NHS
Telford and Wrekin
Clinical Commissioning Group

# Ciclosporin
## Dermatology and Rheumatology Effective Shared Care Agreement

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| Patient's Name:<br>Address:<br><br>Date of Birth:<br>NHS No.: |

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| Specialist Name:<br>Contact telephone:<br>Location:<br>Signature: | GP Name:<br>Contact telephone:<br>Location:<br>Signature: |

This Effective Shared Care Agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.

**The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

## Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of ciclosporin
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests:
    - **FBC** including differential white cell count
    - **LFTs**
    - **U&Es including creatinine** (twice, 2 weeks apart to obtain mean value) and eGFR.
    - **Fasting lipids**
    - **Blood pressure** (≤140/90 on 2 occasions 2 weeks apart)
    - **CRP +ESR** (Rheumatology only)

- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss this with the patient.
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Titrate ciclosporin to an effective dose. If both GP and Consultant feel it is appropriate, prescribing by the GP may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next Consultant appointment.
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

## Responsibilities of the General Practitioner

- Prescribe ciclosporin by brand name.
- Arrange and record on-going monitoring as agreed with specialist

- **U&E** including potassium and creatinine every 2 weeks until dose and trend stable for 3 months and then monthly.
- **Blood pressure** each time patient attends mentoring clinic and maintain ≤140/90
- **FBC & LFTs** monthly until dose stable for 3 months, then every 3 months
- Fasting Lipids every six monthly
- **CRP + ESR** (Rheumatology only) may be required 3 monthly.

- Frequency of monitoring may be increased if ciclosporin dose is adjusted
- Report any adverse drug reactions to the initiating specialist and the MHRA (via Yellow card)
- Ensure no drug interactions with other medicines
- Administer influenza vaccine annually unless otherwise advised by the initiating specialist
- Check patient has had ONE DOSE of pneumococcal vaccine (revaccination is not recommended except every five years in patients whose antibody levels are likely to have declined more rapidly e.g. asplenia.) - see BNF or Green Book
- Passive immunisation using Varicella immunoglobulin (VZIG) should be considered in non-immune patients exposed to chickenpox or shingles.
- Ask about oral ulceration/sore throat; unexplained rash or unusual bruising at every consultation

Withhold ciclosporin and contact the specialist if:

- Creatinine Increase by > 30% of baseline value
- Potassium > 5.5mmol/L
- Platelets < 150 x $10^9$/L (except BMT and ITP)
- AST / ALT > 2 times the upper limit of normal (except BMT)
- Blood Pressure > 160/95 (or > 50% of baseline) despite addition of standard antihypertensive therapy
- Significant rise in lipids
- Oral Ulceration / sore throat
- Unexplained rash / abnormal bruising

Please note: A rapidly increasing or decreasing trend in any values should prompt caution and extra vigilance. Some patients may have abnormal baseline values, specialist will advise

**General information on ciclosporin**

**Licensed Indication**

- Severe rheumatoid arthritis
- Short-term treatment of severe atopic dermatitis
- Severe psoriasis

**Dosage and administration**

**Rheumatoid arthritis:**
2.5mg/kg/day in 2 divided doses for 6 weeks and then may be increased at 2-4 week intervals by 25mg until clinically effective or a maximum dose of 4mg/kg/day is reached.

Maintenance dose: often effective between 2.5-3.2mg/kg/day. Adjust to patient's tolerance and benefit. Constantly evaluate response and toxicity before increasing to maximum dose (4mg/kg/day).

Consider lower range in patients with very high BMI (maximum 200-250mg daily)

**Psoriasis and severe atopic dermatitis:**
2-5 mg/kg/day in 2 divided doses. Adjust as required to achieve lowest possible maintenance dose.

Patients should be stabilised on a single brand of oral ciclosporin because switching between formulations without close monitoring may lead to clinically important changes in bioavailability. **Prescribing and dispensing of ciclosporin should be by brand name to avoid inadvertent switching.**

## Contraindications

Known hypersensitivity to ciclosporin.

Ciclosporin is contraindicated in psoriatic and atopic dermatitis patients with abnormal renal function, uncontrolled hypertension, uncontrolled infections or any kind of malignancy other than that of the skin

Ciclosporin is contraindicated in rheumatoid arthritis patients with abnormal renal function, uncontrolled hypertension, uncontrolled infections or any kind of malignancy.

Ciclosporin should not be used to treat rheumatoid arthritis in patients under the age of 18 years.

Ciclosporin is contraindicated in nephrotic syndrome patients with uncontrolled hypertension, uncontrolled infections, or any kind of malignancy.

## Side effects

Hypertension is common. Standard antihypertensive therapy can be used. Refer if hypertension remains uncontrolled.

Nephrotoxicity: can be acute. If serum creatinine consistently >30% above patients baseline decrease ciclosporin dose by 25-50%.

Benign gingival hyperplasia is relatively common. Patients should be advised on good oral hygiene.

Hypertrichosis – discuss management with specialist.

Headache, tremor and parathesia are frequently seen. If persistent or severe they may reflect toxic levels of ciclosporin - refer to initiating specialist.

Hyperlipidaemia: ciclosporin can induce a reversible increase in blood lipids. It is therefore advisable to perform lipid determinations before treatment and thereafter as appropriate.

Cancer risk: patients receiving ciclosporin are at increased risk of lymphomas and malignancies of the skin: avoiding excessive exposure to the sun and use of high factor sunscreens are advised.

Pregnancy/Contraception: women of childbearing potential receiving ciclosporin should be advised to use effective contraception. Patients discovered or planning to become pregnant should be referred to the initiating specialist at the earliest opportunity without stopping ciclosporin.

Breastfeeding: patients should not breastfeed whilst receiving ciclosporin.

## Drug Interactions[1]

**There are numerous drug interactions and the Summary of Product Characteristics (www.medicines.org.uk) should be consulted both before treatment and when new drugs are introduced.**

**Live Vaccines** (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided

**Diclofenac** does should be halved when co-prescribed with ciclosporin

**Colchicine** and **nifedipine** should be avoided

**Grapefruit juice** should be avoided

Concomitant use of **tacrolimus** is specifically contraindicated.

Concomitant use of **rosuvastatin** is specifically contraindicated

[1] BNF 66 September 2013-March 2014