DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Ciclosporin for adult services

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring
- When transfer agreed the patient will be given a supply of Ciclosporin sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant/ specialist responsibilities
1. If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1) **2.** Prescribe the dose and formulation recommended by consultant. Taking into account potential drug interactions. **3.** Adjust the dose as advised by the specialist. **4.** Perform monitoring tests as specified in section vii. **5.** Manage adverse effects; Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arise. **6.** Ensure the patient is offered an annual flu vaccination and a one off pneumococcal vaccination. Live vaccinations may be recommended on case by case basis following consultant/ specialist advice. – See section v **7.** Refer the management back to the specialist if the patient becomes or plans to become pregnant. **8.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme	**1.** Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol. Assess for contraindications and cautions and interactions. **2.** 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 to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet. **3.** Perform baseline tests (as recommended in section vii) and provide results of baseline tests **4.** Prescribe ciclosporin for the first three months or until medication monitoring is stable. **5.** To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol. **6.** Recommend dose of the drug and frequency of monitoring. Alongside the recommendations for routine monitoring more frequent monitoring may be appropriate in patients at high risk of toxicity. These will be communicated to the GP on a case by case basis. **7.** Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist. **8.** Provide advice to primary care on the management of adverse effects if required. Advise primary care if treatment should be discontinued. Ensure that clear backup arrangements exist for GPs to obtain advice and support. **9.** Advise on the suitability for e.g. herpes zoster vaccination in accordance with national screening programme **10.** Communicate any dose increase to the GP and transfer monitoring to GP when the patient's condition is stable or predictable following 6 weeks period of titration. **11.** Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant. **12.** Report any adverse effects to the MHRA yellow card scheme and GP

Patient responsibilities

- Report to the specialist or GP if there is not a clear understanding of the treatment and share any concerns in relation to treatment.
- Take ciclosporin as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Inform specialist or GP of any other medication being taken including over-the-counter products.
- Report any adverse effects or warning symptoms to the specialist or GP whilst taking the drug. See section v for more detail.
- Take part in all national screening programmes, e.g. for breast, bowel and cervical cancers.
- 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.

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:	ii. Out of hours contacts and procedures:
Chesterfield Royal Hospital NHS Foundation Trust Contact the referring consultant/nurse via switchboard: 01246 277271 Rheumatology Nurse advice line: 01246 513097 Available Mon-Thurs 9am-4pm, Friday 9am- 12pm IBD advice line 01246 512884 (answerphone) GP mobile contact 07717700489 Dermatology 01246513106 **University Hospitals of Derby and Burton NHS Foundation Trust** **Derby Hospitals** Rheumatology- Rheumatology helpline: 01332 787710 Gastroenterology- IBD helpline: 01332 785504 Consultant/specialist nurse via switchboard: 01332 340131 Renal- Specialist Pharmacist: 07500 976569 If unable to contact the specialist renal pharmacist consultants secretaries can be contacted: 01332 789344 Dermatology- specialist via switchboard: 01332 265500 Respiratory- consultant via switchboard: 01332 340131 **Burton Hospitals** Switchboard: 01283 511511 / 566333 Rheumatology Dr R Laximinarayan ext. 3167 Dr S Das ext. 3211/ Dr D Ray ext. 3247 Clinical Rheumatology Nurse Specialist ext. 4112 Bhft.rheumatologynurses@nhs.net Dermatology Dr Beswick and Dr Cartwright secretary ext. 4061 Dr Elston and Dr Tudor secretary 5202 Gastroenterology Dr Palejwala / Dr Dor secretary ext. 3004 Dr Watmough / Dr Guerra secretary ext. 3002 IBD Nurse Specialist ext. 5854 (voicemail service only) bleep: 590 Dhft.ibdcnc@nhs.net	**Chesterfield:** Contact the on-call Medic for the relevant speciality via switchboard: 01246 277271 **Derby:** Pharmacy, UHDB, ask for on-call pharmacist via switchboard: 01332 340131 Messages can be left on the Derby Rheumatology nurse advice line: 01332 787710 The aim is to address these next working day **Burton:** Burton Hospitals 01283 511511 / 566333 ask for on-call pharmacist via switchboard Burton Rheumatology Messages can be left on the nurse advice line out of hours on 01283 511511 ext. 4112. If the advice line is not staffed, messages may be left 24 hours a day. The team aim to respond at latest within two working days. The specialist nurses may also be bleeped via switchboard for urgent enquiries.

iii. Specialist support/resources available to GP including patient information:

Rheumatology

British Society of Rheumatology Specialist website: http://www.rheumatology.org.uk/
Arthritis Research Campaign Patient Information website: http://www.arthritisresearchuk.org/arthritis-information.aspx
Versus Arthritis PIL: https://www.versusarthritis.org/about-arthritis/treatments/drugs/ciclosporin/

Dermatology: https://www.bad.org.uk/for-the-public/patient-information-leaflets/ciclosporin
Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=ciclosporin

iv. CLINICAL INFORMATION

i. Prescribed indications	**Licensed** Nephrotic syndrome Rheumatoid arthritis Psoriasis Atopic Dermatitis Organ transplantation	**Unlicensed** Systemic lupus erythematosus Scleroderma Inflammatory Bowel Disease (For patients less than 75 years) Autoimmune hepatitis
ii. Therapeutic summary	Ciclosporin is a potent immunosuppressant which is thought to act specifically and reversibly on lymphocytes. Ciclosporin blocks the amplification of certain T Cell immune responses and suppresses IL-2 synthesis and release.	
iii. Dose & Route of administration	**Nephrotic syndrome** Adult: 5 mg/kg in 2 divided oral doses. Then adjusted according to ciclosporin levels **Rheumatoid arthritis** 2.5mg/kg daily in 2 divided doses, increased if necessary up to 4mg/kg daily after 6 weeks. **Psoriasis** 1.25mg/kg twice daily (max. per dose 2.5mg/kg twice daily), increased gradually to maximum if no improvement within 1 month, initial dose of 2.5mg/kg twice daily justified if condition requires rapid improvement.	

<table>
<tr><td></td><td>Atopic Dermatitis
The recommended dose range is 2.5 to 5 mg/kg/day given in 2 divided oral doses. If this does not achieve a satisfactory response within 2 weeks, the daily dose may be increased to a maximum of 5 mg/kg.

Organ transplantation
Initially 6.5mg/kg every 12 hours then reduced to maintenance therapy of 2-6mg/kg daily in divided doses

For other indication see BNF or as per specialist advice. Doses outside the recommended range may be considered with prior agreement with the specialist team and GP involved. Lower doses should be considered for frail elderly and patients with renal impairment.

NB Ciclosporin should be prescribed by brand and formulation, regardless of the indication (to avoid variation in bioavailability), and patients kept on the same brand unless consultant decides to change. Switching between formulations without close monitoring may lead to clinically important changes in blood-ciclosporin concentration. The switch from one oral ciclosporin formulation to another should be made under specialist supervision.

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.</td></tr>
<tr><td>iv. Duration of treatment</td><td>Time to response: three months. If NO clinical response at maximum tolerated dose for 3 months, then withdraw treatment.
Rheumatology – long term if benefits outweigh risks
Dermatology
Psoriasis – maximum treatment usually 1 year unless other treatments cannot be used.
Atopic Dermatitis - Although an 8-week course of therapy may be sufficient to achieve clearing, up to 12-18months* of therapy has been shown to be effective and well tolerated, provided the monitoring guidelines are followed. *local consultant variation from SPC
Renal/GI/Liver- Indefinite but may be withdrawn after a prolonged period of disease remission in selected cases</td></tr>
<tr><td>v. Immunisation</td><td>• Live vaccinations - JCVI Green book recommends that low dose corticosteroids (prednisolone <20mg daily) and oral traditional DMARD therapy at standard doses are not a contraindication in most patients, although clinician discretion is advised. Live vaccinations may be recommended on case by case basis following consultant/ specialist advice.
• Annual flu vaccination is recommended
• One off Pneumococcal vaccination recommended unless severely immunocompromised where a different schedule is needed. See JCVI for more information.
• Patients aged 70-79 years old could be eligible for the shingles vaccine (herpes zoster). A non-live shingles vaccine is available; specialist input may be required.
• Covid-19 vaccination is safe and recommended</td></tr>
<tr><td>vi. Adverse effects

See BNF/SPC for full detail</td><td>Examples of common adverse effects with oral use (source BNF):
Appetite decreased; diarrhoea; electrolyte imbalance; fatigue; fever; flushing; gastrointestinal discomfort; gingival hyperplasia; hair changes; headaches; hepatic disorders; hyperglycaemia; hyperlipidaemia; hypertension; hyperuricaemia; leucopenia; muscle complaints; nausea; paraesthesia; peptic ulcer; renal impairment (renal structural changes on long-term administration); seizure; skin reactions; tremor; vomiting

<table>
<tr><td>Adverse effects</td><td>Action for primary care</td></tr>
<tr><td>Infection requiring antibiotics</td><td>During serious infections temporarily withhold ciclosporin until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.</td></tr>
<tr><td>Gum hypertrophy (gingival hyperplasia)</td><td>Discuss with specialist team</td></tr>
<tr><td>Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, purpura, mouth ulcers.</td><td>Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.</td></tr>
</table>

The patient should be advised:
• 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.</td></tr>
</table>

	• 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.
vii. Monitoring Requirements	**<u>Before commencing immunosuppressant therapy</u>** **Consultant/specialist responsibilities** • Record blood pressure, and height and weight if clinically indicated. • Screening for lung disease should be undertaken at clinician discretion on a case-by-case basis. The extent of screening should be influenced more by a patient's clinical features and risk factors for lung disease (e.g. underlying autoimmune disease or smoking history) rather than subsequent immunomodulating choice. Pre-existing lung disease should not be considered an absolute contraindication to any immunomodulating medication. • Screen for viral hepatitis B&C and HIV in patients at increased risk of infection • Investigate patient medical history including co-morbidities and previous immunomodulating medication use. • Consider baseline pregnancy testing, if clinically appropriate **Consultant/specialist monitoring schedule** **Ciclosporin levels, where appropriate remain under the hospitals' responsibility** Baseline and 2 weekly until on a stable dose for at least 6 weeks, then monthly • Blood pressure • Glucose monitoring – HbA1c (only 1 test required during titration & 3month period) • FBC • U&E including creatinine clearance; serum magnesium at baseline • ALT and/or AST and albumin, bilirubin • Serum lipids and uric acid at baseline and after 1 month Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist. 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 serum creatinine and BP. For rheumatology patients CRP/ESR may be done every 3 months (this is not done for dermatology patients). These tests are part of the assessment of the underlying rheumatic disease rather than a requirement for monitoring of immunomodulating therapy. The monitoring CRP/ESR may be coordinated between secondary and primary care on an individual basis. **GP responsibility monitoring schedule** In patients following at least 6 weeks of dose stability, conduct **monthly monitoring thereafter** for duration of treatment • Blood pressure • Glucose monitoring – HbA1c (3 monthly) • FBC • U&E including creatinine and CrCl • ALT and/or AST and albumin, bilirubin Patients who have been stable for 12 months can be considered for reduced frequency of monitoring on an individual patient basis. Monthly monitoring has been locally agreed. Longer interval monitoring is by exception liaising directly with consultant **<u>6 monthly</u>**: Serum lipids, uric acid, serum magnesium **<u>Dosage increase</u>** For dose **<u>increase</u>**, monitor 2 weekly until stable for 6 weeks. Dose and monitoring to be agreed with consultant. GP's to then continue monthly monitoring thereafter • Blood pressure • Glucose monitoring - HbA1c • FBC • U&E including Creatinine and CrCl • ALT and/or AST and albumin, bilirubin

Actions to be taken in Primary care

1. Immunosuppressants prescribed to prevent transplant rejection should not be stopped without discussion with a member of the specialist team.
2. In addition to responding to absolute values in laboratory tests, it is also relevant to observe trends in results (e.g gradual decreases in white blood cells (WBC) or albumin, or increasing liver enzymes)
   NB – a rapidly increasing or decreasing trend in any value should prompt caution irrespective of actual value.
3. Parameters below are to be used as a guide for clinicians rather than absolute values, where monitoring should be based on individualized basis. It is important to consider alternative explanations other than the immunomodulation agents, especially in patients who have been stable for prolonged periods

FBC WBC <3.5 x10^9 /l Lymphocytes <0.5 x10^9 /l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Eosinophilia > 0.5x10^9	Discuss **urgently** with specialist team and consider interruption* Isolated low lymphocytes more likely to be due to disease or other factors- GP to consider non-drug related causes (contact specialist for advice if unsure). The specialist may advise on individual cases if the abnormality is thought to be due to other factors and in this instance may set differential parameters which can be communicated to the GP.
Mean cell volume >105 f/l	Withhold and check **serum B12, folate & TFT** and alcohol history. Discuss with specialist team.
LFT ALT and/or AST >100 U/I, or any sudden increases (e.g. double of baseline); Unexplained fall in albumin <30g/I, jaundice	Contact Specialist **urgently** and consider interruption* Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
Renal function Creatinine increase >30% over 12 months and/or CrCl <60ml/min	Contact Specialist **urgently** and consider interruption*
Hyperkalaemia	Review other medicines affecting potassium levels, e.g. ACE inhibitors, diuretics. Discuss with specialist team.
Hypomagnesaemia	See shared care pathology guideline
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 ≥140/90 mmHg on two consecutive occasions two weeks apart	Manage hypertension according to local pathways. Care should be taken to avoid drugs which may interact. 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

*Treatment is not to be stopped if being prescribed for transplant related indications

When restarting treatment after an abnormality has been detected repeat bloods in 2 weeks and then monthly monitoring. Following this resume monitoring frequency to what it was prior to the abnormality.

viii. Contraindications and cautions

Contraindications

- Hypersensitivity to ciclosporin or any excipients
- Malignancy
- Uncontrolled hypertension
- Suspected serious infection (requiring IV antibiotics or hospitalization) treatment should be discontinued.
- 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

Cautions:

- Hepatic impairment
- Elderly; monitor renal function particularly closely
- Renal impairment
- 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. • 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. • 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 • All oral dosage forms of ciclosporin contain a form of ethanol • 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.
ix. Clinically relevant drug interactions For a full list of interactions please refer to the BNF	**Ciclosporin is associated with a large number of interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring.** • ***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 increases 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.
x. Pregnancy, paternal exposure and breastfeeding	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. The specialist should reassume prescribing responsibilities if a woman becomes or wishes to become pregnant. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed. Pregnancy: 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 as a consequence of the pharmacokinetic changes which may be associated with pregnancy. All oral dosage forms of ciclosporin contain a form of ethanol. 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. All oral dosage forms of ciclosporin contain a form of ethanol. Information for healthcare professionals: https://www.sps.nhs.uk/medicines/ciclosporin/ Paternal exposure: Based on limited evidence, ciclosporin is compatible with paternal exposure. Fertility There is limited data on the effect of ciclosporin on human fertility.
xi. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. **To be read in conjunction with the following documents** • RMOC Shared Care Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
xii. Supply of ancillary equipment	Not applicable

xiii. **Supply, storage and reconstitution instructions**	Not applicable
Prepared by	The Shared Care Guidelines Group; Derby Hospitals; Chesterfield Royal Hospital Derbyshire Medicines Management Clinical Effectiveness Team
In consultation with	Dr Badcock, ACD Consultant Rhuematologist UHDB Dr R Laxminaryan, Deputy ACD Rheumatology UHDB Dr. K Fairburn, Consultant rheumatologist CRH Angela Lawrence, Rheumatology Lead Clinical Nurse Specialist CRH Kath Phillis, Advanced Clinical Nurse Specialist IBD CRH The Derbyshire Medicines Management Shared Care and Guidelines Group
Reviewed (2023)	In line with In line with NHSE/ RMOC Shared Care Protocols- Ciclosporin (oral) for patients within adult services (non-transplant indications), July 2022. https://www.england.nhs.uk/publication/shared-care-protocols/ The Derbyshire Medicines Management Shared Care and Guidelines Group

This does not replace the SPC, which should be read in conjunction with it

Date Prepared: October 2011 **Reviewed:** August 2023 **Review Date**: July 2026

References

1. NHSE/RMOC National shared care protocol- Ciclosporin (oral) for patients within adult services (non-transplant indications) 4 July 2022, Version 1
2. British National Formulary accessed online July 2023
3. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, The British Society for Rheumatology, February 2017
4. The Green book, Immunisation against infection disease, September 2017, accessed online sept 2019, July 2023

Sample Transfer Letter

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_POSTCODE»

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable): **See overleaf for initiation criteria.**		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
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	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care*)
* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
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 patients 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 in order 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 in order 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 in order 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)**	

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

{GP name}
{Surgery}

Please send a copy of this response to the specialist/consultant requesting shared care