

South West Yorkshire Area Prescribing Committee

CICLOSPORIN Shared Care Guideline

Introduction	
General Statements	<ul style="list-style-type: none"> The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and primary care prescriber. The primary care prescriber must reply in writing to the request for shared care as soon as practicable if <u>unwilling</u> to participate. Responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and primary care prescriber notes. The agreement to consider the use of a shared care guideline should only be considered when the patient's clinical condition is stable or predictable.
Indication	<p>Licensed indications - Rheumatoid arthritis, Psoriasis</p> <p>Unlicensed indication - Psoriatic arthritis</p>

Individual's Responsibilities	
Hospital Specialist's Responsibilities	<ul style="list-style-type: none"> ➤ Record patient consent to unlicensed use in medical notes (if applicable) ➤ Baseline monitoring and initial prescribing until the patient is established on treatment (minimum of 8 weeks). ➤ Monitoring disease progression and treatment response ➤ Supporting and advising primary care prescribers, including which brand to prescribe ➤ Monitoring booklets are available and may be beneficial in certain circumstances, for example if the patient receives blood monitoring at a location where results are inaccessible to the clinician. In these situations the Hospital Specialist will communicate this fact to the primary care prescriber at the point when prescribing and monitoring is transferred ➤ Ensure that the patient has an adequate supply of medication until primary care prescriber supply can be arranged. ➤ Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the primary care prescriber. ➤ Provide patient with rheumatology nurse helpline contact number.
Primary Care Prescribers Responsibilities	<ul style="list-style-type: none"> ➤ Ensure hospital is notified if <u>unwilling</u> to undertake prescribing and monitoring when requested ➤ Prescribing following written request from specialist care – prescribe by brand name, as recommended by the hospital specialist ➤ Ensure monitoring is undertaken according to shared care guideline and only continue prescription if compliance with monitoring and results satisfactory. ➤ Follow guidance in the event of reaction or abnormality, record it and report back to specialist ➤ Update patient's monitoring booklet as appropriate (including test dates & results, when available) ➤ Encourage influenza and pneumococcal vaccination as per Green Book

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	<ul style="list-style-type: none"> ➤ Ensure no drug interactions with concomitant medicines ➤ To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring.
Monitoring Required	<p>Baseline- FBC, U&E, LFTs, serum urate, lipids, BP, creatinine twice at least 1 week apart, eGFR, urinalysis.</p> <p>The Hospital Specialist must confirm to the primary care prescriber which stages of the maintenance monitoring have already been completed at the point when prescribing and monitoring are transferred to the primary care prescriber</p> <p>Maintenance - Repeat BP, FBC, U&E, creatinine, LFT 2 weekly until stable dose then, monthly for 4 months then 3 monthly</p> <p>Repeat serum urate and lipids at 2- 3 months (optional)</p>
When and How to Discontinue Treatment	<p>Loss of efficacy, intolerance, uncontrolled hypertension, hyperkalaemia – serum K+ >5.5mmol/L.</p> <p>Please see overleaf for detailed guidance as regards stopping treatment.</p>
Information given to the patient	Patient information leaflet and monitoring booklet
Contact Details	Documented in letter from specialist care to primary care prescriber

Product Information

Product Information	
<p>The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics</p>	
Dosage	Starting dose 1-2mg/kg daily in 2 divided doses for 6 weeks then 25mg increments every 2 weeks until clinically effective or toxicity occurs; maximum dose 4mg/kg/day. Prescribe by brand name.
Adverse Effects	<p>Mucocutaneous – hypertrichosis, gingival hyperplasia, allergic rash</p> <p>Biochemistry – hyperkalaemia, hyperuricaemia, hypercholesterolaemia, abnormal liver function. Impaired renal function with potential long term renal damage with chronic use.</p> <p>Hypertension</p> <p>CNS – headache, tremor, confusion</p> <p>Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.</p>
Precautions and Contra-indications	<p>Contraindications – renal or hepatic impairment, uncontrolled hypertension, uncontrolled infection, breastfeeding, malignancy</p> <p>Precautions –pregnancy.</p> <p>Avoid live vaccines – examples could include oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster – for full details check the latest SPC before administration</p>
Clinically relevant Drug Interactions and their	<p>Ciclosporin increases bioavailability of diclofenac – either reduce diclofenac dose by 50% or change to alternative NSAID.</p> <p>Grapefruit, pomelo and grape juice increases bioavailability of ciclosporin and should be avoided.</p>

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management	<p>Ciclosporin interacts with a considerable number of other medicines, primarily via the CYP3A4 pathway. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.</p> <p>St John's Wort significantly decreases ciclosporin levels and the two should not be used concomitantly</p>
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Recommended action for abnormal results

Investigation	Action
Creatinine >30 % above baseline	Halve dose & repeat in 1-2 weeks; contact specialist if renal function does not improve.
ALT/AST above normal range but below 3x upper limit	Repeat bloods every 2 weeks Ask patient about viral/bacterial infections Check that it is not due to another drug or NSAID, particularly diclofenac, and stop this first. Stop and contact specialist
ALT/AST > 3x upper limit	
WCC <3.5 10 ⁹ /L Neutrophils <2.0 10 ⁹ /L Platelets <150 10 ⁹ /L	Stop medication and contact specialist
Potassium >5.5mmol/L	Stop and contact specialist
Blood pressure >160/95 or risen >20mg Hg from baseline	Repeat BP in 2 weeks. If still raised after 2 weeks, stop and contact specialist.

Recommended action for adverse effects

Adverse effect	Action
Itching	Reduce dose and review
Rash	Check for other causes e.g. Complications of disease, vasculitis, steroid effects. Mild – reduce dose Severe – stop
Hirsutism	Reduce dose, stop if severe
Gingival hyperplasia	Reduce dose, stop if severe
Significant increase in lipids	Withhold and contact specialist
Headache	Check BP and consider other causes Mild – try analgesia and reduce dose Severe - stop
Confusion, tremor	Stop