic is preferred to the Accuhaler[®] device.**
- Guidance on managing chronic asthma in children is available in the updated [Respiratory Guidance Notes](#) within the 2nd Edition of the TAPG.

Triptorelin 11.25mg (Decapeptyl[®] SR) – advanced prostate cancer

SMC recommendation

Advice: following an abbreviated submission.

Decapeptyl[®] SR 11.25mg is accepted for use within NHS Scotland for the treatment of advanced prostate cancer in patients for whom the use of triptorelin is appropriate and who would benefit from reduced frequency of administration compared with Decapeptyl[®] SR 3mg (every 3 months vs every 28 days)

Tayside recommendation

Not recommended

Points for consideration:

- Gonapeptyl[®] is a further monthly triptorelin preparation not yet evaluated by the SMC. The above SMC advice relates only to the 3 monthly Decapeptyl[®] SR injection.
- The cost of triptorelin is comparable to other gonadorelin analogues (goserelin, leuprorelin)
- **Goserelin and leuprorelin are the gonadorelin analogues recommended locally for the treatment of advanced prostate cancer.**
- Triptorelin is not stocked by the hospital pharmacy.

Valdecoxib (Bextra[®]) – dysmenorrhoea

SMC recommendation

Advice: following a full submission.

Valdecoxib is not recommended for use within NHS Scotland for the treatment of primary dysmenorrhoea. In this indication, it has shown similar efficacy and tolerability to naproxen at a higher daily cost. In general, selectivity for cyclo-oxygenase 2 may confer advantages in the treatment of patients at high risk from the gastro-intestinal adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs). However, the absolute risk is likely to be very small in this target population given their age and the intermittent nature of the treatment. In addition, trials for this indication showed no apparent difference in gastro-intestinal events between valdecoxib and naproxen.

Tayside recommendation

Not recommended

Continued over

Valdecoxib continued

Points for consideration:

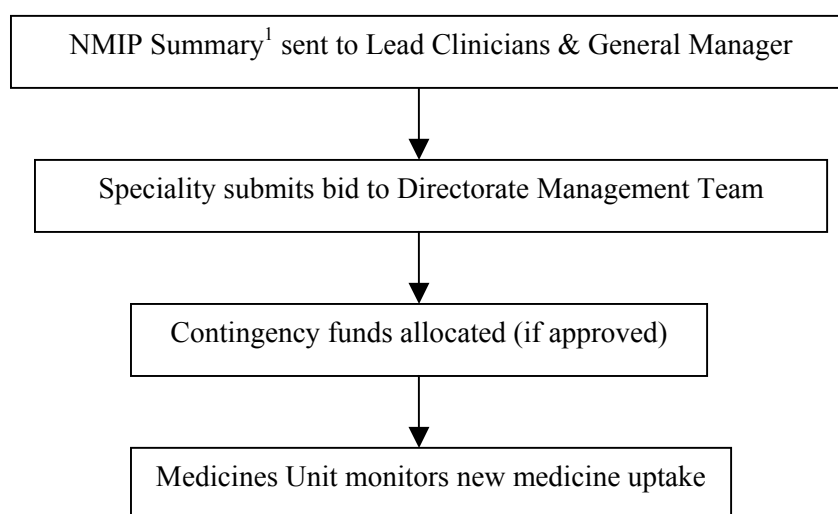
- Valdecoxib is also licensed for symptomatic relief in the treatment of osteoarthritis or rheumatoid arthritis. The above SMC advice relates only to the dysmenorrhoea indication.
- **Mefenamic acid is recommended locally for the treatment of primary dysmenorrhoea.**

Funding of High Cost Secondary Care Mental Health New Medicines

The Mental Health Directorate has reserved funds for high cost secondary care new medicines in 2004-05.

Accessing Mental Health Contingency Funds

The following process has been agreed when a mental health speciality indicates that it is unable to absorb additional costs associated with the introduction of a new medicine.



¹ NMIP Summary includes SMC recommendation, local advice, resource implications, additional NMIP comments and protocol developed by local specialists.

Formulary Update

The 2nd Edition of the **Tayside Area Prescribing Guide (TAPG)** is currently being distributed to all general practitioners, nurse prescribers, community pharmacists, dental practitioners, medical students, hospital doctors, pharmacists and wards within NHS Tayside. It is also available from the DTC website (www.show.scot.nhs.uk/nhstaysideadc), the Central Vision website and the E-health website.

There have been several changes from the previous edition including the combining of the hospital and primary care versions so there is now just one document. The sections are similar to the previous edition with a slight change in format to improve access to information and help in the editing and updating process. Each section has its core formulary drug selection. Drugs are included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness. Formulary drug choice is revised by specialist sub-groups. Outwith these groups, expert advice is sought wherever possible.

Several drugs have been added to the new formulary and there are substantial changes to some of the prescribing guidance notes. Important changes include incorporation of the notes on cardiopulmonary resuscitation at the end of the **cardiovascular guidance notes**, changes in the **respiratory guidance notes** for the management of acute and chronic asthma addressing adults and children under 12 separately, and **pain guidance notes** have been inserted at the end of section 4 – Central Nervous System. There are two new **dermatology guidance notes** on the management of scabies and warts. Changes to the **Adult Antibiotic Policy** include new sections on MRSA and antibiotic prophylaxis in gastrointestinal endoscopy. Newly incorporated also is guidance on early management of suspected bacterial meningitis and meningococcal septicaemia in adults, and the Tayside Critical Care Pathway for the Management of

Community-acquired Pneumonia. Note 4, **Drug Therapy in Relation to Anaesthesia** has been substantially revised.

The formulary/TAPG is intended to guide choice and is designed for the non-specialist user. It contains a rational selection of drugs which provide first and second-line treatment options for the majority of conditions seen in both primary and secondary care, and will thus promote continuity of care.

The TAPG is intended to serve as a foundation for prescribing in Tayside. It is hoped that it will continue to be adopted by practices and hospitals throughout the region and that clinicians will find it a useful document.

Any comments or suggestions for future editions will be welcomed. Please send them to Richard Glet, Chair Formulary Committee, Pharmacy Department, Ninewells Hospital, Dundee. Richard.j.glet@tuht.scot.nhs.uk.

Forthcoming SMC Advice

Gastro-intestinal system
Rabeprazole (Pariet [®])
Esomeprazole IV (Nexium [®])
Cardiovascular system
Losartan (Cozaar [®])
Valsartan/hydrochlorothiazide (Co-Diovan [®])
Candesartan (Amias [®])
Respiratory system
Montelukast (Singulair [®])
Central nervous system
Sumatriptan (Imigran Radis [®])
Risperidone (Risperdal [®])
Methylphenidate (Equasym XL [®])
Buprenorphine patch (Transtec [®])
Atomoxetine (Strattera [®])
Aripiprazole (Abilify [®])
Aprepitant (Emend [®])
Oxycodone (OxyNorm [®])
Paracetamol infusion (Perfalgan [®])
Infections
Mycophenolate (Myfortic [®])
Ertapenem (Invanz [®])
Atazanavir (Reyataz [®])

Endocrine system
Strontium ranelate (Protelos [®])
Testosterone buccal SR (Striant SR [®])
Somatropin (Norditropin SimpleXx [®])
Rosiglitazone (Avandia [®])
Insulin Detemir (Levemir [®])
Ibandronic acid (Bondronat [®])
Pioglitazone (Actos [®])
Premique [®] low dose
Estradot [®] transdermal patch
Obstetrics, gynaecology & urinary tract disorders
Solifenacin (Vesicare [®])
Duloxetine (Yentreve [®])
Malignant disease & immunosuppression
Letrozole (Femara [®])
Rituximab (MabThera [®])
Giladel wafer
Fulvestrant (Faslodex [®])
Docetaxel (Taxotere [®])
Cetuximab (Erbitux [®])
Bortezomib (Velcade [®])
Darbepoetin alfa (Aranesp [®])
Nutrition & Blood
Miglustat (Zavesca [®])
Musculoskeletal & joint diseases
Lumiracoxib (Prexige [®])

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/nhstaysideadtc).