It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs). This guideline reinforces the basic premise that:

When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the "sharing of information with the individual GP and their mutual agreement to the transfer of care."

These are not rigid guidelines. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Drug Name:

CICLOSPORIN - Dermatology

Indications:
Ciclosporin is a potent immunosuppressant which is used within dermatology to treat psoriasis, atopic dermatitis, pyoderma gangrenosum and occasionally autoimmune disorders.
It is nephrotoxic and can cause hypertension.

Dosage and administration:
Dermatology: Initial starting dose is 2.5mg/kg, increasing according to clinical response and results of blood tests and blood pressure to a maximum of 5mg/kg.

Serum ciclosporin concentrations are rarely necessary unless there is significant concomitant renal disease.

Additional Information
- Pneumovac II® and annual influenza vaccine is recommended
- There are numerous drug interactions – see overleaf or check BNF/SPC
- Grapefruit juice should be avoided
- Different brands of ciclosporin are not bioequivalent therefore prescribing by brand is required. Clinically, no brand is superior to any other. Dermatology consultant will start patients on the most cost effective brand according to hospital contracts. Although brands can be switched, it is not advisable since it can cause a loss of therapeutic control.

Monitoring requirements:
Before treatment:
- FBC including platelets, serum creatinine (must be done twice before starting treatment), U&Es, LFTs, fasting lipids
- Blood pressure on two occasions (on two different days)

During treatment:
- FBC, serum creatinine, urea and potassium, and blood pressure weekly for the first four weeks, then fortnightly for 2 months and monthly thereafter if stable
- Monthly LFTs
- Annual fasting lipids (HDL, Cholesterol, HDL/Cholesterol ratio).

Action to be taken if abnormal results/adverse effects:
- WBC< 4 x 10^9/l Check neutrophil count
- Neutrophils < 2.0 x 10^9/l Monitor weekly. If it falls below 1.5 x 10^9/l STOP DRUG and contact supervising consultant
- Platelets < 150 x 10^9/l Monitor weekly. If drop below 100 x 10^9/l contact supervising consultant
- Elevated creatinine: Serum creatinine rise >30% over baseline (on 2 consecutive routine blood tests) will require a dose reduction. Please contact the supervising consultant
- Hypertension: If BP > 140/90 (persistent) then start on calcium channel blocker (eg amlodipine 5 to10mg daily). Do not use verapamil or diltiazem due to interaction.
  If BP is uncontrolled despite medical treatment, reduce ciclosporin by at least 25mg/day and contact the supervising consultant
- If bilirubin and liver enzymes increase 2 fold above upper limit of reference range, a dose reduction may be necessary
- Abnormal bruising or bleeding: Repeat FBC and act on results as above.
- Hyperkalaemia and hyperlipidaemia does not require consultant input

Please note that in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.
### Contraindications:
- Concomitant use of tacrolimus or rosuvastatin
- Abnormal renal function, uncontrolled hypertension, uncontrolled infections or any malignancy other than that of the skin
- Live vaccines are contra-indicated on theoretical grounds.

### Significant Drug interactions:
- Ciclosporin plasma levels are decreased by barbiturates, carbamazepine, oxcarbazepine, phenytoin, rifampicin, octreotide, orlistat, St John's Wort, ticlopidine, sulfipyrazone, terbinafine and bosentan
- Ciclosporin plasma levels are increased by erythromycin, azithromycin, clarithromycin, amiodarone, diltiazem, verapamil, omeprazole, oral contraceptives, corticosteroids, progestogens, danazol, ketoconazole, itraconazole, fluconazole, voriconazole, nicardipine, metoclopramide, allopurinol, colchicine, methylprednisolone, protease inhibitors, imatinib, nefazadone, oral contraceptives.
- Ciclosporin may reduce the clearance of digoxin, colchicine, prednisolone, statins and etoposide
- There is an increased risk of hyperkalaemia with potassium-sparing diuretics, ACE inhibitors, angiotensin-II receptor blockers and spironolactone

### Cautions:
- Administration with other nephrotoxic drugs such as, ciprofloxacin and NSAIDs (including diclofenac, naproxen and sulindac). The dose of diclofenac should be reduced by 50% if given concomitantly.
- Mothers being treated with ciclosporin should not breast feed their infants. Ciclosporin should only be used in pregnancy after a careful assessment of risk versus benefit.
- Ciclosporin increases the blood levels of aliskiren and lercanidipine

For full details see the current edition of the British National Formulary (BNF) and the Summary of Product Characteristics (SPC) for ciclosporin products.

### Adverse Effects:
Increased susceptibility to infection, hypertension, hypercholesterolaemia, renal and hepatic toxicity (should not be severe at maintenance doses), tremor, paraesthesia, hyperkalaemia, hyperglycaemia, hypomagnesaemia, hirsuitism, gingival hypertrophy, bone marrow suppression, GI disturbance, headache.

For full details see the current edition of the BNF and SPC for ciclosporin products.

### Specialist responsibilities:
1. Communicate promptly with the GP when treatment is changed and each time the patient is seen.
2. Ensure baseline monitoring of full blood count and biochemical profile, also subsequent monitoring until dose is stabilised.
3. Review the patient after six to eight weeks and if the patient is tolerating and benefiting from ciclosporin at this first visit, a written request should be made to the GP to continue prescribing the medication and to continue the monitoring.
4. Prescribe the initial 2 months of ciclosporin during the trial period and discontinue if no response or significant adverse effect.
5. Provide the patient with a shared care booklet and enter the blood results into the booklet.
6. Regularly review the patient to monitor efficacy of the treatment and the ability to tolerate it, and consider whether continuation of treatment is appropriate.
7. Undertake any necessary monitoring at review appointments.
8. Ensure clear backup arrangements exist for GPs for advice and support

### GP’s responsibilities:
1. Initial referral to the appropriate consultant.
2. Provide the patient with monthly repeat prescriptions of medication once the specialist has recommended continuation therapy following the trial period. The patient should allow at least 48 hours for the prescription from the GP to be generated once they have agreed to take on prescribing.
3. Continue with the monitoring as outlined on the first page and document the results in the shared care booklet.
4. Report any adverse effects of medication to the consultant.
5. Refer back to the consultant if the patient’s condition deteriorates or if there is a change in the patient’s status.
6. Contact the consultant if they do not agree with the treatment recommendation, or if there is a perceived problem with compliance or concordance, or if they have any questions about the management plan.

### Patient’s responsibilities:
Report any adverse effects, concerns or lack of understanding of the treatment to the GP or specialist. Attend for blood tests and take the monitoring booklet to all appointments.
Maintain safe alcohol limits

### Secondary care review:
Patients will be reviewed one month after starting ciclosporin and thereafter at a frequency determined by the clinical need by the consultant, or if requested to review by the GP.
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<thead>
<tr>
<th>Availability</th>
<th>Telephone</th>
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<tr>
<td>Capimune: Capsules: 30 x 25mg = £13.50, 30 x 50mg = £26.80, 30 x 100mg = £51.30.</td>
<td>0151 482 7780</td>
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<td>Neoral: Capsules: 60 x 10mg = £18.48, 30 x 25mg = £18.59, 30 x 50mg = £36.41, 30 x 100mg = £69.11, Oral solution: 100mg/ml x 50ml = £117.00 (Source: MIMS – March 2013)</td>
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**Back up advice and support:**

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<th>Written By:</th>
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<tbody>
<tr>
<td>Dermatology Specialist Nurse</td>
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<td>Julie Orton, Wirral PCT</td>
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<td>Gareth Malson, Lead Dermatology Pharmacist, Wirral University Teaching Hospital (WUTH)</td>
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<td>Dr S White, Consultant Dermatologist, WUTH</td>
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<td>Dr S Jones, Consultant Dermatologist, WUTH</td>
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