



NHS South of Tyne and Wear

serving Gateshead Primary Care Trust, South Tyneside Primary Care Trust and
Sunderland Teaching Primary Care Trust

SHARED CARE GUIDELINE

For

Ciclosporin for the Management of Rheumatoid Arthritis

Implementation Date: 5th October 2010

Review Date: 12th June 2012

This guidance has been prepared and approved for use within Gateshead, South Tyneside and Sunderland in consultation with Primary and Secondary Care Trusts and Local Medical Committees.

The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe these treatments within a shared care setting

Further copies are available from

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Approved by:

Committee	Date
Gateshead Medicines Management Committee	
South Tyneside Prescribing Committee	
Sunderland Primary Care Prescribing Group	
South of Tyne and Wear Medicines Management Committee	5.10.2010

Name of drug:	Ciclosporin	Form and strength:	Capsules 10mg, 25mg, 50mg, 100mg Oral solution 100mg in 1ml
Brand name:	Neoral	BNF Code:	10.1.3
Conditions(s) to be treated		Rheumatoid arthritis	
Excluded patients	Those where GP has refused shared care		
Eligibility criteria for shared care	All patients		
Initiation	Treatment will be initiated by hospital		
Duration of treatment	Long term. Consultant will advise GP when treatment has to stop		
Usual Maintenance Dose	Ciclosporin is usually within the dose range of 150- 250mg daily in divided doses		
Usual Dose Range	Start at 2.5mg/kg/day then increasing up to 4mg/kg/day as necessary.		
Maximum Dose	4mg/kg/day		
Available Strengths (Colours)	Capsules 10mg (yellow/white), 25mg (blue/grey), 50mg (yellow/white), 100mg (blue/grey) Oral solution (yellow) 100mg in 1ml		
Preparations	capsules		Liquid
Cost 28 days (Drug Tariff)	£250 / month		
Adverse effects	<p>There are many side effects of ciclosporin. The most common and important side effects are dose dependent and include renal dysfunction, hypertension, hypertrichosis, fatigue, gum hyperplasia, painful paraesthesia and abnormal LFTs. Hypertension should be treated with appropriate anti-hypertensive therapy, avoiding calcium channel blockers as they affect ciclosporin levels.</p> <p>Discontinue ciclosporin if hypertension remains uncontrolled. High dose ciclosporin treatment is associated with an increase of lymphoma - if lymphadenopathy develops please refer patient to the rheumatology department.</p> <p>If infection occurs requiring treatment with antibiotics, discuss temporary withdrawal of ciclosporin with the rheumatology team. Discuss with rheumatology team immediately if patient is in contact with chicken pox. In the event of Herpes Zoster stop ciclosporin - patients should be seen within 12 hours by their GP.</p> <p>Photosensitivity may occur and patients have been advised not to use sunbeds and to avoid excessive unprotected sunlight.</p>		
Contra-indications	<p>Known hypersensitivity to the product</p> <p>Suspected systemic infection</p> <p>Renal and liver failure</p> <p>Grapefruit</p>		

Drug-interactions	<p>Drug interactions are very common and clinically significant and include some antibiotics. Common interactions are listed. Check BNF and SPC for further interactions. Check thoroughly before prescribing.</p> <p>Live vaccines should be avoided to prevent disseminated disease developing.</p> <p>ACE inhibitors & ARBs – increased risk hyperkaleamia</p> <p>Half dose of Diclofenac as plasma concentration increased</p> <p>Increased plasma concentration of Digoxin</p> <p>Increased risk of myopathy with statins (maximum simvastatin 10mg daily)</p>
Renal impairment and liver disease	<p>Contra-indicated in abnormal renal function</p> <p>Discontinue ciclosporin and contact the rheumatology department if ALT/AST rise by more than 3 times upper limit of normal</p>
Pregnancy and breast feeding	<p>Seek specialist advice</p>
Monitoring	<p>Base line Creatinine, FBC, ESR, CRP, U+E, LFT, Lipids, Urinalysis +/- MSU, BP (on two separate occasions)</p> <p>Routine monitoring U & Es, LFTs, FBC, ESR and BP fortnightly for the first 3 months of therapy then monthly thereafter. Monitoring frequency must be increased if the dose of ciclosporin is increased or NSAIDs are introduced or their dosage altered. Monitoring frequency may be reduced to 6 weekly after one year if results and dose stable (with 3 monthly LFTs). Lipids to be checked 6 monthly</p> <p>If any of the following occurs:</p> <p>WBC < 4 x 10⁹/L withhold and discuss with rheumatologist</p> <p>Neutrophils < 2 x 10⁹/L withhold and discuss with rheumatologist</p> <p>Platelets < 150 x 10³/L withhold and discuss with rheumatologist</p> <p>Abnormal bruising – check FBC</p> <p>Lymphocytes <0.5 x 10⁹/L withhold and discuss with rheumatologist</p> <p>Hb <11g/dl on 2 separate occasions contact the rheumatology department for investigation of cause – do not stop If there is a steady fall in WBC or platelets (or both) over 3 successive tests and results range within normal range contact rheumatology team for advice – DO NOT STOP</p> <p>If serum creatinine rises to >50% above baseline, decrease ciclosporin dose by 50%, contact the rheumatology department and recheck after one week</p> <p>If serum creatinine rises to >30% but <50% above baseline, repeat U+Es after one week, if remains elevated, decrease ciclosporin dose by 25mg and recheck after one week.</p>

	<p>Discontinue ciclosporin and contact the rheumatology department if</p> <ul style="list-style-type: none">• elevated serum creatinine levels do not decrease within one month <p>ALT/AST rise by more than 3 times upper limit of normal</p> <p>Discontinue ciclosporin and contact the rheumatology department</p> <p>BP >140/90 on 2 occasions 2 weeks apart, treat blood pressure (note interactions with several antihypertensives). If bp cannot be controlled, stop Ciclosporin and discuss with Rheumatology team.</p> <p>Annual 'flu vaccine is recommended and pneumococcal vaccination should be considered</p>
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Responsibilities	<p>DISEASE MONITORING Clinical response to therapy will be assessed by the hospital physician in all cases and communicated to the GP</p> <p>RESPONSIBILITY FOR PRESCRIBING On initiation of therapy the patient will be given a one month supply of ciclosporin by secondary care. Responsibility thereafter for prescribing may be transferred to the patients GP depending on the locality in which the GP is based and the secondary care centre the patient attends. This is detailed below. The GP should not prescribe unless the monitoring has been carried out and the GP is satisfied that it is safe to continue treatment.</p> <p><u>Practices in Sunderland PCT</u> PATIENTS REFERRED TO SUNDERLAND (helpline 0191 5656256 ext 47533–Mon- Fri 9am –5pm). All the blood tests, monitoring, and dosing will be carried out entirely by the rheumatology clinic with the responsibility of secondary care to inform the GP of any abnormalities. The GP will be responsible for prescribing in agreement with the Secondary care service.</p> <p>PATIENTS REFERRED TO GATESHEAD (helpline 0191 445 5240 Mon- Fri 9am- 5pm or consultant secretary) All blood tests, monitoring, prescribing and dosing to be carried out by GP with support from secondary care specialist as required</p> <p>PATIENTS REFERRED ELSEWHERE All blood tests, monitoring, prescribing and dosing to be carried out by GP with support from secondary care specialist as required</p> <p><u>Practices in Gateshead PCT</u> PATIENTS REFERRED TO GATESHEAD (helpline 0191 445 5240 Mon- Fri 9am- 5pm or consultant secretary) Secondary care staff will carry out base line monitoring prior to initiating therapy. GPs will carry out ongoing blood tests and prescribing. Secondary care staff will carry out monitoring and advise GPs of changes to dose or monitoring intervals.</p> <p>PATIENTS REFERRED ELSEWHERE All blood tests, monitoring, prescribing and dosing to be carried out by GP with support from secondary care specialist as required</p>
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	<p>Practices in South Tyneside PCT PATIENTS REFERRED TO GATESHEAD (helpline 0191 445 5240 Mon- Fri 9am- 5pm or consultant secretary) All blood tests, monitoring, prescribing and dosing to be carried out by GP with support from secondary care specialist as required</p> <p>PATIENTS REFERRED TO SUNDERLAND (helpline 0191 5656256 ext 47533–Mon- Fri 9am –5pm). Most blood tests, monitoring and dosing will be carried out entirely by the rheumatology clinic with the responsibility of secondary care to inform the GP of any abnormalities. The GP will be responsible for prescribing in agreement with the Secondary care service. Once stable responsibility may be transferred to GP as agreed between specialist and GP at time of transfer. The GP will then be responsible for monitoring, dosing, blood tests and prescribing.</p>	
Communications	Consultant	Please refer to the standard letter from the patient's consultant. For Gateshead patients a copy of the Gateshead GP information sheet should be enclosed with the letter
	G.P.	If the GP is unwilling to accept prescribing responsibility for an individual patient the consultant should be informed within 1 month of receipt of the shared care request. In such cases the GP must inform the consultant of all relevant medical information regarding the patient and any changes to the patient's medication irrespective of indication.
	Patient	The patient will have received an information leaflet from the hospital. The patient will be informed to contact their GP or Hospital Rheumatology Clinic immediately if any of the following occur: fever, sore throat, cough, skin rash or mouth ulcers. Patients should also contact their GP if blood tests are not being monitored.
Re- referral criteria	Not applicable	
Contact details	Consultant:	
	Additional information for Gateshead patients is available at www.gatesheadhealth.nhs.uk/rheumatology	
Agreed Date	Expiry date	

Reference to full prescribing information e.g. SPC

Appendix 2 Shared Care Request Form

- **Consultant to complete FIRST SECTION of form**
- **GP to complete SECOND section and RETURN to ACUTE TRUST CLINICIAN TEAM if NOT accepting shared care**

Section 1

Consultant	
Hospital address	
Contact Phone Number	

Patient's name	
Address	
This patient is stabilised on	
Dose	
Prescription for 28 days supply given on	

Compliance aid	YES/NO
Monitored by	
Designated community pharmacy	

Their treatment has been explained to them and a review has been arranged for

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Appointments to continue every months

Section 2

Patient's name	
Address	

I do **NOT ACCEPT** the proposed Shared-Care Agreement for this patient

My reasons for not accepting: Please complete this section

Signed**date**.....

Please return to the Secondary Care Trust Clinician team at :



