NHS
Pan Mersey
Area Prescribing Committee

SHARED CARE FRAMEWORK

The Pan Mersey Area Prescribing Committee recommends the prescribing of MYCOPHENOLATE MOFETIL for patients within adult services.

SHARED CARE

1. Background	This shared care framework aims to provide clarity on the responsibilities of all professionals involved in commissioning and prescribing across primary, secondary and tertiary care. Good organisation of care across the interface between primary and secondary/tertiary care is crucial in ensuring that patients receive high quality care – and in making the best use of clinical time and NHS resources in all care. Mycophenolate mofetil (MMF) is a licensed product for prophylaxis of acute rejection in renal, cardiac and hepatic transplantation. It has been used for many years and these remain the licensed indications for the drug. The purpose of this document is to provide guidance on the use of mycophenolate in autoimmune conditions for which the drug is used off-label. Dose adjustments and monitoring requirements for disease modifying drugs (DMDs) (licensed and unlicensed indications) included in this Framework are in line with national guidance published by the British Society for Rheumatology 2017[1].
2. Licensed indications	Transplant: renal, cardiac and hepatic. **Not applicable to this shared care agreement**
3. Locally agreed off-label use	• Treatment of myasthenia gravis in patients intolerant or unresponsive to azathioprine • Systemic lupus erythematosus (SLE) and other rheumatology conditions • Neuromyelitis optica, myasthenia gravis, inflammatory myopathies and neuropathies, vasculitis and other immune-mediated central and peripheral nervous system diseases • Dermatology conditions including psoriasis, atopic dermatitis, lupus erythematosus, sarcoidosis and cutaneous vasculitis • Inflammatory bowel disease • Interstitial lung disease • Myositis • Autoimmune and inflammatory kidney conditions • Sarcoidosis
4. Initiation and ongoing dose regime	Transfer of monitoring and prescribing to primary care is normally 3 months after dose has been initiated. The duration of treatment will be determined by the specialist based on clinical response and tolerability. **Dosing information** 1g – 3g per day in divided doses. Maximum dose in chronic kidney disease (CKD) 4+5 is 1g twice daily. Dose is variable, depends on the clinical indication and will be decided by the clinical team initiating treatment.

	Please note for rheumatology conditions a patient may be initiated on more than one DMD All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. Dose increases should be monitored by FBC creatinine/eGFR, ALT and/or AST and albumin every 2 weeks for 6 weeks after the dose increase, then revert back to previous schedule. **Termination of treatment will be the responsibility of the specialist.**
5. Baseline investigations, initial monitoring, and dose titration to be undertaken by GP.	**Baseline** • Height, weight, BP, FBC, creatinine/eGFR, ALT and /or AST, albumin. • Vaccinations against pneumococcus and influenza are recommended. • Shingles vaccine (Zostavax) is recommended as per the JCVI for eligible patients • Specialist to highlight in the first clinic letter notifying the GP of the decision to initiate DMDs that the GP will need to give the shingles vaccine if the patient is aged 70 years or older and for those 69 years and younger but are deemed clinically eligible for Zostavax by the specialist team. The pneumococcal vaccine should also be administered, if not already given. The GP should also be advised to add the patient to the influenza vaccine list. • DMDs should be started two to four weeks AFTER administration of the shingles vaccine (Zostavax) as stated in the Green Book, therefore the specialist team should arrange this with the GP, in a timely manner so as not to delay commencement of DMDs. • Patients should be assessed for comorbidities that may influence DMD choice, including evaluation of respiratory disease and screening for occult viral infection • Treatment should not be started for 4 weeks after live vaccines (eg oral typhoid, MMR, BCG, yellow fever) **Initiation** • FBC, creatinine/eGFR, ALT and /or AST and albumin every two weeks until on stable dose for six weeks. • Once on a stable dose, monthly FBC, creatinine/eGFR, ALT and /or AST and albumin for three months. Thereafter, FBC, creatinine/eGFR, ALT and/or AST and albumin at least every 12 weeks , or more frequently in patients at higher risk of toxicity.

6. Ongoing monitoring requirements to be undertaken by primary care	**Monitoring**	**Frequency**
	FBC, creatinine/eGFR, ALT and/or AST and albumin CRP and ESR (rheumatology patients only)	After the initial monitoring period (see section 5), every 12 weeks, or more frequently in patients at higher risk of toxicity as advised by the specialist team. NB: Some of the initial monitoring (likely to be 1-2 months of monthly monitoring) may take place in primary care. The exact frequency of the monitoring to be communicated by the specialist in all cases.

7. Pharmaceutical aspects		
	Route of administration:	Oral or subcutaneous injection
	Formulation:	250mg & 500mg tablets and capsules

	Administration details:	Take one hour before or two hours after food
	Other important information:	Generic formulations are suitable for use in all off label indications for the drug. There are two preparations of mycophenolic acid in the UK; mycophenolate mofetil and mycophenolate sodium. The two salts should not be interchanged or substituted because they have differing pharmacokinetic profiles. This guideline relates to mycophenolate mofetil only. **Prescribers should clearly prescribe mycophenolate mofetil NOT mycophenolic acid.**
8. Contraindications	Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction. • Hypersensitivity • Women of childbearing potential who are not using highly effective contraception. • Women who are pregnant or breastfeeding. SPC cautions administration of live vaccines; however, JCVI and BSR recommend that oral DMD therapy at standard doses is not a contraindication in most patients, clinician discretion is advised	
9. Significant drug interactions	For a comprehensive list consult the BNF or Summary of Product Characteristics (SPC). Seek advice from the initiating Specialist if there are any concerns about interactions.	
10. Adverse effects and management	**Adverse effect**	**Management**
	Abnormal bruising or severe sore throat	Stop drug until FBC results available, contact Specialist Practitioner (SP)
	Fall in WCC <3.5 x 10^9/l Fall in neutrophils <1.6 x 10^9/l (<2.0 x 10^9/l for gastro indications) Fall in platelets <140 x 10^9/l	Stop drug, contact SP
	Increased MCV >105fl	Check folate, B12 & TSH. Treat if abnormal, contact SP for advice if normal
	Unexplained reduction in albumin <30g/L Abnormal LFTs – AST or ALT > 100u/l	Contact SP
	Nausea and vomiting, diarrhoea	Discuss with SP
	Localised infection	Discuss with SP
	Increase in serum creatinine >30% over period of 12 months or less OR decline in eGFR > 25%	Contact SP if there is new or unexplained renal impairment.
11. 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 drugs and pregnancy prevention and planning information. Mycophenolate mofetil should be temporarily stopped if the patient has a severe infection and the specialist should be informed.	

12. Pregnancy and breastfeeding	Avoid in pregnancy and breast feeding. If a patient becomes pregnant while on treatment, they should be referred back to the hospital immediately for review. Treatment with mycophenolate should be stopped at least 6 weeks before a planned pregnancy. Male patients or their female partner should use highly effective contraception during treatment and at least 90 days after stopping mycophenolate. MHRA Safety Alert: Mycophenolate mofetil, mycophenolic acid: new pregnancy-prevention advice for women and men MHRA Safety Alert: Mycophenolate mofetil, mycophenolic acid: updated contraception advice for male patients BSR&BHPR guideline on prescribing in pregnancy and breastfeeding January 2016
13. Specialist contact information	See appendix 2
14. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
15. References	1. BSR monitoring guidelines 2. Mycophenolate Summary of Product Characteristics 3. The Green Book - Immunisation against infectious diseases
16. To be read in conjunction with the following documents	• Policy for shared care (Appendix 1) • Shared care agreement (Appendix 2) • RMOC Shared Care for Medicines Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs NHSE 2019 • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care NHSE When two or more DMDs are initiated, one shared care agreement form should be completed that includes all relevant drugs.

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient, and it meets the criteria outlined in the Shared Care section of the Pan Mersey Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary document.

- Prescribing responsibility will only be transferred when the specialist and the patient's GP agree that the patient's condition is stable.
- Before prescribing responsibilities are transferred to primary care, all information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the shared care agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- For Rheumatology patients under Wirral Trust, Specialist to ensure baseline monitoring of full blood count and biochemical profile as described by the shared care framework.
- For all other patients, Specialists to initiate the medicine, prescribe, monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- 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. Patients should be aware that shared care will not always be the best option for them. This is a mutual agreement between the specialist and primary care, which needs to be confirmed with the shared care agreement.
- To confirm the diagnosis.
- To confirm that the patient's care can be suitably maintained by primary care, following their medicine being optimised for approximately 3 months, with satisfactory investigation results.
- To initiate the medicine, prescribe, and monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Is provided with any necessary written information with regard to the individual medicine including patient information leaflets on individual drugs.
    - Provides informed consent when any medicine is prescribed for an off-label indication for any condition
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- Following the request to the patient's GP to initiate shared care; to ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place at the end of 28 days. Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
- To assess the patient regularly as necessary for the duration of therapy. The specialist will send a written summary within 14 days to the patient's primary care prescriber, confirm that ongoing treatment with the monitored medicine is appropriate and record test results on the patient-held monitoring booklet if

applicable confirm the current dosage and clearly highlight any changes made both to the patient and in writing to the patient's primary care prescriber.

- 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
- To review the patient promptly if required by the GP.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate the failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.
- Following the addition of a new drug to an existing regime covered by a shared care agreement, the Specialist must initiate, prescribe, and monitor the new drug in accordance with the relevant shared care agreement including subsequent review and inform the GP of this. A new shared care agreement must then be initiated for the new drug.
- 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.
- Addition of a second DMD: Following the addition of a new drug to an existing regime covered by a Shared Care Agreement, the Specialist must initiate, prescribe, and monitor the new drug in accordance with the relevant shared care agreement, including subsequent review, and inform the GP of this. A new Shared Care Agreement must then be initiated for the new drug.

Primary Care Responsibilities in Shared Care

- To prescribe within their own level of competence.
- To reply to a written request for shared care within 21 days ensuring both copies of the shared care agreement are signed if appropriate.

If agreeing to shared care, the GP is asked:

- To prescribe, manage and monitor the medicine as advised by the specialist and in line with the individual shared care framework.
- To review the patient as required by the shared care framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the shared care agreement on the patient`s clinical record. A Snomed code "268529002 Shared Care- Specialist/GP" can be used. Where applicable, keep the patient-held monitoring record up to date with the results of investigations, changes in dose and alterations in management.
- To be familiar with the individual shared care framework, have the information and knowledge to understand the therapeutic issues relating to the patient's clinical condition and undergo any additional training if necessary.
- To 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/.
- To inform the specialist of any relevant change in the patient's circumstances.
- To seek specialist advice as appropriate.
- To meet any additional requirements as required by the individual shared care framework.

Supporting information

- To respond to specialist communication relating to any change or addition to the patient's treatment or monitoring covered by the shared care agreement.
- Where community nurse involvement is required in the administration of medicines under a shared care framework, 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

Where the GP wishes to withdraw prescribing, for example when the patient fails to attend for monitoring, they need to give the specialist team a minimum of 14 days' notice of their need to resume responsibility for prescribing. The specialist is required to acknowledge this request within the 14-day time period.

Patient Responsibilities in Shared Care

- 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 purchased elsewhere prior to receiving any new prescribed or over-the-counter medication.
- Report 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.

Appendix 2

Shared Care Request letter (Specialist to Primary Care Prescriber)

Disease modifying drugs (DMDs)

Request by specialist clinician for the patient's GP to enter into a shared care agreement

To be signed by consultant / prescribing member of specialist team (circle or underline as appropriate)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*

Date of birth: *[insert date of birth]*

NHS Number: *[insert NHS Number]*

Diagnosis: *[insert diagnosis]*

Please add patient addressograph here

As per the agreed Pan Mersey APC shared care framework for *[insert medicines names and doses]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The risks and benefits of treatment have been explained to the patient	Yes / No
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	Yes / No
A copy of the shared care framework which covers this treatment/the shared care framework can be found here (*insert electronic/ web link*)	Yes / No
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you have provided supporting information to the patient, please insert a copy here

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency].*

If you are in agreement, please undertake monitoring and treatment from *[insert date*] NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Frequency of blood test: .....

I confirm that if this is a shared care agreement for a drug indication which is unlicensed or off label, informed consent has been received.

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Details of Specialist Clinicians

Name ..... Date .....

Consultant / prescribing member of specialist team (circle or underline as appropriate)

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 prescriber who is not the specialist, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: .....

Contact details

Telephone number: ..... Ext: .....

Address for return of documentation .....

.....

.....

Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & Frequency

I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Usual GP signature: ..... Date .....

Usual GP name: ..... (please print)

GP: Please sign and return a copy within 21 calendar days to the address above

GP Practice address/practice stamp

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: