SHARED CARE AGREEMENT

Name of medicine Mycophenolate mofetil (MMF)

Indication For non-transplant indications

Version: 1.2 **Approval date: December 2022** **Review date: December 2025**

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

- Assessing the need for mycophenolate mofetil therapy.
- Stating the target dose of mycophenolate mofetil.
- Undertaking and assessing the relevant baseline investigations.
- Arranging for the patient to receive verbal and written information on mycophenolate.
- Advising the patient regarding fertility, pregnancy and the need for contraception as appropriate.
- Treatment will be initiated by the specialist service and the supply made by secondary care for the first 8 weeks. During this time the specialist service will provide comprehensive patient support including monitoring for adverse effects, addressing any treatment-related issues and responding to patient queries.
- Making arrangements for the results of blood tests to be reviewed during the initial 6 weeks of treatment.
- Making arrangements for the patient to be reviewed 3-4 months after initiation of treatment to assess response.
- Providing advice to the GP regarding monitoring, adverse effects and dose modifications when required.
- Making arrangements for the patient to be kept under long term review.
- Specialist service to refer patients for vaccinations which are out with routine vaccination schedules or recall programmes via the clinician referral form (http://intranet.lothian.scot.nhs.uk/Directory/publichealth/Immunisation/Pages/VTP-(Vaccine-Transformation-Programme).aspx). Please note that Patient Specific Directions (PSD) are required for bespoke vaccination schedules where there is no PGD in place. The referral forms should be sent to the partnership that is responsible for administering vaccinations to their residents.

General Practitioner and primary care non-medical prescribers

- Prescribing of mycophenolate therapy in conjunction with the specialist after the initial 8 weeks.
- On initiation of treatment, the specialist service will provide patients with pre-labelled forms for blood tests.
- Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment. The GP is to arrange for blood tests to be taken at appropriate intervals thereafter as detailed in "Monitoring".
- Monitoring for side effects after the first 8 weeks of treatment as detailed in the manufacturer's Summary of Product Characteristics and "Monitoring".
- Advising on a suitable form of contraception and ongoing provision where relevant.
- Additional blood monitoring to be carried out as requested by consultant if needed and cannot be practically done by secondary care.

Patient, Relatives, Carers

- As listed in the NHS Lothian Policy and Procedures for the Shared Care of Medicines.
- Ensuring adherence to phlebotomy requirements throughout treatment.
- Be aware of need to use contraception where appropriate.

- Patients are advised to purchase and use sunscreens (SPF 50 or above) and protective clothing to reduce sunlight exposure.
- Patients can access advice from the relevant specialist team as follows:
  - Rheumatology Patient Helpline: 0131 537 1405
  - Respiratory Nurse Specialists **RIE**: 0131 242 1878
  - Respiratory Nurse Specialists **SJH**: 01506 523 865
  - Respiratory Nurse Specialists **WGH**: 0131 537 1799
  - Princess Alexandria Eye Pavilion: Triage: 0131 536 3751
  - Ophthalmology Pharmacist: 0131 536 2849 or Bleep 5122
  - Dermatology Pharmacy Lauriston Building 0131 536 2079

Support and Advice for the GP

Rheumatology

SPR or Rheumatology Consultant on call 13.00-17.00 on weekdays and 09.00-12.00 on Saturdays and public holidays via the switchboard (0131 537 1000). Urgent queries out with these times will be dealt with by the on-call medical team.

GPs can access advice from the rheumatology specialist service using the rheumatology on call e-mail which aims to give advice with a 24 hour response time: rheumatology.oncall@nhslothian.scot.nhs.uk. Advice will be communicated back to the GP by 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.

Respiratory

GPs can access advice from the relevant respiratory service as per the details below. Routine enquiries should be directed to the appropriate consultant via respiratory secretaries or respiratory nurse specialists in the first instance. The on call respiratory registrar can be contacted for more urgent/escalation of enquiries.

Hospital site	Respiratory nurse specialist	Respiratory secretaries	Respiratory registrar on call via hospital switchboard
St John's Hospital	01506 523 865	01506 523836 or 523844	-
Royal Infirmary of Edinburgh	0131 2421878	0131 2421872	0131 5361000
Western General Hospital	0131 5371799	0131 5371781	0131 5371000

Renal

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. GPs can also access the general renal advice email: RIE.RenalAdvice@nhslothian.scot.nhs.uk

Ophthalmology

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. Urgent queries will be managed by triage number listed for the Princess Alexandra Eye Pavilion

Ophthalmology Specialist Team Numbers

Princess Alexandra Eye Pavilion Triage and Ophthalmology Pharmacist numbers as per page 1.

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.

Dermatology

Contact the relevant consultant's secretary as detailed on clinic letter. Dermatology advice is also available via the on-call team at the following times: Monday - Thursday (excl. Bank Holidays) 09:00-21:00. Friday - Sunday (and Bank Holidays) 09:00-17:00. Dial switchboard and ask for Dermatology On-Call

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 mofetil is only licensed for the prevention of acute kidney, heart or liver transplant rejection. It is not licensed for all the conditions it is used to treat. However, its use for the indications above are well established, evidence based, and supported by clinical specialists such as British Society for Rheumatology and European Vasculitis Society.

Renal: Mycophenolate is used either as monotherapy or in combination with corticosteroids and/or other disease-modifying immunosuppressive agents in the management of a number of inflammatory renal conditions including systemic lupus erythematosus, anti-neutrophil cytoplasm antibody (ANCA)-associated vasculitis, and some rare glomerulonephritides (e.g., minimal change disease, C3 glomerulopathy).

Respiratory: Mycophenolate mofetil is used as a steroid sparing agent for the management of interstitial lung disease. Interstitial lung diseases (ILDs) encompass a large and diverse group of lung disorders that are generally characterised by inflammation and/fibrosis in the lung parenchyma including chronic hypersensitivity pneumonitis, connective tissue disease related ILD (CTD-ILD) and sarcoidosis. Patients have historically been treated with system oral corticosteroids (OCS). However, long term OCS use is associated with numerous systemic side effects.

Rheumatology: Mycophenolate is used either as monotherapy or in combination with other DMARDs in the management of a number inflammatory rheumatic conditions including lupus, rheumatoid arthritis and vasculitis.

Ophthalmology: Uveitis (also known as iritis) is inflammation of the uveal tract (iris, ciliary body, and choroid). Inflammation of nearby tissues, such as the retina, the optic nerve, and the vitreous humour may also occur. Uveitis is a potentially blinding condition and approximately 5–10% of visual impairment worldwide. Corticosteroids are used to reduce inflammation and prevent adhesions in the eye. People with severe or chronic uveitis may also be given systemic immunosuppressive drugs like mycophenolate. Mycophenolate is used to reduce inflammation whilst being a steroid sparing agent.

Dermatology: Mycophenolate mofetil is used off-label for dermatology patients because there is good evidence for a beneficial effect for immunobullous disorders such as bullous pemphigoid and pemphigus vulgaris. Bullous pemphigoid can be a serious disease, particularly when widespread or resistant to treatment and pemphigus vulgaris can cause very extensive, life-threatening erosions. Mycophenolate is well tolerated with a wide therapeutic range and able to be used in combination with other immunosuppressive drugs. Mycophenolate may also be used, but to a lesser extent, in atopic dermatitis, connective tissue diseases, dermatomyositis, lichen planus, cutaneous vasculitis, pyoderma gangrenosum and other rarer inflammatory skin diseases.

Dosage and administration

Dose to be advised by specialist.

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

Monitoring

On initiation of treatment, patients are provided with pre-labelled forms for blood tests. Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment. Note that abnormal trends in blood monitoring should prompt extra vigilance and may be a sign of toxicity even if absolute levels are normal.

Test	Frequency	Abnormal Result		Action if Abnormal Result
Full blood count (FBC)	Every 2 weeks until dose stable for 6 weeks Then monthly for 3 months Then every 3 months thereafter Revert to initial schedule in the event	Platelets WCC Neutrophils	100-140 2.0-3.5 1.0-1.6	Withhold therapy for 2 weeks and recheck. If normal recommence at lower dose i.e. reduce dose by 500mg/day.
		Platelets WCC Neutrophils Lymphocytes	< 100 < 2.0 < 1.5 <0.5	Withhold treatment and contact the specialist service.
		MCV	>105	Check B12, folate, TFTs and consider discussing with specialist service.

Liver Function Test (LFTs)	of a dose increase or when a new DMARD is added.	ALT >100	Withhold treatment for 2 weeks, and recheck. If ALT <100, recommence at lower dose i.e reduce dose by 500mg/day.
		ALT 50-100	Continue treatment and recheck. If ALT stable, continue treatment. If ALT rising, contact specialist. Repeat LFTs in 2-4 weeks.
Urea & Electrolytes (U&Es)		Elevation in creatinine from patient baseline.	Discuss with specialist service if eGFR <30ml/min
Blood Pressure (BP)		Elevation from patient baseline.	Treat hypertension as per pathway.

Note: Monitoring frequency in this shared care agreement differs to that stated in the British National Formulary.
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.

Due to the sight threating nature of ophthalmology conditions being treated advice to withhold treatment due to monitoring results, should be highlighted to the relevant consultant and ophthalmology pharmacist as soon as possible via email.

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

Pregnancy and Fertility
For full detail please refer to the current Summary of Product Characteristics (SPC) available at www.medicines.org.uk

Any patients planning pregnancy should discuss this with their 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 mofetil should continue to use effective contraception for 6 weeks following the last dose of mycophenolate mofetil. Male patients taking mycophenolate mofetil, and their female partners, should continue to use effective contraception for 90 days following the last dose of mycophenolate mofetil.

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

Adverse effects
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
As with other immunosuppressive agents, mycophenolate mofetil 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.

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

Vaccinations
- Individuals who on immunosuppressant therapy should be given inactivated vaccines in accordance with national recommendations.
- It is recommended that patients with autoimmune inflammatory diseases on immunosuppressant therapy should be offered pneumococcal, COVID19 and influenza vaccination.
- Immunosuppressed patients who are 70 to 79 years of age should be offered the varicella-zoster vaccine, Shingrix, to help protect them against shingles. Shingrix is a non-live alternative to the live

shingles vaccine, Zostavax.

- When considering suitability for live vaccines concurrent DMARD therapy should also be taken into account. · For further information see: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

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 06.06.2023