

## CICLOSPORIN Shared Care Guideline

Introduction	
<b>General Statements</b>	<ul style="list-style-type: none"> <li>The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and GP.</li> <li>The GP must reply in writing to the request for shared care as soon as practicable if <u>unwilling</u> to participate.</li> <li>Responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and GP notes.</li> <li>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.</li> </ul>
<b>Indication</b>	<p><b>Licensed indications</b> - Rheumatoid arthritis, Psoriasis</p> <p><b>Unlicensed indication</b> - Psoriatic arthritis</p>

Individual's Responsibilities	
<b>Hospital Specialist's Responsibilities</b>	<ul style="list-style-type: none"> <li>➤ Baseline monitoring and initial prescribing until the patient is established on treatment (minimum of 8 weeks).</li> <li>➤ Monitoring disease progression and treatment response</li> <li>➤ Supporting and advising GPs, including which brand to prescribe</li> <li>➤ 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 GP at the point when prescribing and monitoring is transferred</li> <li>➤ Ensure that the patient has an adequate supply of medication until GP supply can be arranged.</li> <li>➤ 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 GP.</li> <li>➤ Provide patient with rheumatology nurse helpline contact number.</li> </ul>
<b>General Practitioner's Responsibilities</b>	<ul style="list-style-type: none"> <li>➤ Ensure hospital is notified if <u>unwilling</u> to undertake prescribing and monitoring when requested</li> <li>➤ Prescribing following written request from specialist care – <b>prescribe by brand name, as recommended by the hospital specialist</b></li> <li>➤ Ensure monitoring is undertaken according to shared care guideline and only continue prescription if compliance with monitoring and results satisfactory.</li> <li>➤ Follow guidance in the event of reaction or abnormality, record it and report back to specialist</li> <li>➤ Update patient's monitoring booklet as appropriate (including test dates &amp; results, when available)</li> <li>➤ Encourage influenza and pneumococcal vaccination as per Green Book</li> <li>➤ Ensure no drug interactions with concomitant medicines</li> <li>➤ To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring.</li> </ul>
<b>Monitoring Required</b>	<p><b>Baseline</b>- FBC, U&amp;E, LFTs, serum urate, lipids, BP, creatinine twice at least 1 week apart, eGFR, urinalysis.</p> <p>The Hospital Specialist must confirm to the GP which stages of the</p>

*Approved by South West Yorkshire Area Prescribing Committee for use in the population covered by the geographical area of Calderdale, Greater Huddersfield, North Kirklees and Wakefield CCGs*

*Approved on – 17 July 2015*

*Review Date –17 July 2018*

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	<p>maintenance monitoring have already been completed at the point when prescribing and monitoring are transferred to the GP</p> <p><b>Maintenance</b> - Repeat BP, U&amp;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>
<b>When and How to Discontinue Treatment</b>	<p>Loss of efficacy, intolerance, uncontrolled hypertension, hyperkalaemia – serum K<sup>+</sup> &gt;5.5mmol/L.</p> <p>Please see overleaf for detailed guidance as regards stopping treatment.</p>
<b>Information given to the patient</b>	Patient information leaflet and monitoring booklet
<b>Contact Details</b>	Documented in letter from specialist care to GP

<b>Product Information</b>	
<b>The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics</b>	
<b>Dosage</b>	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. <b>Prescribe by brand name.</b>
<b>Adverse Effects</b>	<p><b>Mucocutaneous</b> – hypertrichosis, gingival hyperplasia, allergic rash</p> <p><b>Biochemistry</b> – hyperkalaemia, hyperuricaemia, hypercholesterolaemia, abnormal liver function. Impaired renal function with potential long term renal damage with chronic use.</p> <p><b>Hypertension</b></p> <p><b>CNS</b> – headache, burning sensation hands and feet, tremor, confusion</p> <p>Refer to the current BNF and <a href="http://www.medicines.org.uk/emc/">www.medicines.org.uk/emc/</a> for complete and up to date information.</p>
<b>Precautions and Contra-indications</b>	<p><b>Contraindications</b> – renal or hepatic impairment, hypertension, uncontrolled infection. Breastfeeding</p> <p><b>Precautions</b> – malignancy, 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>
<b>Clinically relevant Drug Interactions and their management</b>	<p>Ciclosporin increases bioavailability of <b>diclofenac</b> – either reduce diclofenac dose by 50% or change to alternative NSAID.</p> <p><b>Grapefruit juice</b> increases bioavailability of ciclosporin and should be avoided.</p> <p><b>Ciclosporin interacts with a considerable number of other medicines</b>, primarily via the CYP3A4 pathway. Refer to the current BNF and <a href="http://www.medicines.org.uk/emc/">www.medicines.org.uk/emc/</a> 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	Stop medication and contact specialist
WCC <3.5 10 <sup>9</sup> /L Neutrophils <2.0 10 <sup>9</sup> /L Platelets <150 10 <sup>9</sup> /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