Berkshire West Integrated Care System
Representing
Berkshire West Clinical Commisioning Group
Royal Berkshire NHS Foundation Trust
Berkshire Healthcare NHS Foundation Trust
Berkshire West Primary Care Alliance

Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from ***Secondary Care to Primary Care***

Mycophenolate mofetil (MMF) for the treatment of inflammatory joint disease

APC PG 013

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Date
BW Area Prescribing Committee	A Penn, APC Chair	November 2016
RBH Drugs and Therapeutics Committee	S Hussain, DTC Chair	December 2016

Change History

Version	Date	Author	Reason
v.1.0	August 2016	A Scott	New guideline

This prescribing guideline remains open to review considering any new evidence.

This guideline should only be viewed online and will no longer be valid if printed off or saved locally

Author	J MacNally, A Bradlow, S Townsend adapted by A Scott	Date of production:	August 2016
Job Title	Lead Interface Pharmacist	Review Date	August 2019
Protocol Lead	Dr A Chan	Version	v.1.0

Mycophenolate mofetil (MMF) for the treatment of inflammatory joint disease

Introduction

Mycophenolate mofetil (MMF) is a potent reversible selective inhibitor of purine synthesis. MMF inhibits T cell proliferation and antibody production by B cells. MFF is used to treat scleroderma, SLE especially when there is renal involvement. It is also used to treat inflammatory myopathy (such as dermatomyositis and polymyositis) and vasculitis.

This information sheet does not replace the SPC, which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.
Link to the relevant SPC website: www.medicines.org.uk

Dose

A typical dose regimen may be 500mg (1 tablet) twice a day for 2 weeks then if tolerated, 1gram (2 tablets) twice a day thereafter. Tablets should be taken on an empty stomach, either one hour before or 2 hours after a meal.

Cautions and contraindications

- Pregnancy or breastfeeding
- Active gastro-intestinal disease
- Hypersensitivity to MMF
- Severe abnormal liver or renal function
- Cancer risk: patients receiving immunosuppressant regimens are at increased risk of lymphomas and skin malignancies. Avoid exposure to strong sunlight and use high factor sunscreens.

Side effects

- Gastro-intestinal disturbances - Nausea, constipation, flatulence, anorexia and abdominal discomfort, GI inflammation, bleeding
- Taste disturbance
- Hypertension/hypotension
- Disturbances of electrolytes and blood lipids
- Blood disorders

Patients should be advised to avoid exposure to strong sunlight.

Interactions

- **Aciclovir/ valganciclovir** Increases in both aciclovir and mycophenolic acid plasma concentrations occur with concurrent administration but this interaction is only considered to be of clinical significance in patients with impaired renal function.
- **Antacids** With magnesium and aluminium hydroxides, a decrease in the absorption of mycophenolate mofetil may occur.
- **Cholestyramine** A significant decrease in the absorption of mycophenolate mofetil may occur with concurrent administration. Use with caution.
- **Ciclosporin** May reduce mycophenolic acid levels
- **Ganciclovir** Increased ganciclovir and mycophenolic acid concentrations are expected but no dose adjustment of mycophenolate mofetil is required.
- **Sirolimus** Potential increase in mycophenolic acid level with increased incidence of adverse effects. Monitor for adverse effects such as leucopenia, diarrhoea and vomiting.
- **Live vaccines** are contra-indicated and should not be given to immunocompromised individuals. Other vaccines may be less effective**.**

Criteria for Use

RESPONSIBILITIES and ROLES

Specialist responsibilities
1 Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum supply the first month of treatment or until patient is stabilised).
2 Carry out baseline and subsequent monitoring until the GP agrees to share care
3 Send a letter to the GP requesting shared care for the patient.
4 Routine clinic follow-up on a regular basis.
5 Send a letter to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
6 Evaluation of any reported adverse effects by GP or patient.
7 Advise GP on review, duration or discontinuation of treatment where necessary.
8 Inform GP of patients who do not attend clinic appointments.
9 Ensure that backup advice is available at all times

General Practitioner responsibilities
1 Monitor patient's overall health and well being.
2 Prescribe the drug treatment as described
3 Report any adverse events to the hospital specialist, where appropriate
4 Monitor blood results (FBC, U&E's, LFT's & CRP) in line with recommendations below
5 Help in monitoring the progression of disease.

Monitoring requirements and actions

- Pre-treatment FBC, U&Es, LFT's, creatinine
- Subsequent Monitoring
  - **FBC** - Every week for the first 8 weeks, twice weekly for 2 months then if stable monthly thereafter.
  - **LFT** - Monthly until dose is stable
  - **U&E's** - Every 6 months (more frequently if there is any reason to suspect deteriorating renal function).

FBC	WBC	<4.0 but > 3.0x 10^9/L	Withhold and discuss with the rheumatology team
	Lymphocytes	< 0.5 x 10^9/L	Discuss with the rheumatology team
	Neutrophils	< 2.0 x 10^9/L	Discuss with the rheumatology team
		< 1.5 x 10^9/L	Stop treatment and contact the rheumatology team
	Platelets	< 120 x 10^9/L	Withhold treatment and contact the rheumatology team
LFT's	> 2 fold rise in AST, ALT or Alk Phos (from upper limit of reference range)		Withhold treatment and discuss with the rheumatology team
MCV	> 105fl		Investigate and if B12 or folate low start appropriate supplementation

Symptoms and actions	
Abnormal bruising or sore throat	Withhold until FBC available. Contact the rheumatology team
Nausea, diarrhoea and abdominal pain	Contact the rheumatology team if severe or persistent

Patient's / Carer's role
1 Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment. 2 Tell the specialist or GP of any other medication being taken, including over-the-counter products. 3 Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP. 4 Patients will be given a booklet for the blood results to be entered and are expected to bring this to each appointment.

BACK-UP ADVICE AND SUPPORT

Royal Berkshire Foundation Trust Hospital, 0118 322511	
Lead Consultant	0118 322 6559
Lead Nurse	0118 322 7665 or 0118 322 6574
Medicines Information	0118 3227803