

## SHARED CARE PROTOCOL - MYCOPHENOLATE MOFETIL FOR PATIENTS WITHIN ADULT SERVICES (NON-TRANSPLANT INDICATIONS)

### Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#)) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#)), to enable the patient to reach an informed decision. If the drug is being initiated in patients of childbearing potential, there should be documented evidence that they have been informed of the risks, and they are aware of the requirement to use effective contraception during treatment and for up to 6 weeks after stopping treatment. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside their license.
- Assess for contraindications and cautions (see [section 4](#)) and interactions (see [section 7](#)).
- Conduct required baseline investigations, arrange, and review the results of any blood tests for the first 12 weeks of treatment (see [section 8](#)).
- Initiate, assess response and optimise treatment as outlined in [section 5](#). Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. Explain the process and the potential timescales for this.
- Prescribe sufficient medication taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is established and stabilised request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter detailing the diagnosis, current and ongoing dose and form, baseline, and most recent test results, confirm the monitoring schedule, and when the next monitoring is required. Include contact information ([section 13](#)).

- Conduct the required monitoring in [section 8](#) and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#) remains appropriate.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Review treatment and provide advice if a patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- Patients should be regularly reviewed, and the risk benefit re-assessed as patients get significantly older and frail with increasing co-morbidities and polypharmacy. Dose optimisation and/or dose tapering should be considered if clinically appropriate aiming for the lowest effective dose.
- Advise primary care if treatment should be discontinued

### Primary care responsibilities

- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per [section 5](#) taking into any account potential drug interactions in [section 7](#).
- Assess for interactions with mycophenolate mofetil when starting new medicines (see [section 7](#)).
- Adjust the dose of mycophenolate mofetil prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist.
- Manage any adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop mycophenolate mofetil and discuss urgently with the specialist if gastrointestinal bleeding or perforation is suspected or the patient becomes pregnant.
- Discuss other adverse effects with the specialist team as clinically appropriate (see [section 10](#)).
- Discuss with the specialist if the patient plans to become pregnant. See [section 12](#).
- Stop treatment as advised by the specialist. If the decision to stop treatment is made in primary care e.g. due to increased frailty index, to let the specialist team know so they can arrange a review as needed.

## Patient and/or carer responsibilities

- Take mycophenolate mofetil as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping their contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend blood monitoring or review appointments.
- Advised to take part in all national screening programmes e.g. for breast, bowel, and cervical cancers.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#).
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of mycophenolate mofetil with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking mycophenolate
- Patients of childbearing potential should use effective contraception during treatment and for up to 6 weeks after stopping the drug. Those of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

## 1. Background

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This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

Mycophenolate mofetil is a pro-drug of the active metabolite mycophenolic acid. Mycophenolic acid is a suppressor of T and B cell proliferation and adhesion and inhibits inosine monophosphate dehydrogenase and eventually blocks the progression to DNA synthesis and proliferation.

Mycophenolate is only licensed for the prevention of acute kidney, heart, or liver transplant rejection (in combination with prednisolone or ciclosporin). It is not licensed for all the conditions it is used to treat. However, its use as a disease modifying anti-rheumatic drug (DMARD) and for the indications below are well established and supported by clinical specialists. This shared care protocol does not cover the use of mycophenolate mofetil for transplant indications.

## 2. Indications

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Off-label use for the treatment of chronic inflammatory conditions where use of mycophenolate mofetil is appropriate, including but not limited to the following specialities and conditions:

- Dermatology (e.g. myositis, severe psoriasis, severe atopic dermatitis/eczema, autoimmune bullous dermatoses, SLE)
- Gastroenterology (e.g. Crohn's disease, ulcerative colitis)
- Haematology (e.g. idiopathic thrombocytopenic purpura)
- Hepatology (e.g. auto-immune hepatitis)
- Neurology (e.g. inflammatory neuropathies, myasthenia gravis)
- Ophthalmology (e.g. uveitis, scleritis)
- Oral medicine (e.g. Behçet's disease, refractory inflammatory oral disease)
- Renal medicine (e.g. immune-mediated nephritis)
- Respiratory disease (e.g. interstitial lung disease)
- Rheumatology (e.g. rheumatoid arthritis, systemic lupus erythematosus [SLE], vasculitis)

These indications are off label. The initiating specialist must specify the indication for each patient when initiating shared care and clearly state when use is off label.

This shared care protocol applies to adults aged 18 and over. It does not include use of mycophenolate mofetil for transplant indications.

## 3. Locally agreed off-label use

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Nil further identified- see above

## 4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

### Contraindications:

- Hypersensitivity to mycophenolate mofetil or any excipients
- Pregnancy or breastfeeding

### Cautions:

- Localised or systemic infection.
- Very frail or elderly patients.
- Patients with suspected lymphoproliferative disorder.
- Patients with unexplained anaemia, leukopenia, or thrombocytopenia.

- Active gastrointestinal disease.
- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever): should usually be avoided in patients taking mycophenolate. Live shingles vaccine should be avoided in patients taking mycophenolate 1g/day or more, or lower doses together with prednisolone 7.5 mg/day or more. Please refer to the [Green Book Chapter 6](#) (cautions and contraindications), together with chapters for the specific vaccine under consideration, for current advice. A non-live vaccine can still be used. Contact the specialist if further guidance is required.
- Dose reduction or discontinuation should be considered for patients in cases of clinically significant COVID-19.
- As there is a potential increased risk of malignancy, any pre-malignant disease should be adequately treated before starting therapy and patients should be up to date with relevant national cancer screening programmes.
- Due to the increased risk of skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor
- Avoid if previous hepatitis B or C infection, or recurrent shingles
- Marked renal failure (CrCl below 25 mL/min).
- Paternal exposure. See [section 15](#).
- Patients should not donate blood during therapy or for at least 6 weeks following discontinuation of mycophenolate. Men should not donate semen during therapy or for 90 days following discontinuation of mycophenolate.

In addition, the MHRA have also issued the following Drug Safety Updates for mycophenolate:

- [Mycophenolate mofetil: pure red cell aplasia](#) (Dec 2014)
- [Mycophenolate mofetil \(CellCept\) and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis](#) (Jan 2015)

## 5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

**Initial stabilisation:**

To be determined by the specialist based on indication and disease severity. Typically, mycophenolate mofetil 250mg or 500mg once or twice daily, increasing in weekly increments.

**The initial period must be prescribed by the initiating specialist.**

**Maintenance dose (following initial stabilisation):**

Typically, mycophenolate mofetil 1 to 2 grams daily in divided doses. Maximum dose: 3 grams daily.

**The initial maintenance dose must be prescribed by the initiating specialist.**

**Conditions requiring dose adjustment:**

The maximum recommended dose in severe chronic renal impairment (Cr Cl <25 mL/min) is:

- Mycophenolate mofetil 1gram twice daily

**6. Pharmaceutical aspects**

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Route of administration:	Oral
Formulation:	<p>Mycophenolate mofetil 250 mg capsules</p> <p>Mycophenolate mofetil 500 mg tablets</p> <p>Mycophenolate mofetil 1g/5mL powder for oral suspension.</p> <p>Mycophenolate should be prescribed generically, and not by brand name. Brands include Cellcept® and Myfenax®; generics are available and may be more cost effective.</p>
Administration details:	<p>Mycophenolate mofetil can be taken with or without food.</p> <p>If a dose is missed it should be taken as soon as remembered, then dosing resumed at the usual times. However, <u>a double dose should not be taken to make up for a missed dose.</u></p>
Other important information:	<p>Capsules and tablets should not be opened crushed, or chewed, to avoid inhalation or direct contact with skin or mucus membranes of the active substance. If such contact occurs, wash thoroughly with soap and water rinse eyes with plain water.</p>

For noting mycophenolic acid 720 mg is equivalent to mycophenolate mofetil 1 gram but unnecessary switching should be avoided, due to pharmacokinetic differences. Switches should only be performed by, or with the advice of, the specialist team. Mycophenolic acid should usually be reserved for patients who do not tolerate mycophenolate mofetil and is not routinely used in the management of inflammatory diseases.

## 7. Significant medicine interactions

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The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

- **Aciclovir / ganciclovir / valaciclovir / valganciclovir:** possible increased plasma concentration of antiviral and mycophenolate metabolite especially in patients with renal impairment; possible increased risk of haematological toxicity
- **Antacids and proton pump inhibitors:** reduced absorption of mycophenolate
- **Further immunosuppression e.g. azathioprine, ciclosporin, sirolimus:** increased risk of bone marrow suppression
- **Cholestyramine / colesevelam:** reduced absorption of mycophenolate
- **Ciclosporin:** reduced mycophenolate exposure
- **Isavuconazole:** possible increased risk of mycophenolate adverse effects due to increased exposure to mycophenolate or its metabolite
- **Telmisartan:** may reduce mycophenolate exposure
- **Live vaccines:** Increased risk of generalised infection. Consult the [Green Book](#) for the most up to date advice
- **Rifampicin:** decreased plasma concentration of mycophenolate
- **Sevelamer:** reduced mycophenolate exposure; separate administration by 1-3 hours

## 8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

### Baseline investigations:

- Full blood count (FBC)
- Urea and electrolytes (U&E), including creatinine and creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and albumin

- Height & weight
- Blood pressure
- Screening for viral infections as per local policy, e.g. HIV and hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- Before starting mycophenolate mofetil treatment in patients of childbearing potential, pregnancy should be ruled out and there should be documented evidence that they have been informed of the risks and that they are aware of the requirement to use effective contraception (two forms of contraception are preferred) during treatment and for up to 6 weeks after stopping treatment. See [MHRA Drug Safety Update](#) for more detail
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)

#### **Initial monitoring:**

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months. After which, the transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 4 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine

- FBC
- U&Es, including creatinine and CrCl
- ALT and albumin (LFTs)
- Rheumatology patients: CRP &/or ESR (for monitoring disease activity/outcomes rather than for safety- this may continue to be monitored by the rheumatology team but will not be part of the primary care safety monitoring parameters)

Following a dose increase repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

#### **Ongoing monitoring:**

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually unless the patient has been stabilised on treatment for a long time and considered suitable for patient initiated follow up (PIFU). Rapid access to the specialist team for advice and guidance should still be available if the patient is enrolled with PIFU.

After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#) remains appropriate.

## 9. Ongoing safety monitoring requirements to be undertaken by primary care

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See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
<ul style="list-style-type: none"> <li>FBC</li> <li>U&amp;Es including creatinine and CrCl</li> <li>ALT and albumin (LFTs)</li> </ul>	<p>Every 12 weeks. Where necessary seek advice on increased frequency of monitoring on a case-by-case basis.</p> <p>The exact frequency of monitoring to be communicated by the specialist in all cases</p>
<ul style="list-style-type: none"> <li>Shingles vaccination- immunocompromised patients aged 50 years and over are eligible for the shingles vaccine (Shingrix®)</li> <li>The eligible age for Immunocompetent patients will change in a phased implementation over a 10-year period</li> <li>For patients taking mycophenolate 1g/day or more, or lower doses together with prednisolone 7.5 mg/day or more, a non-live vaccine should be used. Specialist input may be required. If patient is taking additional DMARDs, check advice for all drugs. Please refer to Green Book <a href="#">Chapter 6 (cautions and contraindications)</a> and <a href="#">Chapter 28a (Shingles)</a> for further details.</li> <li><b>Annual</b> influenza (<a href="#">The Green Book, Chapter 19</a>) vaccinations are recommended.</li> </ul> <p>COVID-19 vaccination is safe and recommended (see <a href="#">The Green Book, Chapter 14a</a>).</p>	<ul style="list-style-type: none"> <li>Shingles vaccination: one-off.</li> <li>Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.</li> <li>COVID-19 vaccination as per national schedule.</li> </ul>

**(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.**

## 10. Adverse effects and other management

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**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
<b>As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance</b>	
<ul style="list-style-type: none"> <li>• White blood cells less than <math>3.5 \times 10^9/L</math></li> <li>• Lymphocytes less than <math>0.5 \times 10^9/L</math></li> <li>• Neutrophils less than <math>1.6 \times 10^9/L</math></li> <li>• Platelets less than <math>140 \times 10^9/L</math></li> <li>• Eosinophilia greater than <math>0.5 \times 10^9/L</math></li> </ul>	Withhold and discuss with specialist team.
Mean cell volume $>105$ fL	<p>Consider interruption in treatment if there is a significant increase from baseline.</p> <p>Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.</p>
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.
<p><b>Infections:</b></p> <p>Systemic infection requiring antibiotics</p> <p>Recurrent or opportunistic infections</p>	Temporarily withhold mycophenolate until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate. Contact specialist for advice as needed

<p>Exposure to chickenpox or shingles</p>	<p>Contact specialist team for advice. See the <a href="#">Green Book (chapter 34)</a> and <a href="#">Guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024) - GOV.UK</a> for detailed advice on risk assessment and post exposure prophylaxis.</p>
<p><b>Liver function tests:</b>                  ALT &gt;100 units/L, or any sudden increases (e.g. double of baseline), OR                  Unexplained fall in serum albumin &lt;30g/L                   Jaundice</p>	<p>Withhold and discuss with specialist team.                   Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.</p>
<p><b>Renal function:</b>                   Creatinine increases of greater than 30% from baseline in the last 12 months, or if CrCl reduces to &lt;60ml/min</p>	<p>Use clinical judgement and repeat in 1 week. Rule out other causes. If still more than 30% from baseline withhold and discuss with specialist team</p>
<p><b>Gastrointestinal disorders:</b>                   Very common adverse effects include nausea and vomiting, abdominal cramps, diarrhoea, and dyspepsia.</p>	<p>Review for reversible causes and treat as appropriate. Advise patient to take with food. If no improvement contact specialist team.</p>
<p>GI ulceration, bleeding, and perforation</p>	<p>Review for reversible causes. Withhold and discuss urgently with specialist team.</p>
<p>Suspected pancreatitis</p>	<p>Withhold and discuss with specialist team</p>
<p><b>Skin disorders:</b>                   Skin hypertrophy, acne, alopecia</p>	<p>Review for reversible causes. Discuss with specialist team if symptoms become troublesome.</p>
<p>Rash</p>	<p>Review for possible causes. If cause of rash thought to be mycophenolate or immune-mediated, withhold and discuss with specialist team.</p>

<p><b>Other:</b></p> <p>Neurological symptoms, psychiatric disorders, sudden onset or worsening of shortness of breath, cough, or dyspnoea</p>	<p>Review for reversible causes. Withhold and discuss with specialist team.</p>
<p>Suspicion of malignancy</p>	<p>Discuss with specialist team. Refer for diagnosis and treatment of malignancy</p>
<p><b>Pregnancy</b></p>	<p>In pregnant patients, stop mycophenolate immediately and discuss with specialist team urgently. See <a href="#">section 12</a>.</p>

## 11. Advice to patients and carers

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The specialist will counsel the patient regarding the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

**The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**

- Rash
- Abdominal pain or jaundice (skin or whites of the eyes appear yellow)
- Signs and symptoms suggestive of bone marrow suppression e.g. sore throat, oral ulceration, abnormal bruising or bleeding, or signs of infection.
- Exposure to chickenpox or shingles or if the patient develops chicken pox or shingles.
- Pregnancy or planning to become pregnant

**The patient and/or carer should be advised:**

- What shared care means for their treatment, what to expect, and their responsibilities under shared care.
- During a serious systemic infection mycophenolate mofetil should be temporarily discontinued until the patient has recovered from the infection.
- If exposed to chickenpox or shingles patient must alert their primary care prescriber or specialist team and seek advice.
- That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.

- Tell anyone who prescribes them a medicine that they are taking mycophenolate. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin.
- Mycophenolate mofetil may cause somnolence, confusion, dizziness, tremor, or hypotension, and therefore patients are advised to use caution when driving or using machines.
- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they or their partners become pregnant or are planning a pregnancy.
- Not to donate blood during treatment or for 6 weeks after stopping, and not to donate semen during treatment or for 90 days after stopping.
- To avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:
  - the [Green Book \(Chapter 34\)](#)
  - [Guidelines on post exposure prophylaxis \(PEP\) for varicella or shingles \(October 2024\) - GOV.UK.](#)

Patient information leaflets:

General information: <https://patient.info/medicine/mycophenolate-mofetil-cellcept-myfenax>

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

Dermatology: [British Association of Dermatologists](#) mycophenolate patient information leaflet

Patient information leaflets are also available from  
<https://www.medicines.org.uk/emc/search?q=mycophenolate>

## 12. Pregnancy, paternal exposure, and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

**All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.**

### **Pregnancy:**

**Mycophenolate is contraindicated during pregnancy or breastfeeding. Contraception should be used for 6 weeks after stopping the drug.**

Because of the genotoxic and teratogenic potential of mycophenolate mofetil, people of childbearing potential must use at least one highly effective form of contraception before and during treatment and for six weeks after stopping mycophenolate unless abstinence is the chosen method of contraception. Two forms of contraception used simultaneously are preferred. See [MHRA Drug safety update](#) and [letter sent to healthcare professionals](#). See also more recent advice:

- [MHRA Drug Safety Update: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?](#)
- [Faculty of Sexual and Reproductive Healthcare statement on contraception for women using known teratogenic drugs or drugs with potential teratogenic effects.](#)

Methods of contraception which are considered 'highly effective' in this context include the long-acting reversible contraceptives (LARC) copper intrauterine device (Cu-IUD), levonorgestrel intrauterine system (LNG-IUS) and progestogen-only implant (IMP) and male and female sterilisation, all of which have a failure rate of less than 1% with typical use. (Note that patients using IMP must not take any interacting drugs that could reduce contraceptive effectiveness).

Information for healthcare professionals:

<https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MYCOPHENOLATE-MOFETIL-IN-PREGNANCY/>

Information for patients and carers: <https://www.medicinesinpregnancy.org/Medicine--pregnancy/Mycophenolate/>

### **Breastfeeding:**

Mycophenolate should not be prescribed for people who are breastfeeding

Information for healthcare professionals: <https://www.sps.nhs.uk/medicines/mycophenolate-mofetil/>

**Paternal exposure:**

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 \(Feb 2018\)](#)

## 13. Specialist contact information

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Please approach the patient's named secondary care clinician via the usual method of communication, this may be via letter or if more urgent:

### **Rheumatology**

- Advice and Guidance.
- Consultant Connect - during office hours
- UHD switchboard – on-call rheumatologist during office hours
- Rheumatology advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

### **Gastroenterology (UHD and DCH)**

- Advice and Guidance
- Consultant Connect- during office hours
- IBD advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

### **Neurology**

- Advice and Guidance
- Consultant Connect- during office hours
- UHD Switchboard- on-call neurologist during office hours

### **Respiratory (UHD and DCH)**

- Advice and Guidance

### **Dermatology (UHD and DCH)**

- Via switchboard to the on-call dermatology doctor (do not use advice and guidance)

## 14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

## 15. References

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- eBNF. [Mycophenolate mofetil | Drugs | BNF | NICE](#)
- Mycophenolate mofetil 250 mg capsules (CellCept®). Last updated 3<sup>rd</sup> May 2024. Accessed via <https://www.medicines.org.uk/emc/product/1102>
- Mycophenolate mofetil 500 mg film-coated tablets (Cellcept®). Last updated 20<sup>th</sup> Jan 2025. Accessed via <https://www.medicines.org.uk/emc/product/1103>
- Mycophenolate mofetil 1g/5 mL powder for oral suspension (CellCept®). Last updated 3<sup>rd</sup> May 2024. Accessed via <https://www.medicines.org.uk/emc/product/1569>
- Mycophenolate mofetil 250 mg hard capsules (Myfenax®). Last updated 15<sup>th</sup> May 2024. Accessed via <https://www.medicines.org.uk/emc/product/9293>
- Mycophenolate mofetil 500 mg tablets (Myfenax®). Last updated 15<sup>th</sup> May 2024. Accessed via <https://www.medicines.org.uk/emc/product/9294>
- British Society for Rheumatology and British Health Professionals in Rheumatology. BSR and BHRP guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Rheumatology 2017;56:865868. doi:10.1093/rheumatology/kew479. Accessed via <https://academic.oup.com/rheumatology/article/56/6/865/3053478#97289271>
- [British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids | Rheumatology | Oxford Academic 2022](#)
- Renal Drug Database. Mycophenolate. Reviewed 10/08/20. Accessed via <https://renaldrugdatabase.com/> on 07/04/21.
- Public Health England. The Green Book: Immunisation against infectious disease. Accessed via <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- MHRA Drug Safety Update. Mycophenolate mofetil, mycophenolic acid: new pregnancy-prevention advice for women and men. Last updated December 2015. Accessed via <https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-new-pregnancy-prevention-advice-for-women-and-men>
- MHRA Drug Safety Update. Mycophenolate mofetil, mycophenolic acid: updated contraception advice for male patients. February 2018. Accessed via

<https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-updated-contraception-advice-for-male-patients>.

- MHRA Drug Safety Update. Mycophenolate mofetil: pure red cell aplasia. July 2009. Accessed via <https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-pure-red-cell-aplasia>.
- MHRA Drug Safety Update. Mycophenolate mofetil (CellCept) and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis. January 2015. Accessed via <https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-cellcept-and-mycophenolic-acid-risk-of-hypogammaglobulinaemia-and-risk-of-bronchiectasis>.

## 16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
- NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.

## 17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

**Via the usual methods**

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*

Date of birth: *[insert date of birth]*

NHS Number: *[insert NHS Number]*

Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]* shared care protocol for *[insert medicine name]* the treatment of *[insert indication]*, this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened regarding this treatment:

	Specialist to complete
<i>The patient has been initiated on this therapy and has been on an optimised dose for the following period:</i>	
<i>Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory</i>	Yes / No
<i>The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care</i>	Yes / No
<i>The risks and benefits of treatment have been explained to the patient</i>	Yes / No
<i>The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed</i>	Yes / No
<i>The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments</i>	Yes / No
<i>I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)</i>	Yes / No
<i>I have included with the letter copies of the information the patient has received</i>	Yes / No
<i>I have provided the patient with sufficient medication to last until</i>	
<i>I have arranged a follow up with this patient in the following timescale</i>	

Treatment was started on, *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you agree, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

**Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.**

**Primary Care Prescriber Response**

Dear *[insert Doctor's name]*  
Patient *[insert Patient's name]*  
NHS Number *[insert NHS Number]*  
Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: \_\_\_\_\_ Date:  
\_\_\_\_\_

Primary Care Prescriber address/practice stamp

## Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

**Re:**

Patient *[insert Patient's name]*  
 NHS Number *[insert NHS Number]*  
 Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]*, in conjunction with local acute trusts have classified *[insert medicine name]* as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

**I regret to inform you that in this instance I am unable to take on responsibility due to the following:**

		Tick which applies
1.	<p><b>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</b></p> <p>As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. 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.</p> <p><b>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.</b></p>	
2.	<p><b>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</b></p> <p>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.</p> <p><b>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</b></p>	

3.	<p><b>A minimum duration of supply by the initiating clinician</b></p> <p>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 to provide them with the medication that you have recommended.</p> <p><b><i>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</i></b></p>	
4.	<p><b>Initiation and optimisation by the initiating specialist</b></p> <p>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 to provide them with the medication that you have recommended.</p> <p><b><i>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</i></b></p>	
5.	<p><b>Shared Care Protocol not received</b></p> <p>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.</p> <p>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 to provide them with the medication that you have recommended.</p> <p><b><i>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</i></b></p>	
6.	<p><b>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)</b></p>	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs

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would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

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

**Primary Care Prescriber signature:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

**Primary Care Prescriber address/practice stamp**