Prescribing Framework for Mycophenolate Mofetil for Immunosuppression in ADULTs

Patient's Name:……..… NHS Number:

…… Patient's

Address:……..……(Use addressograph

sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:……..

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……... ……. Date:…….

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and <u>send back to specialist</u>, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

1. Background

These guidelines aim to provide a framework for the prescribing of mycophenolate by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

For use in renal transplant in adults – please see specific Shared Care Framework

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. Indication

Immune mediated disorders.

Specific information will be provided by the specialist on the indication for immunosuppression in individual patients.

3. Dose

The maintenance dose varies according to response and tolerance.
Start at 500mg daily for one week and escalate to between 1.5 and 3g per day in divided doses according to tolerability and response to therapy.

Doses may vary for individual patients and will be documented in specialist letter.

4. Duration of treatment

Advice will be given to the GP on duration of treatment and dose changes for each individual patient.

5. Contraindications and cautions

Mycophenolate mofetil is contra-indicated in pregnancy and breast-feeding women.

Effective contraception must be established before commencing mycophenolate and continued during treatment and **for 13 weeks (90 days) following discontinuation of therapy.** The combined oral contraceptive is a suitable option for this group of patients.
Sexually active men are recommended to use condoms during treatment, and for a total of 13 weeks (90 days) after their last dose of mycophenolate. In addition, female partners of these male patients are recommended to use highly effective contraception during treatment and for a total of 13 weeks (90 days) after the last dose of mycophenolate.

Patients discovered or planning to become pregnant should be started on folic acid 400micrograms daily and referred to the specialist at the earliest opportunity.

6. Adverse effects

Principal adverse effect is gastrointestinal (diarrhoea, nausea, vomiting, abdominal discomfort and constipation - approximately 30% patients). If this is severe then refer to specialist. Other effects include anaemia, leucopenia, neutropenia and thrombocytopenia and sepsis.

7. Interactions

Patients receiving mycophenolate should be advised against immunization with live vaccines. (Influenza vaccines may be given in this group of patients).

Antacids and cholestyramine should not be taken at the same time of day as they will reduce absorption of mycophenolate mofetil.

Always check with BNF or Data Sheet (available electronically at www.medicines.org.uk).

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Monitoring

Disease monitoring: Clinical response to therapy

Drug monitoring:
Baseline: FBC, BCP (including creatinine, LFTs), chest x-ray within last 6 months (arranged by specialist if not available)
Repeat: FBC, BCP weekly until dose stable for 4 weeks, then 2 weekly for 2 months then monthly

Monitoring parameter	Recommended response
9 WBC < 4.0 x 10 /1	withhold **until discussed** with specialist team
9 Neutrophils <2.0 x 10 /l	withhold **until discussed** with specialist team
9 Platelets <150 x 10 /l	withhold **until discussed** with specialist team
>2 fold rise in AST, ALT (from upper limit reference range)	withhold **until discussed** with specialist team
Rash, abdominal pain or diarrhoea	withhold **until discussed** with specialist team
Abnormal bruising or bleeding	withhold **until FBC results** available & discuss with the specialist team

9. Information to patient

Patients should be informed about benefits and risks of treatment and need for monitoring.

Patients should be told to go to their GP immediately if they experience any fever, rash, bruising, bleeding, jaundice or infection.

10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assess the patient following referral by GP Recommend appropriate treatment to the GP (FP10 either initiated by hospital specialist or recommended to GP if non-urgent) Carry out baseline full blood count, differential WCC, platelets, U&Es and LFTs	Prescribe treatment where requested by Specialist
Maintenance	Assess clinical response to treatment Provide adequate advice and support for the GP Provide information to GP on frequency of monitoring if doses are changed	Prescribe as per specialist recommendations. Monitor FBC and BCP as listed in section 8 Monitor patient for adverse effects (as per section 5,6and 7) and refer to specialist team where appropriate. Fill in patient shared care booklet where relevant.

Contact details: During Office hours:

Contact the relevant consultant's secretary via HUTH switchboard

(01482 875875) Specialist pharmacists

Interface Pharmacist – Antonio Ramirez	(01482) 675207
Neurology - Jane Morgan	(01482) 674411
Renal Medicine – Aaron Acquaye	(01482) 674043
Rheumatology – Emily Hardaker	(01482) 674731

Out of hours:

Contact on-call Registrar for specialty via HUTH switchboard.

APPROVAL PROCESS

Written by:	***Marie Miller, Interface Pharmacist***
Consultation process:	***Specialist teams including Rheumatology, Neurology, Dermatology, Nephrology***
Approved by:	***MMIG (May 2016)***
Ratified by:	***HERPC 2016 Updated May 2019***
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