SHARED CARE AGREEMENT

Name of medicine	Mycophenolate mofetil (MMF) & mycophenolic acid (MPA)
Indication	For use in solid organ transplant adult patients

Version: **4.0** Approval date: **December 2023** Review date: **December 2026**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and Responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Monitoring of full blood counts with communication of these results to the GP.
- If a dose change is necessary then this is communicated to the patient immediately by telephone with additional written confirmation. The letter informing of the dose change is also sent to the GP.
- Frequency of follow up will depend on transplant type and time from transplant.
- Providing the patient with advice on contraception.
- Patient education is the responsibility of the specialist team. The relevant patient information leaflets for Mycophenolate Mofetil and Mycophenolic acid can be found at www.medicines.org.uk.

General Practitioner and primary care non-medical prescribers

- Prescribing of mycophenolate therapy as recommended by consultant from Transplant Unit. Please note there are a number of different preparations available and they do not need to be prescribed by brand name. Mycophenolate mofetil and mycophenolic acid are not interchangeable and the preparations should not be confused.
- Liaison with the hospital consultant regarding any complications of treatment.
- Although blood level monitoring is routinely carried out by the specialist team during clinic visits, in exceptional circumstances the team may request that the GP arranges for blood tests to be taken locally for patient convenience – see Monitoring section below.

Patient, Relatives, Carers

- As listed in the NHS Lothian Policy and Procedures for the Shared Care of Medicines
- For administration tablets or capsules should not be opened or crushed.
- Be aware of need to use contraception where appropriate.
- Patients are advised to use sunscreens [SPF 50 or above] and protective clothing to reduce sunlight exposure.

Support and Advice for the GP and primary care non-medical prescribers

For patient-related queries, contact the relevant consultant, as detailed on any correspondence or discharge letter, directly either via phone or e-mail. E-mail requests should copy in the practice's clinical e-mail address and ask that the reply is sent to all, so that the reply is picked up even if the sender is not available.

Specialist Team Numbers

Transplant Unit Ward:	0131 242 2068
Renal Transplant Pharmacist:	0131 536 1000 Bleep 2294
Liver Transplant Pharmacist:	0131 536 1000 Bleep 5132

The names and contact details of the patient`s consultant and their secretary are given on the discharge letter. Please phone directly if there is an urgent enquiry

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, 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 drug for the given indication

Mycophenolate is a reversible inhibitor of inosine monophosphate dehydrogenase, thereby inhibiting the de novo pathway of guanosine nucleotide synthesis on which T- and B-lymphocytes are dependent for proliferation. Its mode of action is therefore similar to that of azathioprine but more specific.

Indication

Mycophenolate mofetil (MMF) is licensed for prophylaxis of acute rejection in hepatic and renal transplant patients. It is used routinely post transplant for the prevention of rejection in combination with other agents. Patients may also be transferred to mycophenolate from azathioprine when an increased level of immunosuppression is indicated.

Mycophenolic acid (MPA) is an alternative formulation of mycophenolate, licensed in renal transplant only. It is used as alternative in patients who are unable to tolerate gastrointestinal side effects from mycophenolate mofetil. Mycophenolic acid (MPA) should be initiated by a transplant specialist but can be continued by GPs under this Shared Care Agreement.

Dosage and Administration

Dose to be advised by specialist.

The recommended initial dose of mycophenolate mofetil is 500mg to 1g orally twice daily, depending on concomitant immunosuppression prescribed or age of patient at the time of transplant. Gastrointestinal side effects may be alleviated by further splitting the daily dose into four divided doses or reducing the total daily dose.

Mycophenolic acid dose is 720mg twice daily. 720mg of mycophenolic acid is approximately equivalent to mycophenolate mofetil 1g but **they should not be considered interchangeable** as there are pharmacokinetic differences.

Due to potential teratogenic effects mycophenolate mofetil tablets or mycophenolic acid capsules should not be crushed or opened and inhalation or direct contact with skin or mucous membranes should be avoided.

Monitoring

The following blood tests are performed by the transplant specialist team at clinic visits.

Test	Frequency	Abnormal Result	Action if Abnormal Result
Full blood count	As directed by transplant team*	Neutropenia (absolute neutrophil count <1.3 x10^9L)	Testing is undertaken and reviewed by the transplant consultant

*Note: monitoring frequency in this SCA differs to that stated in the BNF as it is individualised for each patient. Immunosuppression regimen should also be reviewed at 6 months post-transplant by the consultant responsible for the care of the patient.
In exceptional circumstances the team may request that the GP arranges for repeat blood tests to be taken at the GP practice for patient convenience. If the GP agrees to this, the specialist will give advice on the management of abnormal results.

Cautions, contraindications

For full detail of cautions and contraindications please refer to the current Summary Product Characteristic (SPC) available at www.medicines.org.uk.

Any patient planning pregnancy should discuss this with their transplant consultant.

Women of child bearing potential, male patients and their female partners must use effective contraception during

treatment. Female patients should use two forms of contraception at the same time (such as the pill/coil and barrier methods such as condoms/diaphragms). Male patients should use condoms – this includes men who have had a vasectomy. Female patients taking mycophenolate should continue to use effective contraception for 6 weeks following the last dose of mycophenolate. Male patients taking mycophenolate, and their female partners, should continue to use effective contraception for 90 days following the last dose of mycophenolate.

Patients wishing to breastfeed should seek specialist advice from their transplant consultant.

Adverse effects

For full detail of adverse effects please refer to the current Summary Product Characteristic (SPC) available at www.medicines.org.uk.

As with other immunosuppressive agents, mycophenolate increases the risk of developing malignancies of the skin. Therefore exposure to UV light and sunlight should be limited by wearing protective clothing and using sunscreen with a high protection factor (factor 50).

Drug interactions

For full detail of drug interactions please refer to the current Summary Product Characteristic (SPC) available at www.medicines.org.uk.

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 5th December 2023