Lancashire & South Cumbria Medicines Management Group

SHARED CARE GUIDELINE

DRUG: MYCOPHENOLIC ACID

Introduction	**This protocol only applies to the unlicensed indications listed below. Transplant protocols should be followed for licensed indications.** **Unlicensed:** Severe rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, connective tissue diseases with severe / organ-threatening manifestations, interstitial lung disease (not to be used in idiopathic pulmonary fibrosis IPF), vasculitidies, as maintenance post cyclophosphamide in patients for whom azathioprine is contra-indicated or is inappropriate. **Background:** Mycophenolic acid is a suppressor of T and B cell proliferation and adhesion and inhibits inosine monophosphate dehydrogenase that eventually blocks the progression to DNA synthesis and proliferation. **Please note that this guideline only relates to mycophenolic acid, there is a separate shared care guideline for mycophenolate mofetil.** **Mycophenolic acid 720 mg is approximately equivalent to mycophenolate mofetil 1 g 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.**
Dose & Administration[1]	**Typical dose:** 720 to 1440mg/daily (in divided doses). **Starting dose:** 360mg daily for the 1st week, 360mg twice daily for the 2nd week then increase dose gradually by 360mg each week until the optimal or maximum tolerated dose is reached. (For interstitial lung disease the starting dose is 180-360mg daily increasing by 180mg per week up to 720-1080mg twice daily.[6]) **Maximum dose:** Up to 2160 mg/day. **Time to response:** 6 weeks to 3 months.
Secondary Care Responsibilities	• Discuss the benefits and side effects of treatment with the patient. Ensure that the patient understands which warning signs and symptoms to report. • Ensure that women and men understand the need for effective contraception and to immediately consult a physician if there is a possibility of pregnancy (See cautions section below and MHRA warning for more information) • Ensure that the patient is aware that the use of the drug for this condition is unlicensed. Make a clear, accurate and legible record of medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine (as per GMC guidance). • Perform pre-treatment screening (chest X-ray [only if pre-existing lung disease], height, weight, BP, FBC, LFT's, CrCl/ calculated GFR, albumin and pregnancy test in women of childbearing potential). • Patients should be assessed for co-morbidities, including evaluation for respiratory disease and screening for occult viral infection. • Provide the patient with prescriptions for Mycophenolic acid until on stable dose and they have undergone monthly monitoring for a minimum of 3 months. • Provide the patient with a monitoring and dosage record booklet and ensure that the patient knows when and where to attend for monitoring. Encourage the patient to take responsibility for ensuring that results of tests are entered in the monitoring booklet. • Arrange shared care with the patient's GP and continue to provide treatment until shared care arrangements have been confirmed. • Review the patient to monitor the patient's response to therapy. Advise the GP of the secondary care monitoring and follow up arrangements.

	• Conduct laboratory monitoring (see below) TWO WEEKLY until dose stable for SIX weeks, then every MONTH for THREE months • Request copies of test results for the patient's GP by completing the "copy to" section on the pathology form (where available or follow local protocols). • Advise the GP when to stop treatment. • Ensure that clear backup arrangements exist for GPs to obtain advice.
Primary Care Responsibilities	• Provide the patient with prescriptions for Mycophenolic acid once on stable dose and having undergone monthly monitoring for a minimum of 3 months. • Arrange on-going monitoring at the recommended frequencies (see MONITORING below) ensure that test results are recorded in the monitoring booklet. Request copies of test results for the patient's consultant by completing the "copy to" section on the pathology form (where available or follow local protocols). • Report any adverse events to the consultant or specialist nurse and stop treatment on their advice or immediately if an urgent need arises (see MONITORING below). • Report any worsening of control of the condition to the consultant or specialist nurse.
Immunisations	• Annual flu vaccination is recommended. • Pneumococcal vaccination is recommended • COVID-19 vaccination is recommended. • In patients exposed to chicken pox or shingles, if required, passive immunisation should be considered for varicella. Refer to Green book: Varicella: the green book, chapter 34 - Publications - GOV.UK • Live vaccines should be avoided including shingles unless specialist advice has been sought. See 'Green Book' for details of vaccines in patients who may be immunosuppressed. **Live vaccines should be avoided until specialist advice has been sought.**
Drug Interactions	Caution should be exercised when switching combination therapy from regimens containing immunosuppressants, which interfere with enterohepatic recirculation, e.g. ciclosporin, to others devoid of this effect, e.g. tacrolimus, sirolimus, belatacept, or vice versa. Drugs which interfere with Mycophenolic acid's enterohepatic cycle (e.g. cholestyramine, antibiotics) should be used with caution due to their potential to reduce the plasma levels and efficacy of Mycophenolic acid. It is recommended that Mycophenolic acid should not be administered concomitantly with azathioprine because such concomitant administration has not been studied. **Other clinically significant interactions:** Rifampicin decreases the plasma concentration of Mycophenolic acid.[7]
Cautions	**Neoplasms** As general advice to minimise the risk for skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor. **Infections** Patients treated with immunosuppressants, including Mycophenolic acid, are at increased risk for opportunistic infections (bacterial, fungal, viral and protozoal), fatal infections and sepsis. There is a risk of hypogammaglobulinaemia or bronchiectasis when used in combination with other immunosuppressants. Measure serum immunoglobulin levels if recurrent infections develop, and consider bronchiectasis or pulmonary fibrosis if persistent respiratory symptoms such as cough and dyspnoea develop – **see monitoring section.** Mycophenolic acid has a cytostatic effect on B- and T-lymphocytes, therefore an increased severity of COVID-19 may occur, and appropriate clinical action should be considered.

	Blood and immune system Patients receiving Mycophenolic acid should be monitored for neutropenia – **see monitoring section for details.** Cases of pure red cell aplasia (PRCA) have been reported in patients treated with Mycophenolic acid in combination with other immunosuppressants – **see monitoring section.** **Patients receiving Mycophenolic acid should be instructed to report immediately any evidence of infection, unexpected bruising, bleeding or any other manifestation of bone marrow failure – see monitoring section also** **Gastro-intestinal** Mycophenolic acid has been associated with an increased incidence of digestive system adverse events, including infrequent cases of gastrointestinal tract ulceration, haemorrhage and perforation. Mycophenolic acid should be administered with caution in patients with active serious digestive system disease. Mycophenolic acid is an IMPDH (inosine monophosphate dehydrogenase) inhibitor. Therefore, it should be avoided in patients with rare hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan and Kelley-Seegmiller syndrome. **Special populations** Elderly patients may be at an increased risk of adverse events such as certain infections (including cytomegalovirus tissue invasive disease) and possibly gastrointestinal haemorrhage and pulmonary oedema, compared with younger individuals. Mycophenolic acid contains some sodium (26mg in 360mg tablet) and lactose.
Contra-indications	• Mycophenolic acid should not be given to patients with hypersensitivity to mycophenolate mofetil, mycophenolic acid or to any of the excipients. Hypersensitivity reactions to Mycophenolic acid have been observed. • Mycophenolic acid should not be given to women of childbearing potential who are not using highly effective contraception. • Mycophenolic acid treatment should not be initiated in women of childbearing potential without providing a pregnancy test result to rule out unintended use in pregnancy. • Mycophenolic acid should not be used in pregnancy. • Mycophenolic acid should not be given to women who are breastfeeding.
This guidance does not replace the SPCs, which should be read in conjunction with this guidance.	

Monitoring

The team responsible for prescribing the medication should also hold responsibility for monitoring.

Treatment Status	FBC	LFT	Albumin	Creatinine/ calculated GFR
Initial monitoring until on stable dose for 6 weeks	Every 2 weeks	Every 2 weeks	Every 2 weeks	Every 2 weeks
For next three months	Every month	Every month	Every month	Every month
Thereafter, *	Every month	Every month	Every month	Every month

***Please note:** If the patient is also being treated with **leflunomide**, increased monthly monitoring is required, as specified in the leflunomide shared care guidance. (Where other biologic/DMARDs are used in combination with Mycophenolic acid, the standard monitoring requirements, as outlined above, continue to apply).

As per secondary care responsibilities, for clarity the frequency of monitoring should be specified in the initial shared care request.

N.B. Secondary care will be responsible for:
FBC, LFTs and CrCl and albumin every TWO WEEKS until dose stable for SIX weeks, then every MONTH for THREE months.

Primary care will then take ongoing responsibility for:
FBC, LFTs and CrCl and albumin every MONTH.

Dose increases should be monitored by FBC, creatinine / calculated GFR, albumin and LFTs every 2 weeks until on stable dose for 6 weeks and then revert to previous schedule.

Patients who have been stable for 12 months can be considered for reduced frequency monitoring on an individual patient basis.

Laboratory adverse event*

WBC	< 3.5 x 10^9/L or less than the lower limit of the reference as per lab
Neutrophils	< 1.6 x 10^9/L or less than the lower limit of the reference as per lab
Eosinophils	>0.5 x 10^9/L or greater than the upper limit of the reference as per lab
Platelets	< 140 x 10^9/L or less than the lower limit of the reference as per lab
AST, ALT	> 100 U/l
Albumin	<30g/L
MCV*	> 105 fL
U&E (including creatinine)	Increase in creatinine of >30% over 12months or CrCl <60ml/min
Potassium	>5.5mmol/L

* Withhold and check vitamin B12, folate and TSH. If abnormal, treat any underlying abnormality. If normal, discuss with the specialist team.

STOP treatment unless otherwise advised by secondary care (For patients with SLE neutropenia can be a manifestation of disease and therefore in some instances it may be appropriate to continue treatment outside the above reference range on specialist advice).

As well as responding to absolute values in laboratory tests, it is also relevant to observe trends in results e.g. gradual decreases in white blood cells or albumin, or increasing liver enzymes.

	Bruising with or without sore throat - Check FBC immediately and discuss with specialist team. Recurrent infection – measure serum immunoglobulin levels, discuss with the specialist team if low. Persistent cough or dyspnoea – discuss with the specialist team, bronchiectasis or pulmonary fibrosis should be considered. **Patients receiving Mycophenolic acid should be instructed to report immediately any evidence of infection, unexpected bruising, bleeding or any other manifestation of bone marrow failure**
Adverse Effects	**Common or very common:** Acidosis; alopecia; anaemia; appetite decreased; arthralgia; asthenia; bone marrow disorders; chills; constipation; cough; depression; diarrhoea; drowsiness; dyslipidaemia; dyspnoea; electrolyte imbalance; fever; gastrointestinal discomfort; gastrointestinal disorders; gastrointestinal haemorrhage; headache; hyperglycaemia; hypertension; hypotension; increased risk of infection; insomnia; leucocytosis; leucopenia; malaise; nausea; neoplasms; oedema; oral disorders; pain; pancreatitis; paraesthesia; renal impairment; respiratory disorders; seizure; sepsis; skin reactions; tachycardia; thinking abnormal; thrombocytopenia; tremor; vomiting; weight decreased. **Uncommon:** Agranulocytosis. **Frequency not known:** Endocarditis; hypogammaglobulinaemia; malignancy; meningitis; neutropenia; polyomavirus-associated nephropathy; progressive multifocal leukoencephalopathy (PML); pure red cell aplasia.[8] **Specific side-effects:** **Common or very common:** With oral use: Anxiety; burping; confusion; dizziness; gout; hepatic disorders; hyperbilirubinaemia; hyperuricaemia; neuromuscular dysfunction; taste altered; vasodilation.[8]

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References

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RELEVANT CONTACT LIST

Speciality	
Name and Title	Tel. No.

Appendix 1

Optional Shared Care Agreement form

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

PLEASE NOTE: The use of this form is not compulsory, but the same information must be communicated between the specialist service and primary care in advance of entering into a shared-care agreement.

Part 1 - To be signed by Consultant / Associate Specialist / Speciality Trainee or Specialist Nurse (who must be a prescriber)

Dear Doctor:	Click or tap here to enter text.
Name of Patient:	Click or tap here to enter text.
Address:	Click or tap here to enter text.
	Click or tap here to enter text.
	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Patient NHS Number:	Click or tap here to enter text.
Patient Hospital Number:	Click or tap here to enter text.
Diagnosed Condition:	Click or tap here to enter text.

I request that you prescribe:

(1) Click or tap here to enter text.
(2) Click or tap here to enter text.
(3) Click or tap here to enter text.
(4) Click or tap here to enter text.

for the above patient in accordance with the LMMG shared care guideline(s) (Available on the LMMG website).

Last Prescription Issued:	Click or tap to enter a date.
Next Supply Due:	Click or tap to enter a date.
Date of last blood test (if applicable):	Click or tap to enter a date.
Date of next blood test (if applicable:	Click or tap to enter a date.
Frequency of blood test (if applicable:	Click or tap here to enter text.

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care guideline.

If this is a Shared Care Agreement for a drug indication which is unlicensed or off label, I confirm that informed consent has been received from the patient.

I will accept referral for reassessment at your request. The medical staff of the department are available if required to give you advice.

Details of Specialist Clinicians

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Position:	Choose an item.
Signature:	Click or tap here to enter text.

(An email from the specialist clinician will be taken as the authorised signature)
In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a Specialist Nurse, it is the supervising consultant who takes medicolegal responsibility for the agreement.

Consultant	Click or tap here to enter text.

Contact Details	
Telephone Number	Click or tap here to enter text.
Extension	Click or tap here to enter text.
Email Address	Click or tap here to enter text.

Part 2 - To be completed by Primary Care Clinician (GP)

I agree to prescribe and monitor Click or tap here to enter text. for the above patient in accordance with the LMMG shared care guideline(s) commencing from the date of next supply / monitoring (as stated in Part 1 of the agreement form).

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.

*Please sign and return a copy **within 14 calendar days** to the address above* **OR**

If you **do not** agree to prescribe, please sign below and provide any supporting information as appropriate:

I **DO NOT** agree to enter in to a shared care agreement on this occasion.

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.
Further information:	Click or tap here to enter text.