Frimley Health Area Prescribing Committee

Frimley Health NHS Foundation Trust
North East Hampshire and Farnham CCG
East Berkshire CCG
Surrey Heath CCG
Chiltern CCG

SHARED CARE Guideline – Amber Traffic Light Classification	
Name of medicine	**Ciclosporin** (Oral)
Indication (for adults)	**Licensed:** Rheumatoid Arthritis **Unlicensed:** Psoriatic Arthritis, Other Connective Tissue Diseases
Author(s): Amit Sahni(Rheumatology and Biologics Pharmacists) Abigail Saffer (Rheumatology and Biologics Pharmacists) Jenny Watkins (Rheumatologist) *Alexandra Hicks – (Pharmacist) Updated March 2019* **Organisation(s):** Frimley Health NHS Foundation Trust	
Date ratified by Frimley Health APC (FH APC):	February 2018
Review Date	July 2021

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.
The SCG must be used in conjunction with the agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

- Diagnosis and assessment of suitability for ciclosporin treatment
- Discuss the aims, benefits and side effects of treatment with the patient
- Explain to the patient their treatment plan including the dosing schedule
- Pre-treatment assessment and initial monitoring as detailed in monitoring table below
- In patients with psoriatic arthritis: check for previous treatment with PUVA and discuss with dermatologist
- Prescribe and monitor ciclosporin until shared care in place
- Discuss shared care with the patient and ensure they understand the plan for treatment
- Agree shared care with the patient's general practitioner (GP)
- Review results of pre-treatment assessment
- Monitor disease response to treatment and need to continue therapy
- Continue to review patient at agreed specified intervals and send a written summary to the GP when patient is reviewed
- Advise GP if treatment should be discontinued at any point
- Inform GP if patient does not attend follow-up appointments

Primary Care Prescriber

TEMPLATE VERSION CONTROL **Template**		**Adapted from the Prescribing Clinical Network**
Reason for Update or New: New		Author: PCN
Valid from: July 2019	Review date: July 2021	Approved by: FH APC
Version: 1	Supersedes version: N/A	

- Return the shared care agreement to the consultant, to indicate agreement with this guideline. If for any reason the GP is unhappy with the arrangements they should contact the named hospital specialist within 14 days
- If the notification form is not received within 14 days, the hospital team will assume compliance with the shared care guidance
- Prescribe ciclosporin as specified by the consultant
- An annual influenza vaccine should be given, and a pneumococcal vaccine should be given preferably before starting the DMARD. Pneumococcal vaccine should be repeated at 10-yearly intervals if given before starting the DMARD, or at 5-yearly intervals if given after starting the DMARD
- Arrange on-going monitoring as specified below, ensuring practice systems are in place to recall patients for monitoring blood tests
- Prevent on-going prescription if patient is not compliant with monitoring and report back to consultant
- Report any adverse drug reactions to the initiating specialist and the usual bodies (e.g. MHRA/CHM)
- Ensure no drug interactions with other medicines (see SPC/BNF for further details)
- Monitor patients overall health and wellbeing
- Report adverse effects to the Consultant

Patient Relatives & Carers
As listed in agreed core roles and responsibilities for the shared care of medicines – annex A

Key information on the medicine
Please refer to the current edition of the British National Formulary (BNF), available at https://bnf.nice.org.uk/ and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication
Ciclosporin is a disease modifying anti rheumatic drug and potent immunosuppressant used in inflammatory arthritis and other types of connective tissue diseases. Ciclosporin should only be initiated on the recommendation of a Rheumatologist.

Ciclosporin must be prescribed as Neoral. This formulation allows greater predictability and consistency than other preparations.

Indication
- Inflammatory Arthritis
- Psoriatic Arthritis
- Connective Tissue Disease

Dosage and Administration
Include only where no SPC is available, i.e. for unlicensed /off-label use, and in line with approved use as per FH formulary

Monitoring *(Reference: BSR and BHPR guideline 2017 https://doi.org/10.1093/rheumatology/kew479)*

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: • Height, weight • Blood pressure if >140/90 treat hypertension before starting ciclosporin • Full blood count, creatinine/calculated GFR, liver function tests (ALT and or/AST), albumin • Glucose	Consultant
Initiation: • Weight and height of patient – dose based on ideal body weight • Check blood pressure (BP) • Glucose, FBC, creatinine/calculated GFR, liver function tests (ALT and/or AST) and albumin every 2 weeks until on stable dose for 6 weeks then can increase monitoring interval to monthly.	Consultant
Maintenance:	GP

• BP, glucose, FBC, creatinine/calculated GFR, liver function tests (ALT and/or AST) and albumin every month. • If patient is considered at higher risk of toxicity, can reduce monitoring interval (to be discussed with consultant) • Once stable for 12 months, can consider increasing monitoring interval if appropriate (to discuss with consultant)	
If dose change when on maintenance: • Dose changes should be monitored by full blood count, creatinine/calculated GFR, liver function tests (ALT and or/AST), albumin every 2 weeks until on stable dose for 6 weeks, then revert back to previous schedule.	GP

Abnormal results – Actions to be taken

Test	Abnormal Result	Action if Abnormal Result
WBC	< 3.5 X 10^ 9 /l	Urgently consider interruption in treatment and repeat WBC, if normal continue, otherwise contact rheumatology team
Neutrophils	< 1.6 X10^9/l	Contact rheumatology team and urgently consider interruption in treatment.
Eosinophils	>0.5 x10^9/l	Contact rheumatology team and urgently consider interruption in treatment.
Platelets	<140 X10^9/l	Contact rheumatology team and urgently consider interruption in treatment.
Liver function	ALT and/or AST >100IU/l	Contact rheumatology team and urgently consider interruption in treatment. Transaminase increase 2 X normal is common within 2 days of drug administration. Consider rechecking ALT/AST at trough level.
MCV	> 105 fl	Check folate, TFT, B12. If B12 or folate low, start appropriate supplementation Contact rheumatology team and urgently consider interruption in treatment.
Renal Function	Creatinine increase >30% over 12 months and/or calculated GFR <60ml/min	Contact rheumatology team and urgently consider interruption in treatment. Consider increasing frequency of monitoring in patients with mild-moderate renal impairment.
Albumin	Unexplained fall in albumin <30g/l (in absence of active disease)	Contact rheumatology team and urgently consider interruption in treatment.
Blood pressure	>140/90 on 2 consecutive readings 2 weeks apart	If hypertension is not controlled by anti-hypertensive ciclosporin should be stopped. Discuss with specialist team.
Please note that in addition to absolute values for haematological indices a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.		

Cautions, contraindications:
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects and action to be taken (if appropriate):
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Support and Advice Contact Details for Primary Care Prescribers:

Name	Speciality	Telephone No.	Email address
Janet Lartey Mona Pandit	Rheumatology Clinical Nurse Specialists for Wexham Park Hospital	01753 633 299	Janet.lartey@nhs.net Adedamola.ige@nhs.net Mona.pandit@nhs.net
Jeannette Cameron Rosealeen Kilick	Rheumatology Clinical Nurse Specialist for Frimley Park Hospital	01276 604 348	Jeannette.cameron@nhs.net Rosealeen.kilick@nhs.net
Alex Hicks	Rheumatology and Biologics Pharmacist for Wexham Park Hospital	01753 633 285	alexandra.hicks@nhs.net
Sandra Smith	Rheumatology and Biologics Pharmacist for Frimley Park Hospital	01276 604 348	Sandra.smith4@nhs.net
Out of Hours	Medical Team on call	Frimley Park Hospital 01276 604 604 Wexham Park Hospital 01753 633 000	N/A

Annex A: Agreed core roles and responsibilities for the shared care of medicines

Patients
To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. • You must make sure that you understand about your treatment • If you do not understand ask for more information from the person prescribing the medicine • Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication • You must raise any concerns about your treatment with the person prescribing the medicine • Talk to the specialist and come to an agreement of how the treatment should be provided to you • Give permission to have aspects of your care communicated to healthcare providers • You must attend all appointments • You must keep a written list of all of the medicines you are taking • You must keep lists of any additional vitamins, minerals, or other dietary supplements • You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital • You must carry these lists on you in case of an emergency • You must not let anyone else take your medication. It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit: www.gov.uk/government/publications/the-nhs-constitution-for-england
Relatives and Carers
• To support the patient in fulfilling their roles and responsibilities as outlined above.
Consultant/ Specialist
Good Prescribing Guidelines • Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC). • Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. • Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the Frimley Health Foundation Trust Area Prescribing Committee with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care. • Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the Frimley Health Formulary. • Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley Health Foundation Trust Area Prescribing Committee. **Before initiating treatment** • Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions. • Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences • Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment. • Undertake baseline monitoring and assessment. **Initiating and continuing treatment in secondary care** • Prescribe initial treatment and provide any associated training and counselling required. • Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record

- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the Frimley Heath Area Prescribing Committee as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation's Frimley Health Foundation Trust Area Prescribing Committee representative who will facilitate an update at the Committee.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Frimley Health Foundation Trust Formulary

For the attention of the Practice Manager

E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To: [Recipient Name]
From: [Your Name]
Re: [Subject]
cc: [Name]

Date: [Click to select date]
Pages: [number of pages]

[Notes]

Name of medicine	Ciclosporin
Indication	Inflammatory arthritis, psoriatic arthritis, connective tissue disease

Person receiving	
Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	Yes/ No
If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	
Discharge letter written and sent:			
Please refer to the Frimley Health Foundation Trust Formulary for relevant shared care documents.			

Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient