THE SHEFFIELD AREA PRESCRIBING GROUP

Shared Care Protocol

For

Mycophenolate Mofetil Tablets in Adult Patients

Shared care developed by:

Sharron Kebell, Senior Pharmacist - High-cost Drugs SY ICB
Karen Guymer, MOT Pharmacist, NHS Sheffield CCG
Dr James Maxwell, Consultant Rheumatologist, STHFT
Nikki Newell, Specialist Rheumatology Nurse, STHFT

Date approved: February 2021
Date Amended: April 2026

Review Date: February 2026

Shared Care Protocol for Mycophenolate Mofetil (MMF)

Statement of Purpose

This shared care protocol (SCP) has been written to enable the continuation of care by primary care clinicians of patients initiated on MMF by the rheumatology / nephrology department, STHFT, where this is appropriate and in the patients' best interests. Primary care will only be requested to take over prescribing of MMF for off label indications, listed below. Users should be aware that this document is guidance on the management of a condition, not a commissioning arrangement.

Responsibilities of specialist clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent, in line with national guidance. This is particularly important as the indications for use under the SCP are off label
- To provide patient / carer with contact details for support and help if required; both in and out of hours
- To provide advice on the need for contraception to male and female patients on initiation and at each review
- To carry out pre-treatment tests including pregnancy tests, if applicable
- To initiate MMF in appropriate patients and issue with patient information leaflet and counsel on contraceptive advice, if applicable
- To prescribe until patient ready for 3 monthly monitoring
- To report any serious adverse reaction to the appropriate bodies eg: MHRA and to the patient's primary care clinician
- To contact patient's primary care prescriber to request prescribing and monitoring under shared care using the Shared Care Transfer Form and send a link to or copy of the shared care protocol.
- To advise the primary care prescriber regarding continuation of treatment, including the duration of treatment
- To discuss any concerns with the primary care prescriber regarding the patient's therapy
- To monitor disease appropriately whilst the patient is under shared care
- The patient to normally remain under the specialists' care until the point of stopping MMF

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- Confirm the agreement and acceptance of the shared care prescribing arrangement by returning completed shared care transfer form to relevant department
- To contact the requesting specialists if concerns in joining in shared care arrangements,
- To provide ongoing advice on the need for contraception to male and female patients
- To report any serious adverse reaction to the appropriate bodies eg: MHRA and the referring specialist
- To continue to prescribe for the patient as advised by the specialist
- Ensure monitoring as indicated in monitoring section below
- To inform the specialist if the patient discontinues treatment for any reason

- To seek the advice of the specialist if any concerns with the patient's therapy
- To conduct an annual medication review with patient or more frequent if required.
- In the event that the primary care prescriber is not able to prescribe, or where the SCP is agreed but the specialist is still prescribing certain items e.g. Hospital only product; the primary care prescriber will provide the specialist with full details of existing therapy promptly by a secure method on request.
- For medication supplied from another provider prescribers are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems

Responsibilities of Patients or Carers

- To be fully involved in, and in agreement with, the decision to move to shared care
- To attend hospital and primary care clinic appointments and to bring monitoring information eg: booklet (if required). Failure to attend will potentially result in the medication being stopped.
- Present rapidly to the primary care prescriber or specialist should their clinical condition significantly worsen or they develop unexplained bruising, bleeding, fever or sore throat
- Report any suspected adverse effects to their specialist or primary care prescriber whilst taking MMF
- To read the product information given to them
- To take MMF as prescribed
- Inform the specialist, primary care prescriber and community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.
- To take responsibility for appropriate contraceptive precautions, where applicable, and to consult their physician immediately should pregnancy occur

Indication

MMF is licensed for prophylaxis of acute rejection in renal, cardiac and hepatic transplant recipients in combination with other agents. Whilst unlicensed for other indications, it is used extensively in an off label manner by rheumatologists in the treatment of connective tissue disease, and in particular SLE, for which there is strong evidence of efficacy in lupus nephritis in particular. Please note patients are managed in a jointly run clinic for SLE & polyarteritis nodosa, involving both rheumatologists and nephrologists.

Mycophenolate in scleroderma NICE Evidence Summary
https://www.nice.org.uk/advice/esuom32/chapter/Key-points-from-the-evidence

Mycophenolate in SLE NICE Evidence Summary
https://www.nice.org.uk/advice/esuom36/chapter/key-points-from-the-evidence

Selection of patients

Adult rheumatology patients with connective tissue disease treated and stabilised on mycophenolate by a secondary care specialist.

Dosage

Starting dose 500mg twice daily in week one, increasing gradually over a few weeks to 1g twice daily. If there is gastric intolerance consider giving as 500mg four times a day. If required a maximum dose of 3g daily can be used.

If eGFR is < 25ml/min/1.73m$_2$, doses should NOT exceed 1g twice a day.

It is recommended that MMF is only prescribed as generic 500mg tablets as these are more cost effective than the 250mg capsule formulation.

Please note the 180mg / 360mg gastro-resistant mycophenolic acid tablets (Myofortic® and Ceptava®) which are used by the renal physicians are NOT dose equivalent to the 500mg MMF tablets and are excluded from this shared care protocol.

Contra-indications

The details below are not a complete list and the BNF and the SPC remain authoritative

Pregnancy - MMF has the potential to affect the development of the unborn child. Mycophenolate is contraindicated during pregnancy or breastfeeding. Patients or partners of treated male patients should be referred urgently to the specialist if become pregnant or are planning to become pregnant or breastfeed.

- **Female patients of childbearing potential** must be using reliable and highly effective contraception before, during and for six weeks after stopping treatment. See link for more details: Medicines with Teratogenic Potential

  Before starting mycophenolate mofetil treatment, people of childbearing potential should have a negative pregnancy test. Two serum or urine pregnancy tests with a sensitivity of at least 25 mIU/mL are recommended. A second test is advised 8-10 days after the first one and immediately before starting mycophenolate mofetil, unless exceptional circumstances exist whereby a delay in the initiation of treatment would cause harm to the patient and the prescriber is satisfied that a single test is adequate to rule out pregnancy. Pregnancy tests should be repeated as clinically required (e.g. after any gap in contraception is reported). See MHRA Drug Safety Update for more detail. **The specialist will determine the child bearing potential.**

- **Male patients** Limited evidence does not indicate an increased risk of malformations or miscarriages in pregnancies where the father is taking mycophenolate. However, mycophenolate is genotoxic, and the risk cannot be fully excluded. It is therefore recommended that male patients or their female partners use reliable contraception during treatment, and for at least 90 days after stopping mycophenolate. See MHRA Drug Safety Update: Mycophenolate mofetil, mycophenolic acid, updated contraception advice for male patients (Feb 2018)

Breast feeding-Because of the potential for serious adverse reactions to MMF in breast-fed infants, MMF is contraindicated in nursing mothers

Hypersensitivity to the parent compound or metabolites.

Side –effects

The details below are not a complete list and the BNF and the SPC remain authoritative

- **Gastrointestinal disturbances** e.g. diarrhoea, gastritis, nausea, abdominal discomfort, vomiting and constipation; GI side effects may be transient
- **CVS effects**: hypertension, oedema and tachycardia
- **CNS effects**: headache, insomnia, anxiety
- **Metabolic effects**: increased glucose, increased cholesterol
- **Infections:** increased risk (viral, bacterial and fungal)
- **Increased blood creatinine**
- **Blood dyscrasias** - leucopenia, anaemia and thrombocytopenia

Monitoring

Secondary Care
Baseline assessment: pregnancy test (if clinically indicated), height, weight and blood pressure
Baseline blood tests: FBC, extended LFTs, U&E, eGFR, CRP, lipids
Then every 2 weeks until on stable dose for 6 weeks;
Once on stable dose monthly for 3 months, then every 3 months

Primary Care
FBC, extended LFTs, CRP, U&Es and eGFR three monthly
GPs will only be asked to take on shared care when patients are considered stable and ready for 3 monthly monitoring.

Remind patients to report any abnormal bruising, dyspnoea, cough, fever, and presence of oral ulceration or sore throat at each monitoring visit.
Specialist will advise GPs regarding any changes in monitoring if doses are increased

Caution needed:
If CRP is significantly and persistently raised above what is normal for that patient, the first step is to consider infection, and ask the patient about a flare in symptoms of their disease. If infection is present, this should be treated and blood tests then repeated. If there is no apparent explanation for the elevated CRP, this should be repeated a few weeks later, and if remains unchanged or higher, the secondary care team should be contacted.

Falling trend in WBC or platelets over 3 counts

Stop MMF and contact helpline (see below) if:
WBC <3.5 x 10^9/L
Neutrophils <1.6 x 10^9/L *Please note for rheumatology patients with SLE low WBC, lymphocyte, neutrophil and platelet counts may be a manifestation of the SLE. If low counts are new, please contact rheumatology department within 48 hours for advice. If previously known, please follow advice in clinic* letters
ALT and /or AST >100U/L
Platelet count <100 x 10^9/L
eGFR <40 ml/min/1.73m^2
Patient becomes pregnant, see pregnancy and breastfeeding sections above
Overdose - contact secondary care
Non compliance with monitoring

In the event of the following abnormalities, MMF can be continued, but tests repeated within 2-3 weeks and then seek advice from department initiating MMF if the abnormality is persistent.
eGFR < 50 (but above 40) ml/min/1.73m^2
Unexplained eosinophilia >0.5x10^9/L
Lymphocytes < 0.5x10^9/L
MCV>105fL: check B12, folate and thyroid function - if abnormal prescribe as appropriate
Platelet count <130 (but >100) x 10^9/L
Unexplained reduction in albumin <30g/L
ALT and or AST 70-100 U/L (consider recent flu vaccination i.e. within the last 2-3 weeks, as possible cause)
Unexplained bruising / bleeding, fever, sore throat with oral or pharyngeal ulceration

The monitoring arrangements above differ from those specified in the SPC which describes the use of MMF in licensed indications.
The STHFT rheumatologists have developed and amended the monitoring arrangements described in the BSR (the national guidelines for rheumatology), to advise primary care prescribers on how to respond to different monitoring values and when to seek advice from secondary care specialists.

Infections
In the event of a patient developing an infection requiring antibiotic treatment, check FBC and CRP and withhold mycophenolate for the duration of antibiotic treatment.

Interactions

The details below are not a complete list and the current BNF and the SPC remain authoritative.

- Absorption of mycophenolate reduced by antacids, colestyramine, metronidazole, norfloxacin, and sevelamer
- Mycophenolate level reduced by rifampicin
- Mycophenolate increases plasma concentration of aciclovir and ganciclovir
- Mycophenolate level increased by aciclovir
- Vaccines may be less effective in immunocompromised patients – see Additional information below and the Green book

Additional information

- Live vaccines, e.g. rubella, BCG, small pox, yellow fever, etc., should not be given to patients taking MMF (refer to Green book for further advice on vaccines).
- Patients on MMF for the management of inflammatory conditions may not be sufficiently immunosuppressed to contraindicate administration of Zostavax® (shingles vaccine). The degree of immunosuppression should be assessed on a case by case basis. Practitioners should refer to the latest edition of the Green Book Chapter 28a for advice. If clinicians administering the vaccine have concerns about the degree of immunosuppression they should contact the relevant specialist.
- Pneumococcal polysaccharide vaccine, annual inactivated flu and COVID -19 vaccines should be given.
- Advise patients to avoid exposure to sunlight and UV light with protective clothing and a high protection sunscreen. Encourage OTC vitamin D supplementation, as per national advice.

Re-Referral guidelines

See under monitoring section above.
Pregnancy and / or preconception advice / management
Deterioration of disease

Financial implications

If mycophenolate is issued under the shared care arrangements then drug costs will move from secondary to primary care. In primary care mycophenolate will be issued on FP10 prescriptions. Outpatient appointments at STHFT will be reduced, but there will be an increase in payments to GPs under the DMARD Local Commissioned Service.

Contacts for Support, education and information

A drug information sheet and shared care booklet has been issued to your patient.

If any problems occur or you have any concerns please contact relevant specialist:
Rheumatology help line (Mon-Fri 0900-1600) **(0114) 2713086 (option 3)**

On call specialist via STH NHS FT switchboard: (0114) 2711900

Alternatively, messages can be sent to this advice line: Sth.ropd@nhs.net ; health care professionals should use a secure email e.g. an nhs.net address.

Nephrology Department (01142715326)

Patient information leaflets
These are provided to patients by secondary care, but can also be downloaded here

https://www.versusarthritis.org/about-arthritis/treatments/drugs/mycophenolate

Amendment May 2024: added contact details of nephrologists as patients are managed in a jointly run clinic for SLE & polyarteritis nodosa, involving both rheumatologists and nephrologists.
Amendment April 2026: by Sharron Kebell, Senior Pharmacist High- cost drugs, and Dr Ruth Smith, Consultant Rheumatologist, STHT: added latest pregnancy – prevention advice for women and men.

References

British Society for Rheumatology (BSR) guideline for the prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs(opens in a new tab) **(2025)**

Mycophenolate in scleroderma NICE Evidence Summary
https://www.nice.org.uk/advice/esuom32/chapter/Key-points-from-the-evidence

Mycophenolate in SLE NICE Evidence Summary
https://www.nice.org.uk/advice/esuom36/chapter/key-points-from-the-evidence

Yorkshire Rheumatology Regional DMARD guidelines, 7th edition, March 2019 link

BNF https://www.medicinescomplete.com/mc/bnf/current/

Mycophenolate mofetil summary of product characteristics (SPC)
https://www.medicines.org.uk/emc/

https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

Mycophenolate mofetil, mycophenolic acid: a new pregnancy- prevention advice for women and men
MHRA Drug Safety Update **(2015)**

Mycophenolate mofetil, mycophenolic acid: updated contraception advice for male patients
MHRA Drug Safety Update **(2018)**

Mycophenolate Risk Minimisation guide

BSR Guideline on Pregnancy-and-breastfeeding-prescribing DMARDs **(note: under review April 2026)**