DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Ciclosporin for patients 16+ years

i. 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.

ii. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant responsibilities
1. If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1) **2.** Ensure compatibility with other concomitant medication. **3.** Prescribe the dose and formulation recommended by consultant. **4.** Perform monitoring tests as specified in section vii. **5.** Adjust the dose as advised by the specialist. **6.** Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arise. **7.** 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 vi **8.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme	**1.** Discuss the possible benefits and side effects of treatment with the patient. **2.** Perform baseline tests (as recommended in section vii) **3.** 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.** Ensure that clear backup arrangements exist for GPs to obtain advice and support. **9.** Report any adverse effects to the MHRA yellow card scheme and GP **10.** Advise on the suitability for e.g. herpes zoster vaccination in accordance with national screening programme **11.** 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.
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. • 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 table in section vii for information.	

iii. 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-4:30pm, Friday 9am- 12:30pm IBD advice line 01246 512884 (answerphone) GP mobile contact 07717700489	**Chesterfield:** Contact the on-call Medic for the relevant speciality via switchboard: 01246 277271

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** Consultant/specialist nurse 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) IBD Nurse Specialist bleep: 590 Dhft.ibdcnc@nhs.net	**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/

iv. CLINICAL INFORMATION

i. Prescribed indications	**Licensed** Rheumatoid arthritis Psoriasis Organ transplantation Nephrotic syndrome Atopic Dermatitis	**Unlicensed** Inflammatory Bowel Disease (For patients less than 75 years) Scleroderma Systemic lupus erythematosus Autoimmune hepatitis
ii. Therapeutic summary	Ciclosporin blocks the amplification of certain T Cell immune responses and suppresses IL-2 synthesis and release. Time to response: three months. If NO clinical response at maximum tolerated dose for 3 months, then withdraw treatment.	
iii. Dose & Route of administration	**Organ transplantation** Initially 6.5mg/kg every 12 hours then reduced to maintenance therapy of 2-6mg/kg daily in divided doses **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. **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. 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 (to avoid variation in bioavailability) and patients kept on the same brand unless Consultant decides to change.
iv. Duration of 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
v. Adverse effects See BNF/ SPC for full details	Examples of common adverse effects: Anorexia GI disorders – nausea, diarrhoea and vomiting Electrolyte imbalance Gingival hyperplasia (gum hypertrophy) Hirsutism Hyperlipidaemia Hypertension, flushing Leucopenia Renal dysfunction, hepatic disorders Tremor, headache and paraesthesia Myalgia, muscle cramps
vi. Immunisation	• **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
vii. Monitoring Requirements	**Consultant/specialist responsibilities** Best practice recommends the following precautions for specialists before commencing immunosuppressant therapy: • 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 imunomodulating medication. • Glucose monitoring – HBA1C • 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. 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. **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 • FBC • ALT and/or AST and albumin • U&E including Creatinine/ calculated GFR • Blood pressure • Glucose monitoring – HBA1C (only 1 test required during titration and 3 month

period)

Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist.

GP responsibility monitoring schedule
In patients following the 6 weeks of dose stability, conduct **monthly monitoring thereafter** for duration of treatment

- FBC
- ALT and/or AST and albumin
- U&E including Creatinine/ calculated GFR
- Blood pressure
- Glucose monitoring – HBA1C (3 monthly)

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

Actions to be taken

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)
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

WBC <3.5 x10^9 /1	Contact Specialist **urgently** and consider interruption*
Neutrophils <1.6 x 10^9/l	Contact Specialist **urgently** and consider interruption*
Platelets <140 x 10^9/l	Contact Specialist **urgently** and consider interruption*
ALT and/or AST >100 U/l	Contact Specialist **urgently** and consider interruption*
Unexplained fall in albumin <30g/l	Contact Specialist **urgently** and consider interruption*
Mean cell volume >105 f/l	Withhold and check **serum B12, folate & TFT** and discuss with specialist team.
Creatinine increase for example >30% over 12 months and/or calculated GFR <60ml/min/1.73m²	Contact Specialist **urgently** and consider interruption*
Drug specific	
Abnormal bruising	Immediate FBC & withhold until the result is available.
CRP/ESR	*Measured to allow disease activity evaluation*
Blood Pressure ≥140/90mmHg on two consecutive occasions two weeks apart	Treat hypertension before stopping the ciclosporin. If BP cannot be controlled, stop ciclosporin and obtain BP control before restarting. Also ***discuss with specialist team.***

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

Note: specific monitoring of eosinophil counts has been removed, as historically eosinophilia was an important marker for identifying toxicity from only gold therapy. This has been agreed with local specialists.

NB – a rapidly increasing or decreasing trend in any value should prompt caution irrespective of actual value.

<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

- FBC
- ALT and/or AST and albumin
- U&E including Creatinine/ calculated GFR
- Blood pressure
- Glucose monitoring - HBA1C

GP's to then continue monthly monitoring thereafter

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. Clinically relevant drug interactions **For a full list of interactions please refer to the BNF**	**Ciclosporin interacts with a wide range of medicines; please refer to the BNF for details. Noted below are a few of the common interactions:-** • Amiodarone, digoxin • Calcium Channel Blockers • Clarithromycin, erythromycin, azole antifungals, rifampicin • Carbamazepine, phenytoin • Colchicine • Dabigatran, edoxaban • Lipid regulating drugs • NSAID – diclofenac dose should be reduced by 50% • Potassium sparing diuretics • St Johns Wort • Grapefruit juice Herbal/Complimentary medications are not recommended when taking Ciclosporin due to interactions.
ix. Contraindications and cautions	**Contraindications** • Abnormal renal function • Malignancy • Uncontrolled hypertention • Suspected serious infection (requiring IV antibiotics or hospitalization) treatment should be discontinued. Pregnancy & breastfeeding- Manufacturer advises avoid unless potential benefit out weights risk Seek specialist advice **Cautions:** • Grapefruit Juice • Patients with poor respiratory reserve • Patients with clinically significant renal impairment from any cause • Localised or systemic infection including hepatitis B or C and a history of TB. • Appropriate to continue with therapy in patients with minor infections (EG. Uncomplicated urinary tract infections treated with a short course of antibiotics) seek advice from specialist • Unexplained anaemia and/or cytopenia associated with marrow failure. • Patients with deranged liver biochemistry or synthetic function • Patients with Chronic Kidney disease
x. Supply of ancillary equipment	Not applicable
xi. Supply, storage and reconstitution instructions	Not applicable
Prepared by **Reviewed by** **In consultation with (2019)**	The Shared Care Guidelines Group Derby Hospitals Chesterfield Royal Hospital Derbyshire Medicines Management Clinical Effectiveness Team 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

References

1. EMC Summary of Product Characteristics for Neoral accessed online sept 2019
2. British National Formulary accessed online sept 2019
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

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_ADDRESS_3»
«GP_ADDRESS_4»
«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_ADDRESS_3»
«CURRENT_ADDRESS_4» «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