Working in Partnership

SHARED CARE PRESCRIBING GUIDELINE

Mycophenolate Mofetil / Mycophenolic acid for Renal Autoimmune Disease

General Shared Care Guideline (SCG) Principles

- Medicines considered suitable for shared care are those which should be initiated by a Specialist, but where prescribing and monitoring responsibility may be transferred to Primary Care. Due to their potential side effects, shared care medicines usually require significant regular monitoring, and regular review by the Specialist is needed to determine whether the medicines should be continued. The best interest, agreement and preferences of the patient should be at the centre of any shared care agreement.

- The transfer of prescribing responsibility from the Specialist to the patient's General Practitioner (GP) or Primary Care prescriber should occur when both parties are in agreement that the patient's condition is stable or predictable, and that the Primary Care prescriber has the relevant knowledge, skills and access to equipment to allow them to monitor treatment as indicated in this shared care prescribing guideline.

- The aim of this guideline is to equip Primary Care prescribers with the information to confidently take on clinical and legal responsibility for prescribing the medication under a shared care agreement within their own level of competence.

- Within the Bedfordshire, Luton and Milton Keynes (BLMK) Integrated Care System (ICS), shared care guidelines are produced and updated through a robust governance process, following consultation with a wide range of key stakeholders. On this basis for BLMK ICS approved shared care guidelines, it is anticipated that Primary Care prescribers, upon individual assessment, will accept shared care for the patient if they felt it was clinically appropriate to do so and seek patient consent.

- If the Primary Care prescriber feels that a request for shared care cannot be accepted, i.e. falls outside of their own level of competence, they should initially seek further information or advice from the clinician who is sharing care responsibilities or from another experienced colleague in line with the General Medical Council (GMC) guidance.

- If the Primary Care prescriber is still not satisfied clinically to accept shared care, they should make appropriate arrangements for the patient's continuing care where possible. This may include asking another colleague in their practice to undertake the shared care. In the event that other colleagues in the practice also decline to share care, the Primary Care prescriber could seek assistance and advice from their Primary Care Network (PCN) (e.g. PCN Pharmacist).

- If the decision, after discussion with the PCN, is to decline shared care, the Primary Care prescriber must notify the Specialist clinician of their decision and reason (See appendix 1) to decline as soon as they can and in a timely manner (within a maximum of 14 to 21 days upon receipt of request) in writing and ensure the patient is aware of the change. In this scenario, the prescribing responsibility for the patient remains entirely with the Specialist. This principle also applies where shared care needs to be terminated in primary care e.g. due to lack of patient engagement. It is anticipated that these would be very rare events.

- The requirement for the Primary Care prescriber to send confirmation in writing via letter or approved electronic communication to the Specialist team for acceptance of shared care is NOT mandated.

- Where the hospital or Specialist clinician retains responsibility for monitoring drug therapy and/or making dosage adjustments, the Primary Care prescriber must be informed of any dose changes made as soon as possible to avoid medication errors. Similarly, if the Primary Care prescriber makes changes to the patient's medication regimen, the Primary Care prescriber must inform the Specialist in a timely manner. Primary Care prescribers can contact the Specialist team for advice, training and support as required.

- An agreed method of communication of blood test results and results of investigations between the Specialist, the Primary Care prescriber, the Community Pharmacist and the patient should be agreed at the onset of shared care and documented in the patient's notes in both Secondary care and Primary Care. Blood test results can usually be accessed electronically by both Secondary Care and Primary Care prescribers in the majority of cases. For some medications and in certain cases, the patient may elect to have a patient-held monitoring booklet, e.g. those on warfarin and lithium therapy.

- The principles above apply to shared care arrangements that involve the Specialist service sharing care with GPs and/or other Primary Care prescribers, e.g. Community Nursing Services. Where patient care is transferred from one Specialist service or GP practice to another, a new shared care agreement request must be commenced.

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Mycophenolate Mofetil / Mycophenolic acid for Renal Autoimmune Disease

Introduction and Aims of Shared Care (including a brief overview of the condition being treated for):

Mycophenolate mofetil (MMF) is a prodrug of mycophenolic acid (MPA). It is a reversible inhibitor of inosine monophosphate dehydrogenase and therefore inhibits purine synthesis with potent cytostatic effects on both T-lymphocytes and B-lymphocytes. Time to response is usually 6 weeks to 3 months.
It does not inhibit interleukin production.
The drug is only licensed for use in prevention of transplant rejection in combination with steroids or ciclosporin. However it has well established use in other indications as listed below.

MMF/MPA use within this SCG is for treatment of renal autoimmune conditions such as:

- Systemic Lupus Erythematosus
- Vasculitis
- Minimal Change Disease
- Membranous Nephropathy
- Focal Segmental Glomerulosclerosis

1. AREAS OF RESPONSIBILITY

Secondary/Tertiary Care Prescribers or Specialist Team

- To obtain patient informed consent for sharing of care between the Specialist, Primary Care prescriber and patient. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily and must be documented in the patient's notes.
- To confirm the working diagnosis.
- To confirm that the patient's condition has a predictable course of progression and the patient's care can be suitably maintained by Primary Care, following their medicine being optimised with satisfactory investigation results for at least 4 weeks.
- If shared care is considered appropriate for the patient, the patient's treatment regimen is confirmed, and benefit from treatment is demonstrated, the Specialist will contact the Primary Care prescriber to initiate shared care.
- At the point of initial contact, the Specialist should check if the Primary Care prescriber can access blood test results electronically. If access is unavailable, the Specialist and the Primary Care prescriber should agree a process of communication to ensure blood test results and relevant results of investigations can be accessed by both parties in a timely manner.
- Following the request to the patient's Primary Care prescriber to initiate shared care; to ensure that the patient has an adequate supply of medication until shared care arrangements are in place. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place by the anticipated start date of the shared care (usually within 28 days or once the patient is stabilised on the medication). Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
- To ensure that the Primary Care prescriber has sufficient information to enable them to monitor treatment, identify medicines interactions, and prescribe safely. This should include access or direction to a current copy of the SCG and contact details for the initiating Specialist. As a partner in the shared care agreement, the patient should, where appropriate, be provided with access or direction to a copy of the shared care guideline.
- The Specialist will provide the patient's Primary Care prescriber with the following information:
  - diagnosis of the patient's condition with the relevant clinical details
  - details of the patient's specialist treatment to date
  - details of treatments to be undertaken by the Primary Care prescriber (including reasons for choice of treatment, medicine or medicine combination, frequency of treatment, number of months of treatment to be given before review by the Specialist)
  - the date from which the Primary Care prescriber should prescribe the treatment
  - details of other specialist treatments being received by the patient that are not included in shared care
  - details of monitoring arrangements required
- Whenever the Specialist sees the patient, he/she will:
  - send a written summary to the patient's Primary Care prescriber in a timely manner, noting details of any relevant blood test results or investigations if applicable
  - confirm that ongoing treatment with the monitored medicine is appropriate
  - record test results on the patient-held monitoring booklet if applicable and if this method of communication has been agreed at the onset of shared care
  - confirm the current dosage and clearly highlight any changes made both to the patient and in writing to the patient's Primary Care prescriber who will action any of them as required
- The Specialist team will:
  - provide training, advice and guidance (as appropriate) for Primary Care prescribers if necessary to support the shared care agreement
  - provide contact details for both working and non-working hours
  - supply details for fast track referral back to secondary/specialist care
  - provide the patient with details of their treatment, follow-up appointments, monitoring requirements and, where appropriate, nurse specialist contact details
  - provide continued support for the Primary Care prescriber and answer any questions they may have on the treatment and the condition for which the medicine is being used
- Prior to transfer of prescribing, the Specialist will:
  - Ensure that patients (and their caregivers, where appropriate) are aware of and understand their responsibilities to attend appointments and the need for continued monitoring arrangements.
- The Specialist will document the decision to transfer prescribing of the treatment to the Primary Care

prescriber via the shared care guideline in the patient's hospital medical notes. If the Primary Care prescriber declines the request for shared care and the Specialist is therefore responsible for the prescribing of the medication for the patient, the Specialist will document this also in the patient's hospital medical notes.

All of the above information should be provided to the Primary Care Prescriber in writing via a letter or approved electronic communication.

Secondary care prescribers will also ensure to:

- Prescribe and monitor treatment during the initial stabilisation period of 12 weeks
- Undertake baseline and ongoing tests for monitoring, review results and adjusting doses or requesting more tests as required
- Notify Primary care prescribers of non-attendance to clinic repeatedly and advise on action to take
- Reinforce the importance of strict sun protections measures, to reduce the risk of skin cancer, to patients
- Ensure women of child bearing potential are aware of the importance of effective contraception and the need to discuss with their specialist if they want to become pregnant or think they may be pregnant.
- Ensure male patients and female partners are aware of need for effective contraception. Males planning to have children should discuss this with their specialist.
- Encourage all women aged 25-64 years old to participate in national cervical cancer screening programmes – there is no need to attend more frequently than recommended.

Primary Care Prescribers

- To prescribe within their own level of competence. The (GMC) guidance on "Good practice in prescribing and managing medicines and devices" states that doctors are responsible for the prescriptions they sign and their decisions and actions when they supply and administer medicines and devices, or authorise or instruct others to do so. They must be prepared to explain and justify their decisions and actions when prescribing, administering and managing medicines.
- The same principles apply to non-medical prescribers as well as medical prescribers as outlined in the "Competency Framework for all Prescribers".
- To confirm that the patient or carer consents to sharing of care between the Specialist, Primary Care prescriber and patient. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily and must be documented in the patient's notes.
- If shared care is accepted, commencement of shared care must be clearly documented in the patient's Primary Care medical notes.
- If declining the request for shared care, the decision and rationale should be explained to the Specialist in writing as soon as is possible and in a timely manner, within a maximum of 14 to 21 days upon receipt of request. The patient should also be informed of the decision.
- Ensure that he/she has the information and knowledge to understand the therapeutic issues relating to the patient's clinical condition.
- Undergo any additional training necessary in order to carry out the prescribing and monitoring.
- Agree that in his/her opinion the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within Secondary/Specialist care.
- Prescribe the maintenance therapy in accordance with the written instructions contained within the SCG or other written information provided, and communicate any changes of dosage made in Primary Care to the patient. It is the responsibility of the prescriber making a dose change to communicate this to the patient.
- If it has been agreed that a patient-held monitoring booklet will be used and where applicable, keep the patient-held monitoring record up to date where possible with the results of investigations, changes in dose and alterations in management and take any actions necessary.
- Report any adverse effect in the treatment of the patient to the Specialist team, and via the MHRA Yellow Card Scheme https://yellowcard.mhra.gov.uk/.
- The Primary Care prescriber will ensure that the patient is monitored as outlined in the SCG and will take the advice of the referring Specialist if there are any amendments to the suggested monitoring schedule.
- The Primary Care prescriber will ensure a robust monitoring system is in place to ensure that the patient attends the appropriate appointments in Primary Care for follow-up and monitoring, and that defaulters from follow-up are contacted to arrange alternative appointments. It is the Primary Care prescriber's responsibility to decide whether to continue treatment for a patient who does not attend appointments required for follow-up and monitoring, and to inform the Specialist of any action taken.
- Primary Care prescriber are not expected to be asked to participate in a shared care arrangement where:
    - no locally approved SCG exists, or the medicine or condition does not fall within the criteria defining

suitability for inclusion in a shared care agreement
    - 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
- Where community nurse involvement is required in the administration of medicines under a SCG, nurses should be provided with adequate information and guidance by the prescriber or the Specialist. Arrangements should be made in good time for any potential problems to be resolved to ensure that patient care is not compromised.
- Ensure no drug interactions with other medicines, including any medicines that may not be listed in the patient's treatment record such as any over-the-counter medicines, herbal remedies and recreational drugs. See section 3 for additional information.
- Administer inactivated influenza vaccine and other recommended seasonal vaccines (e.g. COVID) annually unless otherwise advised by the initiating specialist
- Check patient has had ONE dose of pneumococcal vaccine (revaccination is not recommended except every 5 years in patients whose antibody levels are likely to have declined more rapidly e.g. due to asplenia), see BNF or Green Book
- COVID-19 vaccination is safe and recommended (see The Green Book, Chapter 14a).
- For susceptible immunosuppressed individuals with significant exposure to chicken pox (varicella) or shingles (Zoster), follow latest national guidance on post exposure prophylaxis and use on anti-virals and varicella zoster immunoglobulin (VZIG) https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles
- Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding at every consultation
- Organisation of urgent referral to the specialist team or A+E if severe side effects or potential overdose is apparent
- Liaise with specialist team if the medication becomes less effective and/or the patient complains of symptoms
- Reinforce the importance of strict sun protection measures, including high factor sunscreen and protective clothing, to reduce the risk of skin cancer.
- Reinforce the importance of women not becoming pregnant or breastfeeding whilst on mycophenolate. Women who think they may be pregnant need to inform their GP/Specialist. Effective contraception must be used before beginning therapy, during therapy and for 6 weeks post discontinuation of therapy.
- Men who wish to father a child should discuss with their specialist.

Patient and/or carer

- To provide their informed consent for sharing of their care with the Specialist and Primary Care prescriber. Consenting parties must have sufficient, accurate, timely information in an understandable and accessible format. Consent must be given voluntarily and must be documented in the patient's notes. Supporting information is available from NICE "Making decisions about your care".
- To take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
- To meet all necessary monitoring arrangements to ensure the safe prescribing of their medication, and to alert the prescriber where these arrangements are not met.
- To attend all follow-up appointments with the Primary Care prescriber and Specialist. If the patient is unable to attend any appointments, they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
- Inform healthcare professionals of their current medications (both prescribed and non-prescribed where applicable) prior to receiving any new prescribed or over-the-counter medication.
- Report any changes in symptoms and all suspected adverse reactions to medicines to their Primary Care prescriber.
- Store their medication securely away from children and according to the medication instructions.
- Read the information supplied by their Primary Care prescriber, Specialist and Pharmacist and contact the relevant practitioner if they do not understand any of the information given.
- An agreed method of communication of results of investigations between the Specialist, the Primary Care prescriber, the Community Pharmacist and the patient should be agreed at the onset of therapy.
- If it has been agreed to use a patient-held monitoring booklet, the patient needs to arrange for the monitoring booklet to be kept up to date.
- Alert Primary/Secondary care teams of any changes of circumstances which can affect management of the disease (e.g. moving surgery, plans for pregnancy)
- Take adequate precautions to avoid pregnancy
- Be aware all women aged 25-64 years participate in national cervical cancer screening programmes. There

is no need to attend more frequently than recommended

- Be aware skin may be more sensitive to UV light exposure whilst taking mycophenolate. Therefore ensure to use appropriate self care (e.g. sun avoidance, protective clothing, avoid tanning (including tanning beds), and to use broad-spectrum sunscreens of at least SPF 30)

Community Pharmacist

- Know where to access locally agreed shared care guidelines to aid professional clinical check of prescription prior to dispensing.
- Professionally check prescriptions to ensure they are safe for the patient and contact the Primary Care prescriber if necessary to clarify their intentions. It is good practice to check the patient-held record book if applicable to ensure the correct dose is dispensed*.
  * An agreed method of communication of results of investigations between the Specialist, the Primary Care prescriber, the Community Pharmacist and the patient should be agreed at the onset of therapy.
- Fulfil legal prescriptions for medication for the patient unless they are considered unsafe.
- Counsel the patient on the proper use of their medication.
- Advise patients suspected of experiencing an adverse reaction to their medicines to contact their Primary Care prescriber or Specialist/Specialist nurse team.

2. COMMUNICATION AND SUPPORT

Hospital / Specialist contact information *(The referral letter will indicate named consultant)* **Hospital name and address:** Luton and Dunstable Hospital, Bedfordshire Hospitals NHS Foundation Trust **Consultant names:** Dr Miriam Ball **Role and specialty:** Consultant Nephrologist Tel number: 01582 718840 Email address: ldh-tr.nephrology@nhs.net	**Out-of-hours contact details & procedures:** Contact on call Medical Registrar via switchboard on 01582 49116

Specialist support / resources available to Primary Care prescriber including patient information:

This shared care guideline is available online on the BLMK Medicines website https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/ and search shared care guidance. Any dosage adjustments made by the hospital specialist team will be recorded in the electronic medical notes and full details sent to the GP. Blood test results taken by the specialist hospital team will be available on the electronic system, the hospital specialist team will then send a paper copy of the blood test results to the GP in a timely manner. GPs should contact the hospital specialist team if any dose adjustments are required or if the need to discontinue the medication arises. The dosage regime and frequency of blood test monitoring should be clearly explained to the patient. Trust produced patient information leaflets will also be provided to the patient.

3. CLINICAL INFORMATION

Indication(s): **(Please state whether licensed or unlicensed)**	Mycophenolate mofetil / mycophenolic acid are to be used off label within this SCG under a specialist team. • Systemic Lupus Erythematosus • Vasculitis • Minimal Change Disease • Membranous Nephropathy • Focal Segmental Glomerulosclerosis
Place in therapy:	Mycophenolate Mofetil - First line Mycophenolic Acid second line
Therapeutic summary:	Mycophenolate mofetil is the prodrug of mycophenolic acid (MPA). MPA is a potent, selective, non-competitive and reversible inhibitor of inosine monophosphate dehydrogenase, inhibiting purine synthesis. It has potent cytostatic effects on both T-lymphocytes and B-lymphocytes.
Initiation and ongoing dose regime and Route of administration:	*Note: Transfer of monitoring and prescribing to Primary Care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.* *All dose or formulation adjustments will be the responsibility of the initiating Specialist unless directions have been discussed and agreed with the Primary Care prescriber. Termination of treatment will be the responsibility of the Specialist.* **Initial stabilisation:** *(The loading period must be prescribed by the initiating Specialist)* Loading doses are determined by the specialist and based on indication and disease severity. Typically initial doses may be mycophenolate mofetil 250mg or 500mg once or twice daily, increased in weekly increments **Maintenance dose (following initial stabilisation):** (*The initial maintenance dose must be prescribed by the initiating Specialist)* The recommended adult dose is 1g-3g daily in 2 divided doses, however the frequency of doses may be increased to limit gastrointestinal side effects (e.g. 500mg qds rather than 1g bd) Mycophenolic acid (MPA) 720mg is equivalent to Mycophenolate mofetil (MMF) 1g. Switching from MMF to MPA should only be done by, or with advice, of specialist teams, Unnecessary switching should be avoided due to pharmacokinetic differences. MPA is usually reserved for treatment in patients intolerant of MMF. **Conditions requiring dose adjustment:** Renal impairment Mild to moderate hepatic impairment Therapeutic response
Duration of treatment:	Long term as per response

<table>
<tr><td>Preparations available (Manufacturer):</td><td colspan="3">Mycophenolate Mofetil is available as 250mg capsules, 500mg tablets, 1g/5ml powder for oral suspension

Mycophenolic acid is available as 180mg and 360mg gastro-resistant capsules</td></tr>
<tr><td>Summary of adverse effects:
(See Summary of Product Characteristics (SPC) for full list)

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme.</td><td>Adverse effect</td><td>Frequency/ likelihood</td><td>Management</td></tr>
<tr><td></td><td>GI side effects such as nausea and vomiting, abdominal cramps, diarrhoea and dyspepsia</td><td>Very Common</td><td>Review for reversible causes. Medication can be taken with food to help ease mild symptoms. If they persist contact specialist.</td></tr>
<tr><td></td><td>Hypersensitivity reactions (fevers, rash, rigors, myalgia, arthralgia, hypotension, dizziness etc)</td><td>Uncommon</td><td>As per SPC immediate withdrawal, and contact specialist</td></tr>
<tr><td></td><td>Flu-like symptoms / myalgia / headaches</td><td>Common</td><td>If mild, continue treatment
Moderate to severe – stop drug and contact specialist</td></tr>
<tr><td></td><td>Fever, sore throat, ulceration</td><td>Common</td><td>Check FBC and stop if WCC low.</td></tr>
<tr><td></td><td>Abnormal bruising or bleeding</td><td>Uncommon</td><td>Stop until recovery and check FBC. Do not restart if blood tests are abnormal and contact specialist</td></tr>
<tr><td></td><td>Suspected pancreatitis</td><td>Uncommon</td><td>Withhold treatment, and check amylase levels. Refer to specialist for advice.</td></tr>
<tr><td>Monitoring requirements by Specialist (baseline investigations, initial monitoring and ongoing monitoring):</td><td colspan="3"><u>Baseline investigations</u>:

• FBC, LFTs, Albumin, U+E, eGFR,
• ESR and CRP
• Height and weight
• Blood Pressure
• Screening for viral infections as per local policy (e.g. HIV, Hepatitis B and C, Varicella etc)
• Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case by case basis
• Urinalysis
• Lipids
• Negative pregnancy test in women of childbearing potential pre-treatment
• Adequate contraceptive methods for female partners and female patients of childbearing age
• Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)</td></tr>
</table>

Initial monitoring: *(Monitoring at baseline and during initiation is the responsibility of the Specialist until the patient is optimised and stabilised on the medicine with no anticipated further changes)*

To be repeated every 2 weeks until dose has been stable for 6 weeks, then every 4 weeks for 12 weeks, then every 12 weeks:

- FBC, LFTs, Albumin, U+E, eGFR
- ESR and CRP
- Urinalysis
- Pregnancy test in women of childbearing potential – if there is a break in contraception ensure negative pregnancy test in women of childbearing potential

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

Ongoing monitoring:
Specialist teams to review patients regularly throughout treatment (usually annually unless stated otherwise) and to confirm doses with primary care following review.

Ongoing monitoring requirements by Primary Care prescriber:

Monitoring	Frequency	Result	Action for Primary Care prescriber
FBC, LFTs, Albumin, U+E, eGFR,	Every 4 weeks for 12 weeks with hospital undertaking the first 4-week test and primary care to undertake second and third 4-week tests, then every 12 weeks	If Neutrophils <2.0 x10^9/L	If <1.6x10^9/L stop treatment and refer back to specialist If between 1.6-2.0 discuss with specialist and consider 50% dose reduction
		WCC <3.5x10^9/L	If <3.0 stop and contact specialist If 3.0-3.5 repeat and review dose with specialist if still <3.5 (Note it is normal to have a low lymphocyte count – discuss with specialist if concerns)
		Unexplained eosinophilia > 0.5x10^9/L	Contact specialist for advice. Withhold mycophenolate mofetil if no response from specialist in 5-7 days.
		Anaemia	If new – investigate as usual and monitor. If longstanding monitor and contact specialist for concerns.

			Lymphocytes <0.5x10^9/L or Platelets <140x10^9/L	Discuss with specialist and consider withholding treatment if no response within 5-7 days.
			MCV>105fL	Check B12, folate, alcohol history and TFT. If >120fL stop and contact specialist
			AST/ALT > 2 times the upper limit of normal (ULN)	If >3 x ULN hold mycophenolate mofetil and seek specialist advice. For results between 2 - 3 x ULN, continue mycophenolate, repeat bloods and seek specialist advice. Minor elevations of AST/ALT are common.
			If renal impairment develops or there is an unexplained fall in serum albumin	Contact specialist for advice. Withhold mycophenolate mofetil if no response from specialist in 5-7 days.
			Pancreatitis	Discontinue treatment and contact specialist.
	ESR and CRP	Every 4-12 weeks	Rising ESR / CRP	Contact specialist for advice.
	Lipid monitoring	Annually		
	Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/ bleeding	At every consultation		Check FBC and stop treatment if WCC low (actions as documented above)
	Pregnancy test in women of childbearing potential			If there is a break in contraception, ensure negative pregnancy test in women of childbearing potential.

<table>
<tr><td rowspan="2">Clinically relevant drug interactions and advice on management:

Note: This does not replace the SPC and should be read in conjunction with it.</td><td>Drug interaction</td><td>Management / Action for Primary Care prescriber</td></tr>
<tr><td>Aciclovir / ganciclovir / valaciclovir / valganciclovir

Further immunosuppression e.g. azathioprine, ciclosporin, sirolimus:

Mycophenolate absorption or exposure is reduced with the following drugs:
Antacids
Cholestyramine / colesevelam
Ciclosporin
Telmisartan
Rifampicin
Sevelamer separate administration by 1-3 hours
Isavuconazole

Live vaccines</td><td>Possible increased plasma concentration of both antiviral and mycophenolate metabolite, especially in patients with renal impairment – monitor closely and consider dose reductions if prolonged concomitant use.

Increased risk of bone marrow suppression – closely monitor patient and adjust doses as needed.

Avoid prolonged concomitant use and closely monitor.

With sevelamer – consider separating administration hours by 1-3 hours.

Possible increased risk of mycophenolate adverse effects due to increased exposure to mycophenolate or its metabolite – monitor closely

Increased risk of generalised infection. Consult the Green Book for the most up to date advice</td></tr>
<tr><td colspan="3">Please see SPC for comprehensive information.</td></tr>
<tr><td>Clinically relevant precautions and contraindications:

Note: This does not replace the SPC and should be read in conjunction with it.</td><td colspan="2"><u>Cautions/Precautions</u>:

Infections – it is advised to pause medication whilst there is an active infection as MMF/MMA can increase susceptibility to infection. Once the infection has cleared treatment can be resumed. If antibiotic treatment is required specialist advice can be sought to discuss treatment.

Exposure to chickenpox or shingles – follow latest national guidance on post-exposure prophylaxis and use of antivirals and varicella zoster immunoglobulin. Stop mycophenolate and contact the specialist.

<u>Contraindications</u>:
Hypersensitivity to mycophenolate
Severe hepatic impairment
Pregnancy or breast feeding

Please see SPC for comprehensive information.</td></tr>
</table>

Renal impairment:	Caution is advised in patients with severe chronic renal impairment (eGFR <25ml/min^{-1}/1.73m^2)
Hepatic impairment:	If ALT/AST >3 times ULN hold mycophenolate and seek specialist advice If results between 2-3 x ULN, continue treatment, repeat bloods and seek specialist advice. Minor elevations in AST/ALT are common.
Advice to patients and carers: *The Specialist will counsel the patient with regard to 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. **In addition, the patient should be advised:** • 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. • During a serious infection (requiring antibiotics) mycophenolate mofetil should be temporarily discontinued until the patient has recovered from the infection. • 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 • Vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended. • Inform any prescribers or healthcare professional 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.
Pregnancy, paternal exposure and breastfeeding: *It is the Specialist's responsibility to provide advice on the need for contraception to male and female patients where applicable on initiation and at each review, but the ongoing responsibility for providing this advice rests*	**Pregnancy:** Mycophenolate mofetil and its active metabolite are associated with high rates of serious birth defects and spontaneous abortion. Mycophenolate should not be given to women who are pregnant, or likely to become pregnant. It should only be initiated in women of childbearing potential when there is a negative pregnancy test.

with both the Primary Care prescriber and the Specialist.	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, during and for 6 weeks after stopping treatment, unless abstinence is the chosen method of contraception. Two forms of contraception used simultaneously are preferred. Patients planning a pregnancy or who may be pregnant should contact the specialist team. 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. **Breastfeeding:** Mycophenolate mofetil and its active metabolite should be avoided during breast feeding. **Paternal exposure:** It is recommended that male patients or their female partners use effective contraception during treatment and for 90 days after stopping treatment. See MHRA Drug Safety Update: Mycophenolate mofetil, mycophenolic acid, updated contraception advice for male patients (Feb 2018).
Practical issues and Supply of ancillary equipment (where relevant):	N/A
Key references:	SPC for Mycophenolate Mofetil SPC for Mycophenolic acid SPS National Shared Care Protocol for Mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications) Hertfordshire and West Essex Shared Care Protocol
This shared care guideline is to be read in conjunction with the following documents: • **RMOC Shared Care Guidance – link here** • **NHSE/NHSCC guidance – items which should not be routinely prescribed in Primary Care: guidance for CCGs – link here** • **NHSE policy – Responsibility for prescribing between Primary & Secondary/Tertiary Care – link here**	

Appendix 1 – Possible Reasons for a Primary Care Prescriber to decline to accept shared care:

1	I do not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care. I have consulted with other Primary Care prescribers in my practice who support my decision. I have discussed my decision with the patient and request that prescribing for this individual remains with you due to the sound clinical basis given above.
2	The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement (medicine not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine).
3	The patient has not had the minimum duration of supply of medication to be provided by the initiating Specialist. Therefore, please contact the patient as soon as possible in order to provide them with the appropriate length of supply of the medication before transferring the prescribing responsibility to the Primary Care prescriber.
4	The patient has not been optimised/stabilised on this medication. Therefore, please contact the patient as soon as possible in order to provide them with the medication until the patient is optimised on this medication before transferring the prescribing responsibility to the Primary Care prescriber.
5	Shared Care Guideline and/or relevant clinical information as stipulated in the guideline not received. Therefore, please contact the patient as soon as possible in order to provide them with the medication until I receive the appropriate Shared Care Guideline before transferring the prescribing responsibility.
6	Other (Primary Care prescriber to complete if there are other reasons why shared care cannot be accepted or why shared care is to be discontinued if already started, e.g. adverse effects): ……