

**DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE**  
**SHARED CARE AGREEMENT**

**MYCOPHENOLATE mofetil- non transplant indications in adult services**

**1. REFERRAL CRITERIA**

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable.
- When transferred, the patient will be given a supply of mycophenolate sufficient for 4 weeks maintenance therapy.

**2. AREAS OF RESPONSIBILITY**

<b>GP responsibilities</b>	<b>Consultant responsibilities</b>
<ol style="list-style-type: none"> <li>1. If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1)</li> <li>2. If accepted, prescribe ongoing treatment as detailed in the specialist's request taking into any account potential drug interactions</li> <li>3. Adjust the dose of mycophenolate mofetil prescribed as advised by the specialist.</li> <li>4. Conduct the required monitoring as outlined in section vii</li> <li>5. Assess for possible interactions with mycophenolate mofetil when starting new medicines</li> <li>6. Manage any adverse effects and discuss with specialist team when required.</li> <li>7. Stop mycophenolate mofetil and discuss urgently with the specialist if gastrointestinal bleeding or perforation is suspected.</li> <li>8. Refer the management back to the specialist if the patient becomes or plans to become pregnant.</li> <li>9. Stop treatment as advised by the specialist.</li> <li>10. Ensure the patient is offered an annual flu vaccination.</li> </ol>	<ol style="list-style-type: none"> <li>1. Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and communicated to primary care.</li> <li>2. 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. Provide an appropriate patient information leaflet.</li> <li>3. Assess for contraindications and cautions and interactions.</li> <li>4. Conduct required baseline investigations and initial monitoring as outlined in section vii.</li> <li>5. Initiate, prescribe, and monitor treatment for the first three months or until medication monitoring is stable.</li> <li>6. Contact patient's GP to request prescribing under shared care. Complete the shared care documentation and send to patient's GP practice 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.</li> <li>7. Annually review the patient and advise primary care promptly whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring remains appropriate.</li> <li>8. Communicate any dose increase to the GP and transfer monitoring to GP when the patient's condition is stable or predictable following 6 weeks period of titration.</li> <li>9. Review treatment and reassume prescribing responsibility if a patient becomes or wishes to become pregnant.</li> <li>10. Provide advice to primary care on the management of adverse effects and queries on live vaccination if required.</li> </ol>
<b>Patient responsibilities</b>	
<ol style="list-style-type: none"> <li>1. Report to the specialist or GP if there is not a clear understanding of the treatment and share any concerns in relation to treatment.</li> <li>2. Take mycophenolate mofetil as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist. Tell anyone who prescribes them a medicine that they are taking mycophenolate.</li> <li>3. Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.</li> <li>4. Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop unexplained rash; abdominal pain or jaundice; unexplained sore throat, oral ulceration, abnormal bruising/bleeding or signs of infection; exposure or develops chicken pox or shingles; pregnancy or planning to become pregnant.</li> <li>5. 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.</li> <li>6. Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service, and to inform their prescriber as soon as possible if they or their partner become pregnant or wish to become pregnant.</li> </ol>	

### 3. COMMUNICATION AND SUPPORT

<p><b>i. Hospital contacts:</b>  <b><u>Chesterfield Royal Hospital NHS Foundation Trust</u></b>          Contact the referring consultant/nurse via switchboard: 01246 277271          Rheumatology- Rheumatology nurse advice line: 01246 513097          Available Monday-Thursday 9am-4:30pm, Friday 9am- 12:30pm          Gastroenterology- CAO 01246 513274  <a href="mailto:crhft.gastroenterologycao@nhs.net">crhft.gastroenterologycao@nhs.net</a>          IBD advice line 01246 512884 (answerphone)          GP mobile contact 07717700489          Dermatology- 01246513106          Respiratory- Clinical Administration Officer (CAO) 01246513107  <a href="mailto:CRHFT.respiratory@nhs.net">CRHFT.respiratory@nhs.net</a> ILD nurse advice line 01246 516369.          Neurology- Consultant via the neurology secretary on 01246 513111</p> <p><b><u>University Hospital of Derby and Burton NHS Foundation Trust</u></b>          Rheumatology- Rheumatology helpline: 01332 787710          Gastroenterology- IBD helpline: 01332 785504          Consultant/specialist nurse via switchboard: 01332 340131          Dermatology- Consultant/specialist nurse via switchboard: 01332 265500          Respiratory- Consultant via switchboard: 01332 340131          Neurology- secretaries 01332 786478/783548  <a href="mailto:dhft.neurologysecretaries@nhs.net">dhft.neurologysecretaries@nhs.net</a>          Renal- secretaries 01332 789344</p> <p><b><u>Queens Burton Hospital</u></b>          01283 511511/566333          Rheumatology          Dr R Laximinarayan ext. 3167          Dr S Das/ Dr D Ray ext. 3211/3247          Clinical Rheumatology Nurse Specialist ext. 4112          Bleep 274 available during office hours  <a href="mailto:bhft.rheumatologynurses@nhs.net">bhft.rheumatologynurses@nhs.net</a></p> <p>Gastroenterology 01283 511511/66333          Dr Palejwala/ Dr. Dor secretary ext 3004.          Dr Watmough/ Dr. Guerra secretary ext 3002.          IBD nurse: ext 5854 (voicemail only service) Bleep: 590  <a href="mailto:dhft.ibdcns@nhs.net">dhft.ibdcns@nhs.net</a></p>	<p><b>ii. Out of hours contacts and procedures:</b>  <b><u>Chesterfield</u></b>          Contact the on-call Medic for the relevant speciality via switchboard: 01246 277271</p> <p><b><u>Derby</u></b>          Pharmacy, UHDB, ask for on-call pharmacist via switchboard: 01332 340131          Messages can be left on the Derby Rheumatology nurse advice line: 01332 787710          The aim is to address these next working day</p> <p><b><u>Burton</u></b>          01283 511511 / 566333 ask for on-call pharmacist via switchboard          Messages can be left on the nurse advice line out of hours. 01283 511511 ext 4112 (Rheum) / 5854 (Gastro)</p> <p>If the advice line is not staffed, messages may be left 24 hours a day. The team aim to respond at latest within 2 working days. The specialist nurses may also be bleeped via switchboard for urgent enquiries.</p>
<p><b>iii Local arrangements for referral-</b> as per section 2- Areas of responsibility. Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.</p>	
<p><b>Specialist support/resources available to GP including patient information:</b>          Rheumatology British Society of Rheumatology Specialist website: <a href="http://www.rheumatology.org.uk/">http://www.rheumatology.org.uk/</a>          General information: <a href="https://patient.info/medicine/mycophenolate-mofetil-cellcept-myfenax">https://patient.info/medicine/mycophenolate-mofetil-cellcept-myfenax</a>          Rheumatology: <a href="https://www.versusarthritis.org/about-arthritis/treatments/drugs/mycophenolate/">https://www.versusarthritis.org/about-arthritis/treatments/drugs/mycophenolate/</a>          Dermatology: <a href="https://www.bad.org.uk/pils/mycophenolate-mofetil/">https://www.bad.org.uk/pils/mycophenolate-mofetil/</a>          Patient information leaflets are also available from <a href="https://www.medicines.org.uk/emc/search?q=mycophenolate">https://www.medicines.org.uk/emc/search?q=mycophenolate</a></p>	

### 4. CLINICAL INFORMATION

<p><b>i. Prescribed indications</b></p>	<ul style="list-style-type: none"> <li>• Dermatology (myositis, severe psoriasis, severe atopic dermatitis/eczema, autoimmune bullous dermatoses, SLE)</li> <li>• Gastroenterology (Crohn's disease, ulcerative colitis)</li> <li>• Haematology (idiopathic thrombocytopenic purpura)</li> <li>• Hepatology (auto-immune hepatitis)</li> <li>• Neurology (inflammatory neuropathies, myasthenia gravis)</li> <li>• Ophthalmology (uveitis, scleritis)</li> <li>• Oral medicine (Behcet's disease, refractory inflammatory oral disease)</li> </ul>
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	<ul style="list-style-type: none"> <li>• Renal medicine (immune-mediated nephritis)</li> <li>• Respiratory disease (interstitial lung disease)</li> <li>• Rheumatology (rheumatoid arthritis, systemic lupus erythematosus [SLE], vasculitis, scleroderma, myositis)</li> </ul> <p>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.</p>								
<b>ii. Therapeutic summary</b>	<p>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. (Immunosuppressant)</p> <p>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.</p>								
<b>iii. Dose &amp; Route of administration</b>	<p><b><u>Initial stabilisation:</u></b> To be determined by the specialist based on indication and disease severity. Oral: Typically, mycophenolate mofetil 250mg or 500mg once or twice daily, increasing in weekly increments.</p> <p><b><u>Maintenance dose (following initial stabilisation):</u></b> Oral: <b>Typically, mycophenolate mofetil 1-2 grams daily, in divided doses.</b> <b>Maximum dose: 3 grams daily.</b> The maximum recommended dose in severe chronic renal impairment (GFR &lt;25 mL/min/1.73m<sup>2</sup>) is 1 gram, twice daily</p> <p>Prescribe generically as more cost-effective. Mycophenolate mofetil can be taken with or without food. Capsules/ tablets should not be opened crushed, or chewed, to avoid inhalation or direct contact with skin or mucus membranes of the active substance.</p> <p><b>An alternative preparation of mycophenolic acid (Myfortic &amp; Ceptava) is not dose equivalent and not included in this agreement.</b></p> <p><b>Prophylaxis of pneumocystis Jirovecii Pneumonia (PCP) may be required in patients taking concurrent corticosteroids. Follow consultant advice.</b></p>								
<b>iv. Duration of treatment</b>	Indefinite but may be withdrawn after a prolonged period of disease remission in selected cases.								
<b>v. Immunisation</b>	<ul style="list-style-type: none"> <li>• Specialist to advise on the suitability for e.g., herpes zoster vaccination in accordance with national screening programme</li> <li>• <b>Live vaccinations should be avoided</b></li> <li>• Annual flu vaccination is recommended</li> <li>• COVID-19 vaccination is safe and recommended</li> <li>• One off Pneumococcal vaccination is recommended unless severely immunocompromised where a different schedule is needed.</li> </ul>								
<b>vi. Adverse effects</b>	<p>Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a></p> <p>Refer to the SPC for a full list of adverse effects &amp; further information <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a></p> <p>Clinician should review severity of side effect and contact specialist for advice if needed. Below is advice on how to manage some of the adverse effects.</p> <table border="1"> <tr> <td><b>Gastrointestinal disorders:</b> Very common adverse effects include nausea and vomiting, abdominal cramps, diarrhoea and dyspepsia.</td> <td>Review for reversible causes. Advise patient to take with food. If no improvement, contact specialist team.</td> </tr> <tr> <td>GI ulceration, bleeding and perforation</td> <td>Review for reversible causes. Withhold and discuss urgently with specialist team.</td> </tr> <tr> <td>Suspected pancreatitis</td> <td>Withhold and discuss with specialist team</td> </tr> <tr> <td><b>Skin disorders:</b> Skin hypertrophy, acne, alopecia</td> <td>Review for reversible causes. Discuss with specialist team if symptoms become</td> </tr> </table>	<b>Gastrointestinal disorders:</b> Very common adverse effects include nausea and vomiting, abdominal cramps, diarrhoea and dyspepsia.	Review for reversible causes. Advise patient to take with food. If no improvement, contact specialist team.	GI ulceration, bleeding and perforation	Review for reversible causes. Withhold and discuss urgently with specialist team.	Suspected pancreatitis	Withhold and discuss with specialist team	<b>Skin disorders:</b> Skin hypertrophy, acne, alopecia	Review for reversible causes. Discuss with specialist team if symptoms become
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Suspected pancreatitis	Withhold and discuss with specialist team								
<b>Skin disorders:</b> Skin hypertrophy, acne, alopecia	Review for reversible causes. Discuss with specialist team if symptoms become								

		<p>troublesome.</p> <p>Rash</p> <p><b>Other:</b> Neurological symptoms, psychiatric disorders, sudden onset or worsening of shortness of breath, cough or dyspnoea</p> <p>Suspicion of malignancy (particular on the skin)</p>
<p><b>vii. Monitoring Requirements</b></p>	<p><b>Before commencing immunosuppressant therapy</b></p> <ul style="list-style-type: none"> <li>Record patient's blood pressure, weight and height if clinically indicated.</li> <li>Screening for lung disease should be undertaken at clinician discretion on a case by-case basis. The extent of screening should be influenced more by a patient's clinical features and risk factors for lung disease (e.g., underlying autoimmune disease or smoking history) rather than subsequent immunomodulating choice. Pre-existing lung disease should not be considered an absolute contraindication to any immunomodulating medication.</li> <li>Screen for viral hepatitis B&amp;C and HIV as per local policy</li> <li>Investigate patient medical history including co-morbidities and previous immunomodulating medication use.</li> </ul> <p><b>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 should be done 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 <a href="#">MHRA Drug Safety Update</a> for more detail. See also section X. (p.7) on paternal exposure.</b></p> <p><b>Consultant/ specialist monitoring schedule</b>  Baseline, to be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months:</p> <ul style="list-style-type: none"> <li>FBC</li> <li>U&amp;Es, including creatinine and CrCl</li> <li>AST and/or ALT, and albumin</li> </ul> <p>Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist.</p> <p>-----</p> <p><b>GP Ongoing monitoring schedule:</b>  Following the 6 weeks of dose stability, conduct monthly monitoring as above for three months (unless already completed in secondary care), followed by three- monthly monitoring thereafter of:</p> <ul style="list-style-type: none"> <li>FBC</li> <li>U&amp;Es, including creatinine and CrCl</li> <li>AST and/or ALT, and albumin</li> <li>Rheumatology patients: CRP &amp;/or ESR</li> </ul> <p><b>Dosage increase</b>  For dose increase, monitor 2 weekly until stable for 6 weeks then revert to previous schedule (every 3 months). Dose and monitoring to be agreed with consultant.</p> <ul style="list-style-type: none"> <li>FBC</li> <li>U&amp;E including creatinine/ calculated GFR</li> <li>ALT and/or AST and albumin</li> </ul>	

When restarting treatment after an abnormality has been detected repeat bloods in 2 weeks and then monthly for 3 months. Following this resume monitoring frequency to what it was prior to the abnormality.

**Actions to be taken in primary care**

- Parameters below are to be used as a guide for clinicians rather than absolute values, where monitoring should be based on individualised basis. It is important to consider alternative explanations other than the immunomodulation agents, especially in patients who have been stable for prolonged periods.
- 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

<ul style="list-style-type: none"> <li>• White blood cells &lt; 3.5x10<sup>9</sup>/L</li> <li>• Lymphocytes &lt;0.5x10<sup>9</sup></li> <li>• Neutrophils &lt; 1.6x10<sup>9</sup>/L</li> <li>• Platelets &lt; 140x10<sup>9</sup>/L</li> <li>• Eosinophilia greater than 0.5x10<sup>9</sup>/L</li> </ul>	<p>Discuss urgently with specialist team, and consider interruption Isolated low lymphocytes more likely to be due to disease or other factors- GP to consider non-drug related causes (contact specialist for advice if unsure). The specialist may advise on individual cases if the abnormality is thought to be due to other factors and in this instance may set differential parameters which can be communicated to the GP.</p>
<p>Mean cell volume &gt;105 fL</p>	<p>Consider interruption in treatment. 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>
<p>Creatinine rise &gt;30% over 12 months, or calculated GFR reduces to &lt;60ml/min</p>	<p>Withhold and discuss with specialist team</p>
<p>ALT or AST &gt; 3 x upper limit of normal (ULN) <i>or</i> &gt;100 units/ml (<i>local consensus</i>), or any sudden increases (e.g., double of baseline), OR Unexplained fall in serum albumin &lt;30g/L</p>	<p>Withhold and discuss with specialist team. Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.</p>
<p>Signs or symptoms of bone marrow suppression, e.g., unexplained bleeding or bruising with or without sore throat, mouth ulcers</p>	<p>Check FBC immediately and discuss with the specialist team. See haematological monitoring above.</p>
<p>Infection requiring antibiotics Recurrent or opportunistic infections</p>	<p>Temporarily withhold mycophenolate until the patient has recovered. Review for reversible causes. Withhold and discuss with specialist team.</p>
<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="#">PHE guidance</a> for detailed advice on risk assessment and post exposure prophylaxis.</p>



<p><b>viii. Contra- indications</b> Refer to the SPC for more detailed information</p>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity to mycophenolate mofetil or any excipients</li> <li>• Pregnancy or breastfeeding (see below)</li> </ul> <p><b>Cautions:</b></p> <ul style="list-style-type: none"> <li>• Localised or systemic infection.</li> <li>• Very frail or elderly patients.</li> <li>• Patients with suspected lymphoproliferative disorder.</li> <li>• Patients with unexplained anaemia, leukopenia or thrombocytopenia.</li> <li>• Active gastrointestinal disease.</li> <li>• Live vaccines (e.g., oral polio, oral typhoid, MMR, BCG, yellow fever): should usually be avoided. (See section v)</li> <li>• Dose reduction or discontinuation should be considered for patients in cases of clinically significant COVID-19.</li> <li>• 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.</li> <li>• 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.</li> <li>• Avoid if previous hepatitis B or C infection, or recurrent shingles.</li> <li>• Marked renal failure (eGFR below 25 mL/min).</li> <li>• Paternal exposure.</li> <li>• 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.</li> </ul> <p>In addition, the MHRA have also issued the following Drug Safety Updates:</p> <ul style="list-style-type: none"> <li>• <a href="#">Mycophenolate mofetil: pure red cell aplasia</a> (Dec 2014)</li> <li>• <a href="#">Mycophenolate mofetil (CellCept) and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis</a> (Jan 2015)</li> </ul>
<p><b>ix. Clinically relevant drug interactions</b></p> <p>Refer to the SPC for more detailed information on drug interactions <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a>.</p>	<p>Interactions that reduce levels of mycophenolate relate to implications of reduced immunosuppression in transplant patients. For indications covered in this agreement the clinical significance may be less so.</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Antacids and proton pump inhibitors: reduced absorption of mycophenolate</li> <li>• Further immunosuppression e.g., azathioprine, ciclosporin, sirolimus: increased risk of bone marrow suppression</li> <li>• Cholestyramine / colesevelam: reduced absorption of mycophenolate</li> <li>• Ciclosporin: reduced mycophenolate exposure</li> <li>• Isavuconazole: possible increased risk of mycophenolate adverse effects due to increased exposure to mycophenolate or its metabolite</li> <li>• Telmisartan: may reduce mycophenolate exposure</li> <li>• Live vaccines: Increased risk of generalised infection. Consult the <a href="#">Green Book</a> for the most up to date advice</li> <li>• Rifampicin: decreased plasma concentration of mycophenolate</li> <li>• Sevelamer: reduced mycophenolate exposure; separate administration by 1-3 hours</li> </ul>
<p><b>x. Pregnancy, paternal exposure and breastfeeding</b></p>	<p><b>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.</b></p> <p><b><u>Pregnancy:</u></b> <b>Mycophenolate is contraindicated during pregnancy or breastfeeding. Contraception should be used for 6 weeks after stopping the drug.</b> Because of the genotoxic and teratogenic potential of mycophenolate mofetil, people of childbearing potential must use at least one highly effective form of contraception</p>

	<p>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 <a href="#">MHRA Drug safety update</a> and <a href="#">letter sent to healthcare professionals</a>. See also more recent advice:</p> <ul style="list-style-type: none"> <li>• <a href="#">MHRA Drug Safety Update: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?</a></li> <li>• <a href="#">Faculty of Sexual and Reproductive Healthcare statement on contraception for women using known teratogenic drugs or drugs with potential teratogenic effects.</a></li> </ul> <p>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).</p> <p>Information for healthcare professionals: <a href="https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MYCOPHENOLATE-MOFETIL-IN-PREGNANCY/">https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MYCOPHENOLATE-MOFETIL-IN-PREGNANCY/</a></p> <p>Information for patients and carers: <a href="https://www.medicinesinpregnancy.org/Medicine--pregnancy/Mycophenolate/">https://www.medicinesinpregnancy.org/Medicine--pregnancy/Mycophenolate/</a></p> <p><b>Breastfeeding:</b> Mycophenolate should not be prescribed for people who are breastfeeding Information for healthcare professionals: <a href="https://www.sps.nhs.uk/medicines/mycophenolate-mofetil/">https://www.sps.nhs.uk/medicines/mycophenolate-mofetil/</a></p> <p><b>Paternal Exposure:</b> 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. <b>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.</b> See MHRA Drug Safety Update: <a href="#">Mycophenolate mofetil, mycophenolic acid, updated contraception advice for male patients (Feb 2018)</a></p>
<p><b>xi. Additional information</b></p>	<p>Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed</p> <p><b>To be read in conjunction with the following documents</b></p> <ul style="list-style-type: none"> <li>• <a href="#">RMOG Shared Care Guidance</a></li> <li>• <a href="#">NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs</a></li> <li>• <a href="#">NHSE policy- Responsibility for prescribing between Primary &amp; Secondary/Tertiary Care</a></li> </ul>
<p><b>xii. Supply of ancillary equipment</b></p>	<p>N/A</p>
<p><b>xiii. Prepared by</b></p>	<p>Derbyshire shared care and guideline group, in consultation with: University hospitals of Derby and Burton NHS Foundation Trust Chesterfield Royal Hospital NHS Foundation Trust</p> <p>Adapted from NHSE National shared care protocol- Mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications) 4 July 2022, Version1. <a href="https://www.england.nhs.uk/medicines-2/regional-medicines-optimisation-committees-advice/shared-care-protocols/">https://www.england.nhs.uk/medicines-2/regional-medicines-optimisation-committees-advice/shared-care-protocols/</a> (accessed 9/9/2022)</p>

**This does not replace the SPC, which should be read in conjunction with it.**  
**Date Prepared: April 2023      Review Date: March 2026**

Hospital No: «HOSPITAL\_NUMBER» NHS  
No: «NHS\_NUMBER»

{Insert date}

**PRIVATE & CONFIDENTIAL**

«GP\_TITLE» «GP\_INITIALS» «GP\_SURNAME»  
«GP\_ADDRESS\_1»  
«GP\_ADDRESS\_2»  
«GP\_POSTCODE»

**DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER**

Dear «GP\_TITLE» «GP\_SURNAME»

«FORENAME\_1» «SURNAME» «DATE\_OF\_BIRTH»  
«CURRENT\_ADDRESS\_1» «CURRENT\_ADDRESS\_2»  
«CURRENT\_POSTCODE»

Your patient was seen on {Insert date} with a diagnosis of {Insert diagnosis}. I have initiated the following medication {Insert drug name} and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from [www.derbyshiremedicinesmanagement.nhs.uk/clinical\\_guidelines/shared\\_care\\_guidelines](http://www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines)). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement, I have carried these out and results are below.

Dose Regimen	Date {Insert medicine name} started	Date for GP to start prescribing {Insert medicine name} from
The baseline test results are (if applicable):		

I can confirm that the following has happened with regard to 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 of time:</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>	

The next blood monitoring is due on [insert date] and should be continued in line with the shared care guideline. If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely  
{Consultant name}



**GP RESPONSE TO SHARED CARE** (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost-effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		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 in order to provide them with the medication that you have recommended.</p> <p><b>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</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 in order to provide them with the medication that you have recommended.</p> <p><b>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</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 in order to provide them with the medication that you have recommended.</p> <p><b>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</b></p>	
6.	<p><b>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)</b></p>	

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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

{GP name}

{Surgery}

**Please send a copy of this response to the specialist/consultant requesting shared care**