

Prescribing Framework for Ciclosporin (Neoral) for Immunosuppression in ADULTS

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:..... |
| <i>Where prescriber is <u>not</u> a consultant:</i> | |
| 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 **unwilling** 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.

Full copy of framework can also be found at : <http://www.hey.nhs.uk/amber.htm>

1. Background

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

For use in Transplant patients please see specific Shared Care Framework

<http://www.hey.nhs.uk/herpc/ciclosporinRenal.pdf>

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

Immune mediated disorders including rheumatoid arthritis, psoriasis, atopic dermatitis and nephrotic syndrome. Immune mediated neurological disorders including myasthenia gravis, neuromyelitis optica, cranial vasculitis and immune mediated neuropathies.

Specific information will be provided by the specialist on the indication for immunosuppression with ciclosporin.

3. Dose and formulation

N.B. Because of differences in bioavailability, ciclosporin (Neoral) should be prescribed by brand.

Doses may vary for individual patients and will be documented in specialist letter.

ADULT

Initially 50-100mg daily, in 2 divided doses increased, according to response and satisfactory monitoring, to a usual maximum dose of 2.5mg/kg.

Occasionally up to 4mg/kg may be used in rheumatoid arthritis and up to 5mg/kg may be used for psoriasis, atopic dermatitis and nephrotic syndrome.

4. Duration of treatment

Advice will be given to the GP on duration of treatment and dose changes for each individual patient.

5. Contraindications and cautions

Patients with impaired renal function (except in nephrotic syndrome patients with a permissible degree of renal impairment), uncontrolled hypertension, uncontrolled infections, or any kind of malignancy should not receive ciclosporin.

There is limited data for use in pregnancy - patients who are pregnant or planning pregnancy should be referred to specialist.

Ciclosporin is contraindicated in breast feeding women.

6. Adverse effects

A frequent and potentially serious complication is a dose dependant and reversible increase in serum creatinine and urea during the first week of therapy.

Other side effects include hypertrichosis, hirsutism, tremor, headache, hypertension, hepatic dysfunction, gingival hypertrophy, fatigue, GI disturbances and burning sensation of the hands and feet. Ciclosporin increases the risk of developing lymphomas and other malignancies, particularly those of the skin. Hyperlipidaemia / hypercholesterolaemia very commonly occur.

7. Interactions

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

There are many potentially serious drug interactions with ciclosporin, including NSAIDs, antihypertensives and lipid lowering agents. Patients should be advised to avoid grapefruit juice. Always check with BNF or Data Sheet (www.bnf.org or www.medicines.org.uk)

N.B. Ciclosporin may be prescribed in combinations with NSAIDs under specialist advice.

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Monitoring

Disease monitoring:

Clinical response to therapy

Drug monitoring:

Patients should have, at baseline full blood count, differential white cell count, platelets, LFTs, U&Es and blood pressure checked (it is preferable to measure BP and renal function on two occasions prior to starting therapy to establish an accurate baseline).

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.

(increased frequency of testing may be required on advice of a specialist e.g. high dose required)

| Monitoring parameter | Recommended response |
|--|--|
| Hypertension occurs that cannot be controlled with appropriate therapy | Withhold until discussed with specialist team. Check any other reasons such as alcohol or OTC drugs etc. |
| Mouth, throat ulceration, unexplained bruising or bleeding | Withhold until discussed with specialist team |
| Creatinine >30% of baseline | Withhold until discussed with specialist team |
| AST/ALT >2 times normal range | Withhold until discussed with specialist team |
| Platelets <150 x10 ⁹ /l | Withhold until discussed with specialist team |
| Significant rise in lipids | Withhold until discussed with specialist team |
| Potassium rises to above normal range | Withhold until discussed with specialist team |
| WCC <4 x10 ⁹ /l | Check neutrophil count and if <2x10 ⁹ /l withhold until discussed with specialist |

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.

10. Responsibilities of clinicians involved

| Stage of Treatment | Hospital Specialist | General Practitioner |
|--------------------|---|---|
| Initiation | Assess the patient following referral by GP Carry out baseline full blood count, differential WCC, platelets, U&Es, LFTs and blood pressure. Recommend appropriate treatment to the GP by approved DMARDs clinic letter | Prescribe on FP10 <u>by brand</u> . |
| Maintenance | Assess clinical response to treatment Provide adequate advice and support for the GP Provide information to GP on frequency of monitoring if doses are changed | Monitor for adverse effects, refer to the consultant where necessary (see section 7) Serum creatinine and BP fortnightly until the dose has been stable for 3 months and thereafter monthly. FBC and LFTs monthly until dose is stable for 3 months and then 3 monthly. Serum lipids every 6 months. |

DMARDs clinic letter box

| DMARD COMMENCEMENT | Tick box |
|---------------------------------|--------------------------|
| Bloods checked and satisfactory | <input type="checkbox"/> |
| X-Ray checked and satisfactory | <input type="checkbox"/> |
| Information given to patient | <input type="checkbox"/> |
| Counselling given to patient | <input type="checkbox"/> |
| Shared Care Protocol attached | <input type="checkbox"/> |

Contact Details:

During office hours

Contact the relevant consultant’s secretary via HEY switchboard (01482 875875)

Specialist pharmacists

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|--|--------------|
| Rheumatology – Emily Hardaker | 01482 674043 |
| Neurology - Jane Morgan | 01482 674411 |
| Renal Medicine – Aaron Acquaye | 01482 674043 |
| Interface Pharmacist – Antonio Ramirez | 01482 674306 |

Out of hours – Contact on-call Registrar for specialty via HEY switchboard.

APPROVAL PROCESS for Shared Care Framework

| | |
|------------------------------|---|
| Written by: | <i>Interface pharmacist</i> |
| Consultation process: | <i>Specialist teams from, Dermatology, Immunology, Neurology, Renal Medicine, Rheumatology</i> |
| Approved by: | <i>MMIG March 2014</i> |
| Ratified by: | <i>HERPC March 2014 Updated June 2018</i> |
| Review date: | <i>June 2021</i> |