MYCOPHENOLATE mofetil and MYCOPHENOLIC acid Drug Specific Document

TARGET AUDIENCE	Board-wide
PATIENT GROUP	All patients aged 12 years and older taking Mycophenolate mofetil (MMF) or Mycophenolic acid (MPA)

References

- British National Formulary (2024). *BNF | NICE*. [online] NICE. Available at: https://bnf.nice.org.uk/.
- Specialist Pharmacy Service (2021). *Medicines Monitoring*. [online] SPS - Specialist Pharmacy Service. Available at: https://www.sps.nhs.uk/home/tools/drug-monitoring/.
- Electronic Medicines Compendium (2019). *Home - electronic medicines compendium (emc)*. [online] Medicines.org.uk. Available at: https://www.medicines.org.uk/emc
- NHS Lothian Shared Care Agreements. Mycophenolate mofetil (MMF) & mycophenolic acid (MPA) for solid organ transplant adult patients. Available at https://formulary.nhs.scot/east/help-and-support/for-healthcare-professionals/shared-care-of-medicines/nhs-lothian-shared-care-agreements/ Version 4.0; Review date: December 2026

Governance information for drug specific document

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	Area Drug and Therapeutics Committee
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MYCOPHENOLATE / MYCOPHENOLIC ACID Drug Specific Monitoring Document

Medication Name	MYCOPHENOLATE mofetil (MMF) & MYCOPHENOLIC acid (MPA) *All non-transplant indications are off-label*
Actions by specialist clinician before initiation	• LFTs • U&Es • eGFR • FBC • Blood pressure • Height & weight • Pregnancy test: two tests 8-10 days apart in women of child bearing potential; exclude before initiating. • Chest x-ray, if deemed clinically appropriate *For all drugs, specialist clinicians should consider whether vaccination/exclusion of other contraindications (including active infection), is required and arrange as appropriate.*
DIS actions on starting treatment and following dose titration during initiation period	**Non-transplant patients:** Monitor FBC every week for 4 weeks, then every 2 weeks for 2 months (consider interrupting treatment if neutropenia develops) Every 2 weeks for minimum 6 weeks until dose stable; then 3 monthly • LFTs • U&Es • eGFR • FBC **Transplant patients:** Blood monitoring as directed by the transplant specialist team
Ongoing monitoring in Primary Care once stable	**Non-transplant patients:** Monitor FBC every month in the first year (consider interrupting treatment if neutropenia develops). Every 3 months, more frequently in patients at a higher risk of toxicity: • LFTs • FBC • U&Es • eGFR **Transplant Patients:** Although blood level monitoring is routinely carried out by the specialist team during clinic visits, in exceptional circumstances the team may request that the GP arranges for blood tests to be taken locally for patient convenience. If the GP agrees to this, the specialist will give advice on the management of abnormal results.

Action if monitoring is outside reference range	**Non transplant patients**:
	Contact a specialist any of the following develops and consider interrupting treatment if neutropenia develops
	• *Full blood count*
	  ○ WCC less than 3.5 x 10^9/L,
	  ○ Neutrophils less than 1.6 x 10^9/L
	  ○ Unexplained eosinophilia greater than 0.5 x 10^9/L
	  ○ Platelets less than 140 x 10^9/l
	  ○ MCV greater than 105f/L then check B12, folate, thyroid-stimulating hormone levels. If abnormal treat; if normal accept MCV up to 110f/L. Discuss with specialist team if > 110f/L.
	• Liver function
	  ○ Unexplained fall in serum albumin less than 30g/L
	  ○ AST or ALT increase to greater than 100units/L
	• Renal function
	  ○ Creatinine increase greater than 30% above baseline over 12 months
	  ○ Calculated GFR less than 60ml/min/1.73m^2 (repeat in 1 week, if still more than 30% from baseline, withhold and discuss with specialist team)
	Transplant patients:

	The specialist team will give advice on the management of abnormal results. All monitoring and dose adjustments will be performed by the acute specialist teams. No dose adjustment decisions are expected to be made by primary care teams.
Actions to take if restarting medication after treatment break	Actions needed may vary - consult specialist team for further guidance Non transplant patients: Patients should be referred by the specialist clinician to the drug initiation hub if re-titration or enhanced monitoring is required

CONSULTATION AND DISTRIBUTION RECORD	
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Consultation Process / Stakeholders:	LMC, GP Sub-committee, Alison Yule, Eimear Gordon, Richard Shearer, Drug Initiation Service pharmacists, Acute specialist consultants and pharmacists. Agata Paczek (NHS Lothian), Dominique Sweeney (NHS GGC)
Distribution	Acute specialist consultants and pharmacists, Senior primary care pharmacists, all individuals involved with the Drug Initiation Service, LMC and GP sub-committee

CHANGE RECORD			
Date	**Lead Author**	**Change**	**Version**