SHARED CARE PROTOCOL AND INFORMATION FOR GPs	NHS Lothian
Ciclosporin (Neoral®)	
Clinical indication: For use in the treatment of rheumatological inflammatory diseases	
Version 4.0 : September 2009	Due for review: **September 2011**

Introduction
With the exception of sulfasalazine, DMARDs are usually started after assessment by a rheumatologist.
'Rheumatological Management and Shared Care Guidelines' available on website: *www.refhelp.scot.nhs.uk*

Shared Care
A shared care protocol is used to **facilitate the sharing of care and transfer of prescribing.** This would usually take place once the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects. GPs should only take on the prescribing when they are confident in the use of the drug, in the context of the protocol. Contingency plans must be in place to enable the patient to receive the recommended treatment, should the GP decline to prescribe.

Indication for Therapy
Indications – active joint inflammation usually supported by indices of inflammation.
Duration – most drugs require up to 3 to 4 months trial to assess efficacy. Therapy is continued providing the drug is working and there are no side effects.
Relapse is common after withdrawal of therapy.

Preparations available
Neoral® capsules 10mg, 25mg, 50mg, 100mg; Neoral® oral solution 100mg/ml.

Recommended Dosage and Administration
Neoral® should be prescribed by brand name, to avoid confusion with the older ciclosporin preparation Sandimmun®.

First 6 weeks: 2.5mg/kg/day, orally in 2 divided doses, then may be increased by 25mg per day at intervals of 2-4 weeks until clinically effective or maximum dose (4mg/kg/day) reached

Maintenance treatment: dose must be titrated to tolerability. If, after 3 months at maximum permitted or tolerable dose, the response is inadequate, discontinue treatment.

Cost
2.5-4mg/kg/day: £3-£10 per day

Adverse effects and Drug Interactions
Very common: hypertension, hyperlipidaemia, headache, tremor and renal impairment.
Liver function may also be affected.

Refer to the current BNF or SPC for up to date interactions before prescribing new medication.
Drugs which may affect renal function may increase the likelihood of ciclosporin nephrotoxicity. Drugs which alter the function of the liver enzymes which metabolise ciclosporin, CYP3A4 in particular, may increase or decrease ciclosporin levels significantly e.g macrolide antibiotics, azole antifungals; drugs which are metabolised by CYP3A4 may be increased by ciclosporin e.g statins, digoxin, colchicine. Diclofenac should be avoided if possible else its dose halved (see monitoring). Co-administration of potassium-sparing drugs may lead to hyperkalaemia. Live vaccines should be avoided.

Grapefruit juice may increase ciclosporin levels.

Precautions and Contra-indications
Hypersensitivity to ciclosporin; uncontrolled hypertension, renal and liver failure, severe electrolyte imbalance, suspected systemic infection, malignancy. Avoid excess exposure to UV light. Avoid co-prescription with rosuvastatin and tacrolimus.

Pregnancy and lactation
Ciclosporin should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus (data from transplant patients).
Breast feeding should be avoided.

Contact Points
Rheumatology Clinical Nurse Specialists:
0131 537 1405
Rheumatology SpR (via switchboard):
0131 537 1000
Rheumatology Clinical Pharmacist:
0131 537 1000 (bleep 8461)
Rheumatic Diseases Unit (WGH):
0131 537 1798
Rheumatology Secretary (St John's Hospital):
01506 52 3824

Approved for use by the General Practice Prescribing Committee, LPCD and the Drug & Therapeutics Committee, LUHD.

Shared Care Responsibilities

Aspects of Care for which the Consultant is responsible

- Assessing the need for DMARD.
- Arranging for the patient to receive counselling in verbal and written form.
- Providing relevant baseline investigations.
- Following the patient's response to treatment at the out- patient clinic.
- Communicating advice to the patient's GP re monitoring requirements.
- At any stage of treatment, advising GP of concerns re monitoring or potential adverse effects of treatment.

Aspects of Care for which the General Practitioner is responsible

- Prescribing DMARD under the guidance of the consultant.
- Reporting any suspected adverse reactions to the patient's consultant and complete a yellow card if appropriate. Discuss any significant abnormalities with consultant.
- Liaising with the consultant regarding any complications of treatment.
- Monitoring the general health of the patient.
- Monitoring for specific side effects as detailed in "Monitoring" section.
- Provision of pneumococcal and annual influenza vaccination.

Monitoring

Test	Frequency	Abnormal result	Action if abnormal result
FBC	Monthly until dose and trend has been stable for 3 months then three monthly.	platelets <150 x 10^9/l.	Withhold ciclosporin and discuss with specialist team.
LFTs		AST, ALT or alkaline phosphatase > twice upper limit of normal reference range.	Withhold ciclosporin and discuss with specialist team.
U&Es including creatinine	Every 2 weeks until dose and trend stable for 3 months then three monthly. **Return to 2 weekly testing if ciclosporin dose increased or NSAID co-prescribed.**	K+ above upper limit of normal.	Withhold ciclosporin and discuss with specialist team.
		Creatinine >30% rise from baseline.	Repeat in 1week and if still >30% above baseline withhold and discuss with specialist team.
BP	At each visit; maintain at ≤140/90mmHg.	≥140/90mmHg on two consecutive readings two weeks apart.	Treat BP; if BP cannot be controlled, stop ciclosporin and discuss with specialist team.
Fasting lipids	Every six months.	Significant rise.	Withhold ciclosporin and discuss with specialist team.

- Abnormal trends should prompt extra vigilance.
- Temporarily withdraw if the patient reports sore throat unexplained bleeding or bruising, mouth ulcers or other signs of blood dyscrasia or evidence of infection. Perform repeat blood monitoring.
- Plasma ciclosporin levels are not required.
- Trends in ESR are useful in decision-making.

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This information was prepared by the Rheumatic Diseases Unit and Pharmacy Department, Western General Hospital, NHS Lothian through liaison with the General practice Prescribing Committee and LUHD Drug and Therapeutics Committee