NHS Dorset

SHARED CARE PROTOCOL - CICLOSPORIN (ORAL) FOR PATIENTS WITHIN ADULT SERVICES (NON-TRANSPLANT INDICATIONS)

As well this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside of their license
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations, arrange, and review the results of any blood tests for the first 12 weeks of treatment (see section 8).
- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. Explain the process and the potential timescales for this.
- Prescribe sufficient medication taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is established and stabilised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter, detailing the diagnosis, current and ongoing dose and brand, any relevant test results, date the next monitoring is required, and stop date for ciclosporin (if applicable). Include contact information (section 13).

- Conduct the required monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant or breastfeed.
- Provide advice to primary care on the management of adverse effects if required.
- Patients should be regularly reviewed, and the risk benefit re-assessed as patients get significantly older and frail with increasing co-morbidities and polypharmacy. Dose optimisation and/or dose tapering should be considered if clinically appropriate aiming for the lowest effective dose.
- Advise primary care if treatment should be discontinued.

Primary care responsibilities

- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into any account potential drug interactions in section 7.
- Assess for interactions with ciclosporin when starting any new medicines. see section 7.
- Adjust the dose of ciclosporin prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Contact the specialist team for advice if the patient becomes or plans to become pregnant. See section 12.
- Stop treatment as advised by the specialist. If the decision to stop treatment is made in primary care e.g. due to increased frailty index, to let the specialist team know so they can arrange a review as needed.

Patient and/or carer responsibilities

- Take ciclosporin as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping their contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend for the blood monitoring or review appointments.
- Advised to take part in all national screening programmes, e.g. for breast, bowel, and cervical cancers.
- Report adverse effects to their primary care prescriber. Maintain good oral hygiene and seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter (OTC) medications to their primary care prescriber and be aware they should discuss the use of ciclosporin with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking ciclosporin
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant. See section 12.

1. Background

Back to top

This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

Ciclosporin is a potent immunosuppressant which is thought to act specifically and reversibly on lymphocytes. It is licensed for the prevention of transplant rejection, as well as some chronic inflammatory disorders. It is not licensed for all the conditions it is used to treat, however its use for the indications below are well established and supported by clinical specialists.

This shared care protocol does not cover use post-transplant, or the treatment of people less than 18 years old.

2. Indications

Back to top

Licensed indications:

- Endogenous uveitis
- Nephrotic syndrome
- Rheumatoid arthritis
- Psoriasis
- Atopic dermatitis

This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of ciclosporin is appropriate, including, but not limited to, the following specialities and conditions:

- Rheumatology (e.g. psoriatic arthritis, systemic lupus erythematosus, connective tissue disease, vasculitis)
- Dermatology (e.g. urticaria, inflammatory dermatoses, bullous conditions)
- Gastroenterology (e.g. severe ulcerative colitis)
- Renal medicine (e.g. vasculitis, lupus nephritis)
- Neurology (e.g. myasthenia gravis)

These indications are off label. The specialist must specify the indication for each patient when initiating shared care and clearly state when use is off label.

3. Locally agreed off-label use

Back to top

Nil further identified- see above

4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to ciclosporin or any excipients
- Malignancy
- Uncontrolled hypertension
- Uncontrolled infection
- Concomitant use with *Hypericum perforatum* (St John's Wort), tacrolimus, or substrates for P-glycoprotein or organic anion transporter proteins (OATP) e.g. bosentan, dabigatran, aliskiren (see section 7)

Cautions:

- Hepatic impairment
- Elderly; monitor renal function particularly closely
- Renal impairment – see section 10
- Hypertension
- Hyperlipidaemia: ciclosporin may induce a small reversible increase in blood lipids.
- Hyperkalaemia: the risk of hyperkalaemia is increased by ciclosporin treatment.
- Hypomagnesaemia: ciclosporin increases magnesium excretion, therefore supplementation may be required.
- Hyperuricaemia
- Vaccination may be less effective during treatment with ciclosporin. Live attenuated vaccines should be avoided (see section 7).
- Active herpes simplex infections. Allow infection to clear before starting and withdraw if severe infections occur during treatment.
- Staphylococcus aureus skin infections. Not an absolute contraindication if infection is controlled but avoid erythromycin unless no other alternative (see section 7).
- Treat patients with malignant or pre-malignant conditions of skin only after appropriate treatment (and if no other option).
- Neurological Behçet's syndrome – monitor neurological status.
- Lymphoproliferative disorders; discontinue treatment.
- Pregnancy and breastfeeding, see section 12.
- All oral dosage forms of ciclosporin contain a form of ethanol, see section 6.
- Due to the increased risk of skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor.

5. Initiation and ongoing dose regimen

Back to top

- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

Starting doses range from 2.5 mg/kg/day to 5 mg/kg/day in two divided doses depending on the indication. The selected dose will be tailored to the individual patient and decided by the specialist.

The dose titration period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

The maintenance dose will be tailored to the individual patient and should be the lowest effective and well tolerated dose. The usual maximum dose is 5 mg/kg/day in two divided doses.

In certain conditions higher doses may be used for a limited period, this should be under the direct supervision of the specialist.

Please note for rheumatology conditions a patient may be initiated on more than one DMARD.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

- In patients with nephrotic syndrome and impaired renal function the initial dose should not exceed 2.5 mg/kg/day.
- Deteriorating renal function. See section 10.
- Elderly patients: dose selection should be cautious and start at the low end of the dose range.

6. Pharmaceutical aspects

Back to top

Route of administration:	Oral
Formulation:	**Soft capsules** Capimune®: 25 mg, 50 mg, 100 mg Capsorin®: 25 mg, 50 mg, 100 mg Deximune®: 25 mg, 50 mg, 100 mg Neoral®: 10 mg, 25 mg, 50 mg, 100 mg Sandimmun®: 25 mg, 50 mg, 100 mg Vanquoral®: 10mg, 25mg, 50mg, 100mg Generics: 25 mg, 50 mg, 100 mg **Oral solution** Neoral®: 100 mg/mL Capsorin®: 100mg/mL Sandimmun®: 100mg/mL **Ciclosporin should be prescribed by brand and formulation, regardless of the indication**. Switching between formulations without close monitoring may lead to clinically significant changes in blood-ciclosporin concentration. The switch from one oral ciclosporin formulation to another should be made under specialist supervision (see section 8). Where possible, the brand preferred by the patient's local health system should be chosen.
Administration details:	Ciclosporin should be taken in two divided doses equally distributed throughout the day, and on a consistent schedule regarding time of day and in relation to meals. Neoral oral solution should be diluted prior to administration, preferably with orange or apple juice although other drinks can be used according to individual taste (licensed use). Grapefruit juice must not be used. The entire mixture should be stirred and taken immediately after preparation.
Other important information:	All oral dosage forms of ciclosporin contain a form of ethanol; a 500mg dose is the equivalent of up to approximately 15 ml beer or 6 ml wine. Neoral capsules and oral solution contain polyoxyl 40 hydrogenated castor oil, which may cause stomach upsets and diarrhoea. Neoral oral solution has a shelf life of 2 months once opened.

7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

Ciclosporin is associated with many interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring (see section 4).

- ***Hypericum perforatum* (St John's Wort):** contraindicated due to risk of decreased ciclosporin levels.
- **Substrates for P-glycoprotein or organic anion transporter proteins (OATP)** for which elevated plasma concentrations are associated with serious or life-threatening events e.g. **bosentan, dabigatran, aliskiren**. Concomitant use is contraindicated.
- **Digoxin, edoxaban**: dose adjustment recommended; levels increased by ciclosporin.
- **Statins, etoposide, repaglinide, ambrisentan:** plasma levels may be increased by ciclosporin; close clinical observation for toxicity is recommended. Doses of statins should be reduced and temporarily withheld or discontinued if patients develop signs and symptoms of myopathy or have risk factors for severe renal injury secondary to rhabdomyolysis. Avoid simvastatin and rosuvastatin.
- **Colchicine:** levels of ciclosporin and colchicine may be increased. Close clinical observation for toxicity is recommended.
- **Inhibitors of CYP3A4, P-glycoprotein, or OATP**: may increase plasma levels of ciclosporin. Frequent assessment of renal function and careful monitoring for ciclosporin-related side effects may be required; seek specialist advice, e.g. **nicardipine, metoclopramide, oral contraceptives, methylprednisolone (high dose), allopurinol, cholic acid and derivatives, protease inhibitors, imatinib, nefazodone.**
- **Inducers of CYP3A4, P-glycoprotein, or OATP**: may reduce plasma levels of ciclosporin, e.g., **barbiturates, carbamazepine, oxcarbazepine, phenytoin and fosphenytoin, primidone; nafcillin, intravenous sulfadimidine, probucol, orlistat, ticlopidine, sulfinpyrazone, terbinafine, apalutamide, enzalutamide, lumacaftor, pitolisant.**
- **Macrolide antibiotics: erythromycin** can increase ciclosporin exposure 4- to 7-fold and may result in nephrotoxicity. **Clarithromycin and azithromycin** also increase ciclosporin levels.
- **Nephrotoxic drugs, e.g. aminoglycosides (including gentamicin, tobramycin), colistimethate, amphotericin B, ciprofloxacin, vancomycin, trimethoprim (+ sulfamethoxazole); fibric acid derivatives (e.g. bezafibrate, fenofibrate); non-steroidal anti-inflammatory drugs (NSAIDs, including diclofenac, naproxen, sulindac); melphalan, histamine H2-receptor antagonists (e.g. cimetidine, ranitidine);**

methotrexate: may have synergistic effects; close monitoring of renal function is recommended.

- **Doxycycline, tigecycline:** may increase ciclosporin concentrations. Monitoring may be required.
- **Ticagrelor:** exposure increased by ciclosporin. Use with caution or avoid.
- **Potassium-sparing medicines, including potassium-sparing diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists (ARBs), and potassium-containing medicines**: may lead to significant increases in serum potassium.
- **Lercanidipine:** exposure increased by ciclosporin, avoid or use with caution and separate doses by at least 3 hours.
- **Nifedipine:** increased risk of gingival hyperplasia.
- **Azole antimycotics (e.g. ketoconazole, fluconazole, itraconazole and voriconazole), verapamil, telaprevir:** increase exposure to ciclosporin by at least 2-fold.
- **Caspofungin:** exposure increased by ciclosporin. Liver monitoring recommended.
- **Amiodarone and dronedarone:** increases ciclosporin levels. This interaction can occur for a long time after withdrawal of amiodarone, due to its very long half-life (about 50 days). Amiodarone increases serum creatinine.
- **Danazol, diltiazem** (at doses of 90 mg/day)**:** may increase ciclosporin blood concentrations by up to 50%.
- **Rifampicin**: induces ciclosporin metabolism; ciclosporin doses may need to be increased 3- to 5-fold.
- **Rifaximin:** levels markedly increased by ciclosporin. Caution advised.
- **Octreotide, pasireotide, lanreotide:** decreases oral absorption of ciclosporin; increase in the ciclosporin dose or a switch to intravenous administration could be necessary.
- **Tacrolimus:** risk of pharmacokinetic interaction and nephrotoxicity. Avoid.
- **Everolimus and sirolimus**: ciclosporin increases levels of both drugs and may increase serum creatinine.
- **Baricitinib, filgotinib, tofacitinib**: Increased risk of immunosuppression.
- **Ritonavir**: close monitoring advised, ciclosporin dose adjustment may be needed.
- **Grapefruit and grapefruit juice:** predicted to increase ciclosporin exposure.
- **Vaccination:** During treatment with ciclosporin, vaccination may be less effective, and the use of live attenuated vaccines should be avoided.
- **Aprepitant, netupitant:** predicted to increase ciclosporin levels. Use caution.
- **Anti-cancer medicines:** levels of either medicine may be altered, or risk of immunosuppression increased.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

Back to top

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- Height and weight
- Blood pressure (BP)
- HbA1c
- Full blood count (FBC)
- Urea and electrolytes (U&Es) & creatinine clearance (CrCl), ideally on two occasions prior to starting ciclosporin
- Serum magnesium
- Alanine aminotransferase (ALT), bilirubin and albumin
- Serum lipids and uric acid
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis
- Consider baseline pregnancy testing, if clinically appropriate
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)

Initial monitoring and at dose change:

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly. After which, the transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 4 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine.

- BP
- HbA1c
- FBC
- U&Es, including creatinine and CrCl
- ALT albumin and bilirubin (LFTs)
- Rheumatology patients: C-reactive protein (CRP) &/or erythrocyte sedimentation rate (ESR) (for monitoring disease activity/outcomes rather than for safety- this may continue to be

monitored by the rheumatology team but will not be part of the primary care safety monitoring parameters)

Following a dose increase repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

After one month of treatment:

- Serum lipids

More frequent monitoring is appropriate in patients at higher risk of toxicity. Monitoring of ciclosporin drug levels, where clinically appropriate, would be undertaken by the specialist if indicated.
Prescribing and dispensing of ciclosporin should be by brand name to avoid inadvertent switching.
If it is necessary to switch a patient to a different brand, this should be done cautiously under specialist supervision. The patient should be monitored closely for changes in the following:

- Serum creatinine
- BP

At initiation of shared care, communication to primary care should include current and ongoing dose, any relevant test results, date the next monitoring is required, anticipated duration of treatment, and stop date for ciclosporin (if applicable).

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually unless the patient has been stabilised on treatment for a long time and considered suitable for patient initiated follow up (PIFU). Rapid access to the specialist team for advice and guidance should still be available if the patient is enrolled with PIFU.

When a patient is reviewed, advise primary care whether treatment should be continued and for how long, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing safety monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• BP • HbA1c • FBC • U&Es including creatinine and CrCl • ALT, albumin, and bilirubin (LFTs)	In first year of treatment monthly monitoring. Patients who have been stable for 12 months can reduce to 3 monthly monitoring. Where necessary seek advice on increased frequency of monitoring on a case-by-case basis. **The exact frequency of monitoring to be communicated by the specialist team in all cases**.
• Serum lipids • Uric acid • Serum magnesium	6 monthly
• Immunocompromised patients aged 50 years and over are eligible for the shingles (herpes zoster) vaccine (Shingrix®). • The eligible age for Immunocompetent patients will change in a phased implementation over a 10-year period. • Refer to Green Book Chapter 6 (Contraindications and special considerations) and Green Book Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended. • COVID-19 vaccination is safe and recommended. • Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	• Shingles vaccination: one-off. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • Other vaccinations as per national schedule.

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics.

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Full blood count: • White blood cells less than $3.5x10^9$/L • Lymphocytes less than $0.5x10^9$/L • Neutrophils less than$1.6x10^9$/L • Platelets less than$140x10^9$/L • Eosinophilia greater than$0.5x10^9$/L	Withhold and discuss with specialist team.
Mean cell volume >105 fL	Consider interruption in treatment if there is a significant increase from baseline. Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.
Systemic infection requiring antibiotics	Temporarily withhold ciclosporin until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate. Contact specialist for advice as needed
Liver function tests: ALT >100 units/L, or any sudden increases (e.g. double of baseline), Unexplained fall in serum albumin <30g/L Jaundice	Withhold and discuss with specialist team. Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.

Renal function: Creatinine increases of greater than 30% from baseline in the last 12 months or CrCl reduces to less than 60mL/min	Use clinical judgement and repeat in 1 week. Rule out other causes. If still more than 30% from baseline withhold and discuss with specialist team.
Hyperkalaemia	Review other medicines affecting potassium levels, e.g. ACE inhibitors, diuretics. Discuss with specialist team.
Elevated uric acid	If intending to treat as gout, discuss with specialist team due to the potential for interaction of urate-lowering medicines with ciclosporin.
Blood pressure	Manage hypertension according to local pathways. Care should be taken to avoid drugs which may interact (see section 7). Discuss the management with specialist team if required. Discuss with specialist if hypertension does not respond to treatment; discontinuation of ciclosporin may be indicated.
Hyperlipidaemia	Discuss with specialist team; reduction of ciclosporin dose may be considered.
Gum hypertrophy	Discuss with specialist team.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, purpura, mouth ulcers.	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.

11. Advice to patients and carers

Back to top

The specialist will counsel the patient regarding the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Symptoms of chickenpox or contact with a person with chickenpox or shingles.
- Sore throat, high temperature, skin rash, swollen glands, or any other signs or symptoms of infection.
- Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting.
- Unexplained bleeding or bruising, black stools, or blood in the vomit or stools.
- Seizures, confusion, disorientation, visual disturbance
- Gum swelling or growth (gingival hyperplasia)
- Suspected or confirmed pregnancy.

The patient should be advised:

- What shared care means for their treatment, what to expect, and their responsibilities under shared care.
- During a serious systemic infection ciclosporin should be temporarily discontinued until the patient has recovered from the infection.
- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they become pregnant or if they or their partners are planning a pregnancy.
- Tell anyone who prescribes them a medicine that they are taking ciclosporin. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.
- To avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:
    - the Green Book (Chapter 34)
    - Guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024) - GOV.UK

- Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin.
- All oral dosage forms of ciclosporin contain a form of ethanol, a 500mg dose is the equivalent of up to approximately 15 ml beer or 6 ml wine.
- To maintain good oral hygiene, to reduce the risk of gum swelling.

Patient information:
Dermatology: British Association of Dermatologists ciclosporin patient information leaflet
Rheumatology: Versus Arthritis Ciclosporin patient information leaflet
Patient information leaflets are also available from
https://www.medicines.org.uk/emc/search?q=ciclosporin

12. Pregnancy, paternal exposure, and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to all patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.

Pregnancy:
The British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises ciclosporin is compatible throughout pregnancy with monitoring of maternal blood pressure, renal function, blood glucose and drug levels

Ciclosporin is compatible throughout pregnancy at the lowest effective dose. Regular clinical review and monitoring of maternal whole blood ciclosporin concentration is recommended both during and after pregnancy due to the risk of sub-therapeutic or toxic blood concentrations because of the pharmacokinetic changes which may be associated with pregnancy. All oral dosage forms of ciclosporin contain a form of ethanol, see section 6.

Information for healthcare professionals:
https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-CICLOSPORIN-IN-PREGNANCY/

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Ciclosporin/

Breastfeeding:
Patients taking ciclosporin should not be discouraged from breastfeeding. There is limited published evidence of safety, but small amounts are found in breast milk. Infants should be monitored for signs of infection or immunosuppression, and infant plasma levels should be monitored if there is any concern about toxicity. The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises ciclosporin is compatible with pregnancy. All oral dosage forms of ciclosporin contain a form of ethanol, see section 6.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/ciclosporin/

Paternal exposure:
The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises based on limited evidence ciclosporin is compatible with paternal exposure

Fertility
There is limited data on the effect of ciclosporin on human fertility.

13. Specialist contact information

Back to top

Please approach the patient's named secondary care clinician via the usual method of communication, this may be via letter or if more urgent:

Rheumatology

- Advice and Guidance.
- Consultant Connect - during office hours
- UHD switchboard – on-call rheumatologist during office hours
- Rheumatology advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

Gastroenterology

- Advice and Guidance
- Consultant Connect- during office hours

- IBD advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

Neurology

- Advice and Guidance
- Consultant Connect- during office hours
- UHD Switchboard- on-call neurologist during office hours

Dermatology

- Via switchboard to the on-call dermatology doctor (do not use advice and guidance)

14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

Back to top

- eBNF. Ciclosporin. Ciclosporin | Drugs | BNF | NICE
- Ciclosporin 100 mg soft capsules (Capimune®). Last updated 21st May 2025. Accessed via https://www.medicines.org.uk/emc/product/695/smpc.
- Ciclosporin 100 mg soft capsules (Deximune®). Last updated 19th January 2024. Accessed via https://www.medicines.org.uk/emc/product/2613/smpc
- Ciclosporin soft gelatin capsules (Neoral®). Last updated 29th September 2023. Accessed via https://www.medicines.org.uk/emc/product/1034/smpc
- Ciclosporin oral solution (Neoral®). Last updated 29th September 2023. Accessed via https://www.medicines.org.uk/emc/product/5300/smpc
- British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Accessed via https://academic.oup.com/rheumatology/article/56/6/865/3053478.

- British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids | Rheumatology | Oxford Academic 2022
- SPS Ciclosporin monitoring guidance. Date of revision of the text 2nd July 2024. Accessed via https://www.sps.nhs.uk/monitorings/ciclosporin-monitoring/ on 08/12/21.

16. Other relevant national guidance

Back to top

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Via the usual methods

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on, *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you agree, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.

Primary Care Prescriber Response

Dear *[insert Doctor's name]*

Patient *[insert Patient's name]*

NHS Number*[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re*:*
Patient *[insert Patient's name]*

NHS Number*[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which applies
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	

3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason, I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case

we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp