HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Ciclosporin Post Solid Organ Transplant

Patient's Name:…….. NHS Number: ……

Patient's Address:.....(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:…….

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……... ……. Date:…….

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

1. BACKGROUND

Transplantation is an important option in the treatment of chronic renal failure. The introduction of ciclosporin was an important step in the management of such patients.

Standard therapy post renal transplant is tacrolimus (brand to be specified by specialist Renal team) and mycophenolate. However on occasions some patients may be maintained on ciclosporin (Neoral®) and azathioprine.

These guidelines aim to provide a model framework for the prescribing of ciclosporin by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into shared care arrangements for patients who are treated with ciclosporin.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. INDICATION:

Immunosuppressant for the prevention of rejection episodes in patients with renal transplants.

3. DOSE:

The recommended maintenance oral dose is dependent upon body weight initially, and ranges from 2.5-5mg/kg/day, administered in two divided doses. The hospital consultant will advise on the appropriate dose, and dose adjustments for your patient.
Ciclosporin should be prescribed by brand.
Patients' whole blood trough concentrations are used as a guide and the majority of patients are successfully managed if blood levels are maintained between 100 and 200nanograms/ml.

If allograft rejection or adverse events occur then alteration in dose should be considered.

Patients may also be receiving Azathioprine and Prednisolone in varying doses.

4. DURATION OF TREATMENT:

Long term

5. CONTRAINDICATIONS AND CAUTIONS

Contraindicated in breast feeding.
The use of ciclosporin during pregnancy needs to be supervised in specialist units.

6. INTERACTIONS:

Patients receiving ciclosporin should be advised against immunization with live vaccines. (Influenza vaccines may be given in this group of patients).

Ciclosporin is metabolised by Cytochrome P450A, and interacts with other drugs which inhibit or induce this enzyme. e.g. macrolides, antifungals, some calcium channel blockers.

Therefore the following drugs which induce liver enzymes, lead to reduced efficacy: rifampicin, phenytoin, phenobarbitone and carbamazepine.

The following drugs inhibit liver enzymes, and lead to increased toxicity: diltiazem, clarithromycin, erythromycin, ketoconazole and also grapefruit juice.

Care should be taken with other drugs that can be nephrotoxic e.g. NSAIDs Care

should be taken with other drugs that can be neurotoxic e.g. Aciclovir.

Hyperkalaemia is well recognised and the use of potassium affecting agents should be avoided e.g. potassium sparing diuretics.

Ciclosporin also enhances the myopathic side-effects of statins and fibrates

A large number of other drug interactions have been described. Care should be taken with any co-prescribing.

Renal function should be taken into consideration when co-prescribing for renal transplant patients.

Please consult your pharmacist if unsure of the potential interaction between any prescribed medication and ciclosporin.

7. ADVERSE EFFECTS:

Principal adverse effects are: nephrotoxicity, hepatotoxicity and neurotoxicity. Other side-effects are hypertrichosis, gingival hyperplasia and tremor.

8. MONITORING:

Patients should have, at baseline full blood count, differential white cell count, platelets, LFTs, U&Es and blood pressure checked.
Blood pressure biochemical profile (U&Es) should be checked every 2 weeks until the dose has been stable for 3 months and thereafter monthly. FBC and LFTs should be checked monthly until dose and trend stable for 3 months then 3 monthly. Serum lipids should be checked every 6 months.

If clinically relevant changes are detected the patient should be referred to the specialist team.

9. INFORMATION TO PATIENT

Patients should be informed about benefits and risks of treatment and need for monitoring.

Patients should be told to go to their GP immediately if they experience any fever, rash, bruising, bleeding, sore throat, oral ulceration, jaundice or infection.

Patients should be warned to avoid grapefruit juice and to check with pharmacist or doctor before using any “over the counter” medicines.

Patients should remain on the same brand of capsules.

If there are any supply issues in primary care, please contact the renal pharmacist at HRI.

10. RESPONSIBILITIES OF CLINICIANS INVOLVED

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation of Treatment	Prescribe drug and monitor Prescribe by BRAND	Provide information on current medication.
Monitoring of Treatment and maintenance	Once stablised at each clinic visit and in between times depending on clinical need Inform GP when patient is on a stable dose and request that prescribing is transferred. Inform GP of significant findings and necessary changes to therapy. Available for advice.	Take on shared care when patient is stable and requested by the specialist team. Prescribe by BRAND Identify to specialist problems with concordance to therapy. Identify adverse reactions and treat or refer where appropriate. (U&E and FBC will be monitored by the specialist and relevant findings communicated to the GP)

Contact details:
During office hours: Please contact the relevant renal consultant's secretary via Hull Royal Infirmary switchboard. (01482)328541
Out of hours: Contact the on call renal consultant via switchboard
Specialist Transplant Nurses: (01482) 674110
Renal Pharmacist: (01482) 674043, or ask for bleep 140 when you contact the switchboard on 01482-875875.

APPROVAL PROCESS

Written by:	**Marie Miller. Reviewed by Aaron Acquaye, Renal Pharmacist**
Consultation process:	**Specialists teams in Renal Medicine**
Approved by:	**MMIG**
Ratified by:	**HERPC Nov 2010 Updated Mar 2019**
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