Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)

SHARED CARE

Drug: CICLOSPORIN Protocol number: CV 26

Indication: SEVERE PSORIASIS

General Guidance

This protocol sets out details for the shared care of patients taking **ciclosporin** and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Ciclosporin is a potent immunosuppressive agent that has been shown to have marked beneficial effects in patients with severe psoriasis. Oral ciclosporin is indicated for patients with severe psoriais in whom conventional therapy is ineffective or inappropriate.

Responsibilities

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP
2. Baseline and continued monitoring of biochemical, haematological and clinical parameters (see page 2)
3. Initiate therapy following full discussion with the patient of benefits and risks
4. Titrate ciclosporin dose adjusting dose as appropriate and undertake monitoring of clinical response and side effects.
5. When a GP positive response to SC has been received and patient has been stabilised send a letter to GP "handing over" the Shared Care of the patient to the GP.
6. Respond to any request from GP to review the patient due to adverse effects of therapy.
7. Advise the GP on continuing or stopping ciclosporin therapy following medical review of the patient and associated drug therapy

8. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe ciclosporin as part of the shared care agreement.
3. Monitor the general health of the patient.
4. Seek advice from the consultant on any aspect of patient care which is of concern.
5. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
6. Recommend that patient receives pneumococcal vaccination and annual influenza vaccination.
7. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with ciclosporin.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst taking ciclosporin.

Dosage Regimen

The initial dose to induce remission (which would be started in hospital) is 2.5mg/kg/day orally in 2 divided doses. If there is no improvement after one month the dose may be gradually increased to a maximum of 5mg/kg/day. Treatment should be discontinued if sufficient response is not achieved within six weeks at the maximum dose. For maintenance treatment the dosage is titrated to the lowest effective level.

Monitoring

<u>Before treatment</u>

BP & Creatinine (2 separate readings), electrolytes, FBC, Fasting lipids, LFTs, Urate, Creatinine Clearance

<u>During treatment</u>

BP, Creatinine and electrolytes, LFTs ,Urate & urinalysis every 2 weeks for 3 months, then every 3 months.

Lipids every 3 months

If creatinine increases by 30% above baseline on 2 consecutive occasions reduce dose by 25 – 50% for 1 month then if creatinine falls to below 30% of baseline continue ciclosporin then if creatinine remains above 30% of baseline STOP ciclosporin

A persistent diastolic BP between 90 and 99 mm Hg is an indication for a 25-50% dose reduction of ciclosporin. If hypertension persists then treat with anti-hypertensives.

Adverse effects

The principal adverse effects are **impaired renal function** and **hypertension** and these are potentially serious complications. They may necessitate the discontinuation of treatment. Other side effects include: -

- Hypertrichosis
- Tremor
- Fatigue
- Gastrointestinal disturbances

Interactions

NSAIDs increase the risk of nephrotoxicity.

ACE inhibitors and **diuretics** increase the risk of hyperkalaemia.

Diltiazem, verapamil and lercanidipine (calcium channel blockers) and **ulcer healing drugs** including omeprazole increase plasma ciclosporin concentrations.

Care should be taken when prescribing ciclosporin in combination with systemic antibiotics or other compounds known to have nephrotoxic effects e.g. ciprofloxacin, trimethoprim. Drugs inhibiting or inducing hepatic enzymes, in particular cytochrome P450 increase (e.g. erythromycin, doxycycline) or decrease (e.g. phenytoin, carbamazepine) the plasma or whole blood concentration of ciclosporin.

Vaccination may be less effective during ciclosporin treatment and the use of live attenuated vaccines should be avoided.

Special recommendations

The oral solution should be diluted in a **glass** container with cold milk, fruit juice or cola immediately before administration.

Date of review May 2017