TAYSIDE PRESCRIBER

Tayside D&TC Supplement No. 26

May 2003

Produced by Tayside New Medicines Implementation Panel (NMIP) and Tayside Medicines Unit

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Calcitriol 3mcg/g ointment (Silkis®) – mild-moderate plaque psoriasis

➢ **Recommended for use**

- Calcitriol ointment is a topical vitamin D analogue similar to calcipotriol (Dovonex®), it is licensed for mild to moderate plaque psoriasis in adults with ≤35% body surface area involvement.

Points for local consideration:

- Limited data indicates comparable efficacy and similar or better tolerability of calcitriol compared to existing topical vitamin D analogues.
- Calcitriol ointment is a substitute for existing medicines that have similar or increased cost (calcipotriol ointment, tacalcitol ointment).
- Not more than 30g of calcitriol ointment should be used per day.
- Further advice on the management of psoriasis is available in the Dermatology Guidance Notes within the Tayside Area Prescribing Guide (TAPG).

Desogestrel (Cerazette®) – progesterone-only contraceptive (POP)

➢ **Not recommended for use**

- Desogestrel is a progestogen which has been used with oestrogen in combined oral contraceptives for several years. Cerazette® is the first formulation of this drug as a POP.

Points for local consideration:

- Desogesterol could have greater efficacy than other POP's due to increased inhibition of ovulation, however there is currently no evidence that it is more effective in practice.

- Currently, there is no difference in the administration schedule for desogestrol compared with other POP's i.e. extra contraceptive precautions should be taken if administration is delayed by >3 hours.
- Desogestrol is considerably more expensive than other POP's.
- Desogestrel is not stocked by the hospital pharmacy.

Dutasteride (Avodart®) – benign prostatic hyperplasia (BPH)

➢ **Recommended for use**

- Dutasteride is a further 5á-reductase inhibitor licensed for the treatment of moderate to severe symptoms of BPH, and reduction of the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH.

Points for local consideration:

- Dutasteride demonstrates similar efficacy and safety to alternative 5á-reductase inhibitors in reducing prostate volume in patients with BPH.
- Dutasteride is likely to be cost neutral in the treatment of BPH.
- Dutasteride, but not finasteride, can interact with concomitant medications that are metabolised through the hepatic cytochrome P450 isoenzyme CYP3A4 e.g. diltiazem and verapamil.

Irbesartan (Aprovel®) – diabetic renal disease

➢ **Restricted use**

- Irbesartan is an angiotensin II antagonist; its licence has now been extended to allow the treatment of renal disease in patients with hypertension and type 2 diabetes as part of an antihypertensive drug regimen.

Points for local consideration:

- Irbesartan is effective, but has not been shown to be more effective than ACE inhibitors in the treatment of renal disease in patients with hypertension and type 2 diabetes.
- ACE inhibitors are associated with a strong evidence base in diabetic renal disease and other forms of cardiovascular disease and are generally less expensive than irbesartan, particularly if available in a generic form e.g. enalapril, lisinopril.
- Irbesartan should be considered, along with other angiotensin II antagonists licensed for diabetic renal disease, as an alternative in patients unable to tolerate ACE inhibitors.
- Refer to SIGN guideline No. 55 for further information on the treatment of diabetic renal disease.

MicardisPlus® (telmisartan/hydrochlorthiazide) – hypertension

➢ **Recommended for use**

- MicardisPlus® is an angiotensin II antagonist/thiazide combination product licensed for the treatment of essential hypertension.

Points for local consideration:

- MicardisPlus shows similar efficacy, in the treatment of essential hypertension, to the individual constituents (telmisartan and hydrochlorthiazide) added together.
- MicardisPlus and telmisartan are the same cost.
- Combination products may theoretically improve patient compliance, however they may limit the flexibility of patients' medication regimes with respect to dose and drug adjustments.
- Angiotensin II antagonists should be considered as an alternative in patients unable to tolerate ACE inhibitors.
- Losartan and valsartan are recommended within the TAPG as the angiotensin II antagonists of choice locally.

- Further advice on the treatment of hypertension is available in the Cardiovascular Guidance Notes within the TAPG.

Pimecrolimus 1% cream (Elidel®) – atopic dermatitis

➢ **Not recommended**

- Pimecrolimus is a further topical immunomodulator agent, it is licensed for the treatment of mild to moderate atopic dermatitis.

Points for local consideration:

- There is insufficient comparative data to demonstrate that topical pimecrolimus offers clinical advantages over alternative less expensive products currently used to treat mild to moderate atopic dermatitis e.g. hydrocortisone 1%.
- Safety risks associated with the long-term application of topical immunomodulators are unclear.
- No comparative data with tacrolimus ointment exists, however tacrolimus has been shown to be as effective as potent corticosteroids in adults and more effective than weak corticosteroids in children (refer to ADTC Supplement Issue No.21).
- Pimecrolimus cream is not stocked by the hospital pharmacy.

Risedronate sodium (Actonel® once a week)– osteoporosis in postmenopausal women

➢ **Recommended for use**

- Risedronate is a bisphosphonate licensed for the prophylaxis and treatment of osteoporosis in postmenopausal women. It is now available in a once weekly 35mg formulation (previously available as a 5mg daily tablet).

Points for local consideration:

- Risedronate once a week offers a convenient, cost neutral alternative to once daily medication.
- Bisphosphonates have been associated with oesophagitis and oesophageal ulcerations, patients should pay attention to dosing instructions (swallow whole while in the upright position with a glass of water (≥120ml), remain upright for at least 30 minutes after taking the tablet).
- Supplementary calcium and vitamin D should be considered in patients receiving bisphosphonates.
- SIGN guidance on the prophylaxis and treatment of osteoporosis is expected shortly.

Rosuvastatin (Crestor®) – hypercholesterolaemia

➢ **Recommended for use**

- Rosuvastatin is a further HMG CoA reductase inhibitor "statin"; it is licensed for the management of patients with hypercholesterolaemia or mixed dyslipidaemia.

Points for local consideration:

- Reductions in cardiovascular events and mortality have been demonstrated by simvastatin and pravastatin in the primary and secondary prevention of coronary heart disease. These agents are therefore licensed for the prevention of coronary events, whereas the licensed indication for rosuvastatin is limited to hypercholesterolaemia.
- Established statins, such as simvastatin and pravastatin, have a proven safety record and are recommended in the TAPG as the statins of choice locally.
- There is no compelling clinical evidence to support the use of rosuvastatin in place of the above established statins.
- Rosuvastatin is at least as effective as other statins in reducing cholesterol and is currently of comparable cost. However, the patent for simvastatin has recently expired and a price reduction is anticipated.

- Further advice on the use of statins in secondary prevention is available in the Cardiovascular Guidance Notes within the TAPG.

Tadalafil (Cialis®) – erectile dysfunction

➢ **Recommended for use**

- Tadalafil is a further phosphodiesterase type 5 inhibitor licensed for the treatment of erectile dysfunction.

Points for local consideration:

- Tadalafil is an alternative to sildenafil. It has a longer duration of action and may be taken between 30 minutes and 12 hours before anticipated sexual activity, duration of action may exceed 24 hours. This may represent an advantage for tadalfil.
- Side-effect profiles of tadalafil and sildenafil are similar with the exception of the absence of visual disturbances and the presence of myalgia with tadalafil.
- Daily use of medication is strongly discouraged because long-term safety after prolonged daily dosing has not been established.
- Tadalafil and sildenafil are priced similarly.
- Tadalafil may be prescribed under the conditions of Schedule 11 and is subject to the same NHS prescribing restrictions as other treatments for erectile dysfunction in terms of the National Health Service (General Medical Services) (Scotland) Regulations 1995.
- Patients who do not fall under the categories of Schedule 11 may receive a private prescription from their general practitioner.

The following recommendations relate to HOSPITAL ONLY medicines

Docetaxel (Taxotere®) – non-small-cell lung cancer (NSCLC)

➢ **Restricted use**

- Docetaxel is a taxane antineoplastic drug, its licence in patients with unresectable, locally advanced or metastatic (stage III/IV) NSCLC has been extended to allow first-line treatment in combination with cisplatin.

Points for local consideration:

- Docetaxel, in combination with cisplatin, is an effective treatment option for the first-line treatment of unresectable, locally advanced or metastatic (stage III/IV) NSCLC.
- In common with the other drugs recommended for this condition by Quality Improvement Scotland (QIS) benefit has only been proven in patients with good performance status (a Karnofsky Performance Status ≥70%).
- The estimated cost per quality adjusted life year (QALY) gained is relatively high.
- **Docetaxel is restricted to secondary care** and should be initiated by respiratory physicians/oncologists experienced in the treatment of NSCLC.
- The local first-line treatment of NSCLC is under review further to the QIS/HTBS comment on the NICE guidance on the use of docetaxel, paclitaxel, gemcitabine and vinorelbine for the treatment of NSCLC.

Risperidone orodispersable tablet (Risperdal Quicklet®) - schizophrenia

➢ **Restricted use**

- Risperdal Quicklet is a new formulation of the atypical antipsychotic risperidone, designed to disintegrate quickly in the mouth without the need for water. It is licensed for the treatment of acute and chronic schizophrenia and similar psychotic conditions.

Points for local consideration:

- Risperdal Quicklet is a treatment option for patients who are uncooperative or wary of taking medication.
- Risperdal Quicklet is priced slightly below Zyprexa Velotab (orodispersible olanzapine).
- Patients should be transferred onto dosing with the whole tablet formulation, or long acting injectable form of risperidone once the acute episode has come under control.
- **Risperdal Quicklet is restricted to secondary care** for patients in whom rapid absorption is indicated.

Zoledronic acid (Zometa®) - bone metastases

➢ **Restricted use**

- Further to a resubmission by the manufacturer, the SMC has revised their original zoledronic acid advice issued in January 2003 (refer to Tayside D&TC Supplement Issue No. 24)

Points for local consideration:

- Zoledronic acid may offer some minor advantages, in terms of administration, to pamidronate in the prevention of skeletal related events associated with breast cancer and multiple myeloma.
- Although zoledronic acid has shown some efficacy in patients with prostate cancer, NSCLC and other solid tumours, cost-effectiveness in these indications is uncertain.
- **Zoledronic acid is restricted to secondary care** on the recommendation of an oncologist **for patients with breast cancer and multiple myeloma**.

Named Patient Use of New Medicines Prior to SMC Advice

The NMIP fully supports the SMC who have requested that new medicines are not prescribed in NHS Scotland until they have been evaluated by the SMC and a recommendation for use has been made. However, there will be situations when clinicians believe that their patients could benefit from a new medicine that has been licensed in the UK but has yet to be reviewed by the SMC. The Tayside Drug & Therapeutics Committee has agreed that new medicines should only be prescribed ahead of a SMC recommendation in exceptional cases under the following circumstances:

a) in patients who have failed to respond to current treatments and where evidence of benefit, from clinical studies, exists in this refractory patient group, or
b) in patients who experience severe adverse reactions to existing treatment options

and

c) it is unreasonable to expect the prescriber to wait for the issue of SMC advice

Individual cases should be approved by the relevant Clinical Director/LHCC Officer and the Chair of the Tayside New Medicines Implementation Panel, Professor Peter Davey (please send to Dr Jan Jones in the first instance, see contact details below). Prescribing initiated by secondary care specialists should remain within secondary care.

Details of local recommendations for new medicines are available on the Tayside D&TC web-site (www.show.scot.nhs.uk/thb/adtc). Information on which new medicines will be considered by the SMC over the next two to three months is available on the SMC web-site (www.scottishmedicines.org.uk) under "Work Programme".

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