### Mycophenolate Mofetil - for Immunosuppression in autoimmune conditions

#### AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Mycophenolate Mofetil can be shared between the specialist and general practitioner or non-medical prescriber in primary care (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In that case, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe drugs for this treatment, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with autoimmune conditions are under regular specialist follow-up. This provides an opportunity to discuss and to monitor drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

#### RESPONSIBILITIES and ROLES

<table>
<thead>
<tr>
<th>Specialist responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure FBC, liver and renal function are within normal parameters to allow Mycophenolate Mofetil to commence.</td>
</tr>
<tr>
<td>• If abnormalities found at baseline inform GP as soon as possible.</td>
</tr>
<tr>
<td>• Initiate treatment with Mycophenolate Mofetil or advise GP on initiating treatment.</td>
</tr>
<tr>
<td>• Discuss the benefits and side effects of treatment with the patient and inform GP this has occurred.</td>
</tr>
<tr>
<td>• Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.</td>
</tr>
<tr>
<td>• Review the patient’s condition and monitor response to treatment regularly where indicated.</td>
</tr>
<tr>
<td>• Advise GP if monitoring is needed, and the frequency.</td>
</tr>
<tr>
<td>• Monitor any other parameters considered necessary, or advise GP on which to monitor.</td>
</tr>
<tr>
<td>• Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, any results of the monitoring undertaken, and assessment of adverse events.</td>
</tr>
<tr>
<td>• Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.</td>
</tr>
<tr>
<td>• Advise GPs on when to stop treatment (if appropriate).</td>
</tr>
<tr>
<td>• Report adverse events to the MHRA via Yellow Card Scheme.</td>
</tr>
<tr>
<td>• Ensure that clear backup arrangements exist for GPs to obtain advice and support.</td>
</tr>
</tbody>
</table>
General Practitioner responsibilities

- Reply to the request for shared care as soon as practicable.
- Prescribe Mycophenolate Mofetil at the dose recommended.
- Adjust the dose as advised by the specialist.
- Monitor any parameters considered necessary, if agreed with the specialist to do so.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the specialist and to the MHRA via the Yellow Card Scheme.

Patient's role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3. Report any adverse effects to the specialist or GP.

BACK-UP ADVICE AND SUPPORT

<table>
<thead>
<tr>
<th>Contact details</th>
<th>Telephone No.</th>
<th>Email address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist:</td>
<td>01592 648193</td>
<td><a href="mailto:janegibson@nhs.net">janegibson@nhs.net</a></td>
</tr>
<tr>
<td>Rheumatology</td>
<td>01592 265967(fax)</td>
<td><a href="mailto:helenharris@nhs.net">helenharris@nhs.net</a></td>
</tr>
<tr>
<td>Dept</td>
<td></td>
<td><a href="mailto:johnmclaren@nhs.net">johnmclaren@nhs.net</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:sharoncullinane@nhs.net">sharoncullinane@nhs.net</a></td>
</tr>
</tbody>
</table>

Other:
ADTC website - FRDU adverse drug reaction document

SUPPORTING INFORMATION (taken from the SPC)

Licensed indications
Immunosuppression post organ transplant.
Immunosuppression in autoimmune disease. Mycophenolate Mofetil is a licensed medication, but is currently used 'off label' for this indication

Dosage and Administration
The dose of Mycophenolate Mofetil is between 250mg to 1g orally twice daily, depending on concomitant Immunosuppression prescribed. A dose reduction is needed for impaired renal function. Gastrointestinal side effects may be alleviated by further splitting the daily dose into four divided doses. Mycophenolate Mofetil should be taken on an empty stomach either one hour before or two hours after food.
Contraindications and precautions for use

- Live vaccines should not be given to patients taking Mycophenolate Mofetil.
- Pregnancy and breastfeeding should be avoided in patients taking this drug. Reliable contraception should be used during treatment and for at least 6 weeks after treatment discontinued.

Side Effects (also state any specific side-effects which require the consultant to be notified)

- The most frequent side effects include neutropenia, infection, gastrointestinal disturbances, including diarrhoea, constipation, vomiting and indigestion.
- Less common side effects include gastrointestinal haemorrhage, jaundice, hypertension, oedema, hyper and hypokalaemia, hyperglycaemia, hypophosphataemia, hypercholesterolemia, dyspnoea, headache, dizziness, insomnia and tremor.
- There is an increased risk of skin cancers.

For a complete list of side effects see BNF/ Summary of product Characteristics.

Treatment should be withheld and the Rheumatology Department contacted if:

- NEUTROPHILS < 1.5 x10⁹
- PLATELETS < 100 x 10⁹
- >2 fold increase in ALT (from upper limit of reference range)
- RASH, EXCESS BRUIising OR ORAL ULCERATION

Monitoring (State specific monitoring to be undertaken by the GP / Consultant ) see FRDU blood monitoring forms (ADTC website)

Rheumatologist responsibilities:
FBC, liver and renal function are within normal parameters to allow Mycophenolate Mofetil to commence.

General Practitioner responsibilities:
- While taking Mycophenolate Mofetil patients will require WEEKLY FBC, liver & renal function for 4 weeks, 2 weekly for 8 weeks.
- If monitoring remains normal, this can be reduced to monthly.

Drug Interactions

- Antacids and cholestyramine decrease the absorption of Mycophenolate Mofetil.
- Avoid concomitant use of live vaccines.

For a complete list of drug interactions please see the BNF / Summary of Product Characteristics.

Cost
100 X 250mg tabs = £35.00 (March 2012 BNF)
50 X 500mg tabs = £13.25 (Sept 2012 OT)