Drug specific monitoring document:

# MYCOPHENOLATE MOFETIL & MYCOPHENOLIC ACID

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

## Clinical Guidelines Summary

This document is for use within the NHS Lanarkshire for the initiation and monitoring of patients >12 years on Mycocphenolate mofetil (MMF) & Mycophenolic acid (MPA).

Licensing

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

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

**These indications are off-label**. The initiating specialist must specify the indication for each patient when referring to DIS and clearly state when use is off-label.

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| **Medication Name** | **MYCOPHENOLATE MOFETIL (MMF) & MYCOPHENOLIC ACID (MPA)**<br>*All non-transplant indications are off-label* |
| **Actions by specialist clinician before initiation** | • LFTs<br>• U&Es<br>• eGFR<br>• FBC<br>• Blood pressure<br>• Height & weight<br>• Pregnancy test: two tests 8-10 days apart in women of child bearing potential; exclude before initiating.<br>• Chest x-ray, if deemed clinically appropriate<br><br>*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:**<br>To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months:<br>• LFTs<br>• FBC<br>• U&Es<br>• eGFR<br><br>**Transplant patients:**<br>Blood monitoring as directed by the transplant specialist team |
| **Ongoing monitoring in Primary Care once stable** | **Non-transplant patients:**<br>Monitor FBC every month in the first year (consider interrupting treatment if neutropenia develops).<br>Every 3 months, more frequently in patients at a higher risk of toxicity:<br>• LFTs<br>• FBC<br>• U&Es<br>• eGFR<br><br>**Transplant Patients:**<br>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**:<br>Contact a specialist any of the following develops and consider interrupting treatment if neutropenia develops<br><br>• Full blood count<br>  ○ WCC less than 3.5 x $10^9$/L,<br>  ○ Neutrophils less than 1.6 x $10^9$/L<br>  ○ Unexplained eosinophilia greater than 0.5 x $10^9$/L<br>  ○ Platelets less than 140 x $10^9$/l<br>  ○ 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. |

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| | • Liver function<br>  ○ Unexplained fall in serum albumin less than 30g/L<br>  ○ AST or ALT increase to greater than 100units/L<br><br>• Renal function<br>  ○ Creatinine increase greater than 30% above baseline over 12 months<br>  ○ 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)<br><br>**Transplant patients:**<br>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<br><br>Non transplant patients: Patients should be referred by the specialist clinician to the drug initiation hub if re-titration or enhanced monitoring is required |

## References/Evidence


- 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/.
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- NHS Lothian Shared Care Agreements. Mycophenolate mofetil (MMF) for non-transplant indications Available at https://formulary.nhs.scot/media/ra4hri5p/mycophenolate-combined-sca-v1-2-with-dermatology-inclusion-final.pdf Version 1.2; Review date: December 2025
- 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
- NHSE/ Specialist Pharmacy Service guidance (2022). National shared care protocol: Mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications). Available at https://www.england.nhs.uk/publication/shared-care-protocols/#heading-3 Version 1.0; Review date: Jan 2025.

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## 1. Governance information for Guidance document

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| **Lead Author(s):** | Sean Haughey |
| **Endorsing Body:** | Area Drug and Therapeutics Committee |
| **Version Number:** | V2.0 |
| **Approval date** | 17/12/2025 |
| **Review Date:** | 17/12/2028 |
| **Responsible Person (if different from lead author)** | |

| **CONSULTATION AND DISTRIBUTION RECORD** | |
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| **Contributing Author / Authors** | Anthony Carson, Hannah Rae, Sean Haughey |
| **Consultation Process / Stakeholders:** | Drug initiation service governance group, ADTC |
| **Distribution** | Right Decision Service website |

**CHANGE RECORD**

| Date | Lead Author | Change | Version |
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| 17/12/25 | Sean Haughey | • Correction of formatting in line with NHS Lanarkshire approved clinical guideline template<br>• Addition of Clinical Guideline Summary<br>• Correction of “DIS actions on starting treatment and following dose titration during initiation period” to amend error<br>• Updated references<br>• Updated governance information | 2.0 |
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