HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Mycophenolate Mofetil and Mycophenolic Acid Solid Organ Transplant

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 not 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 **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** 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 either mycophenolate mofetil or mycophenolic acid by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

Currently, the preferred immunosuppressant combination for new low risk renal transplants is single agent tacrolimus (brand to be specified by specialist renal team). However, some patients may also be prescribed mycophenolate mofetil (or mycophenolic acid). Studies have shown that Mycophenolic acid may useful in patients who suffer with GI intolerance to mycophenolate mofetil.

Generic versions of mycophenolate mofetil are available and it has been agreed that this agent can be prescribed generically. Mycophenolic acid must be prescribed by brand.

Shared care will be implemented 3 months post-transplant.

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

Immunosuppression following solid organ transplant

3. DOSE

The dose depends on the salt of mycophenolate prescribed.

Mycophenolate Mofetil 1g bd, this may be reduced because of GI intolerance but only on recommendation from the specialist. Gastrointestinal side effects may be limited by splitting the dose throughout the day (e.g. 500mg QDS)

Mycophenolic Acid 720mg BD

4. DURATION OF TREATMENT

Long term

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.

Renal function should be taken into consideration when co-prescribing for renal transplant patients

6. ADVERSE EFFECTS

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

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 absorbtion of mycophenolate mofetil / mycophenolic acid.

NSAIDs (and other nephrotoxic drugs) should preferably be avoided or used with extreme caution.

Renal function should be taken into consideration when co-prescribing for renal transplant patients.

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

Monitor patient to ensure concordance with treatment, monitor for side effects (listed in section 7)
For details and frequency of blood tests see section 10

9. INFORMATION TO PATIENT

See above – pregnancy
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	Treatment is initiated in the Leeds on transplantation	Not involved
Monitoring of Treatment and maintenance	FBC & U&E will be checked as follows: Month 1: Three times a week Month 2: Twice a week Month 3: Once a week. Month 4 and thereafter: At each clinic visit and in between times depending on clinical need Inform GP when patient is on a stable dose and request that prescribing is transferred. Inform GP of significant findings and necessary changes to therapy. Available for advice	Take on shared care when patient is stable and requested by the specialist team. Identify to specialist problems with concordance to therapy. Identify adverse reactions and treat or refer where appropriate. (U&E and FBC will be monitored by the specialist and relevant findings communicated to the GP)

Contact details:
During office hours: Please contact the relevant renal consultant's secretary via Hull Royal Infirmary switchboard. (01482)328541
Out of hours: Contact the on call renal consultant via switchboard
Specialist Transplant Nurses: (01482) 674110
Renal Pharmacist: (01482) 674043, or ask for bleep 140 when you contact the switchboard on 01482-875875.

APPROVAL PROCESS

Written by:	**Paul Kendrew. Reviewed by Aaron Acquaye, Renal Pharmacist**
Consultation process:	**Specialists teams in Renal Medicine,**
Approved by:	**MMIG**
Ratified by:	**HERPC Mar 2010 Updated Mar 2019**
Review date:	**Mar 2022**