FULL SHARED CARE AGREEMENT FOR

MYCOPHENOLATE MOFETIL AND MYCOPHENOLATE SODIUM

in the treatment of

MAINTENANCE IMMUNOSUPPRESSION FOLLOWING RENAL TRANSPLANTATION

Prepared by:
Maria Martinez Martinez – Renal transplant specialist pharmacist

And agreed by
Professor M Nicholson – Consultant transplant surgeon
Professor S Carr – Consultant nephrologist
Dr P Topham – Consultant nephrologist
Professor J Feehally – Consultant nephrologist
Gill Hartley – Principal pharmacist for renal and critical care

On behalf of:
Leicester City Clinical Commissioning Group
East Leicestershire and Rutland Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
University Hospitals of Leicester NHS Trust
Leicestershire Partnership NHS Trust

Date written/reviewed: February 2013
Date of next review: April 2016
Approved by LMSG: April 2013
Version: 2

Additional medicines information is available from:
Trent Medicines Information Centre
Victoria Building, Leicester Royal Infirmary, LE1 5WW
Tel: 0116 255 5779 / 0116 258 6491
Fax: 0116 258 5680
e-mail: medicines.info@uhl-tr.nhs.uk
**Full Shared Care Policy for the prescribing of mycophenolate mofetil and mycophenolate sodium in the treatment of maintenance immunosuppression after renal transplantation**

**Introduction and purpose**

This shared care agreement has been produced following classification of mycophenolate mofetil and mycophenolate sodium in the Leicestershire drug traffic light scheme. See website at [www.lmsg.nhs.uk](http://www.lmsg.nhs.uk)

Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out these responsibilities from initial diagnosis to on going support.

**Disease Background**

Renal transplantation is the gold standard therapy for established renal failure aimed at improving quality of life and survival compared to patients who remain on dialysis.

Maintenance immunosuppression medicines are required following renal transplantation to prevent acute rejection and the loss of the renal allograft. Most immunosuppression regimens include a combination of agents with different mechanisms of action and side effect profile. This strategy aims to maximise effectiveness and tolerability. The Leicester renal transplant unit first line immunosuppression regimen following renal transplantation includes a combination of three agents: prednisolone, tacrolimus and mycophenolate mofetil.

**Drug covered by the agreement**

Mycophenolic acid (MPA) is the active form of both mycophenolate mofetil and mycophenolate sodium (Myfortic®). MPA is a potent, selective, uncompetitive and reversible inhibitor of inosine monophosphate dehydrogenase, and therefore inhibits the de novo pathway of guanosine nucleotide synthesis without incorporation into DNA.

Mycophenolate mofetil is currently the first line agent in preference to mycophenolate sodium (Myfortic®). The starting dose of mycophenolate mofetil used at the Leicester renal transplant unit is 500 mg twice daily. Generic preparations of mycophenolate mofetil are prescribed and supplied from the Leicester renal transplant unit. These generic brands may all be readily interchanged since switching between different generics is not thought to lead to any adverse effects to either the patient or the graft. However, mycophenolate mofetil and mycophenolate sodium are not interchangeable, and any change in formulation should be made by the specialist with appropriate monitoring. A dose of 500 mg of mycophenolate mofetil is equivalent to 360 mg of mycophenolate sodium (Myfortic®).

**Secondary Care Clinician Responsibilities**

- Diagnosis of condition and ensuring other treatment options have been fully explored
- Initiation of treatment and titration of dose to the optimum level
- Monitoring for response and adverse drug reactions (ADRs) during titration period
- Liaison with the general practitioner (GP) to share the patient's care when a stable dose has been achieved and proven benefit has been established using the Shared Care Request Form: [Shared Care Request Form](#).
- Patients receiving mycophenolate should be monitored for neutropenia. They should have complete blood counts (FBC) at least weekly during the first month, twice monthly for the second and third months of treatment, then monthly throughout the first year. After that patients' FBC will be monitored at least twice a year.
- If appropriate outlining to GP when therapy may be reduced and stopped. Review periods to be agreed.
- Responding to issues raised by GP after care of patient has been transferred.
- Advising GP on related issues such as drug interactions etc.

### GP Responsibilities

- Confirm or decline request to share patient's care as soon as possible, using the shared care request form.
- Monitoring the patient's overall health and well being and observing patient for evidence of ADRs/abnormalities and raising with secondary care clinician if necessary.
- GP is NOT expected to undertake any other specific clinical monitoring.
- Prescription of drug after achievement of a stable dose regime by secondary care
- Ensure the patient is being followed up in secondary care at least every 6 months.
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient's physical health status.
- Reducing/stopping treatment in line with secondary care clinician's original request.

### Patient Responsibilities

- Take medication according to the prescriber's instructions.
- Attend follow up and other appointments.
- Report to the specialist or the GP if he or she does not have a clear understanding of the treatment.
- Report any adverse effects or warning symptoms (sore throat, mouth ulcers, nausea, vomiting, fever, abdominal discomfort, shortness of breath) to the specialist or GP whilst taking mycophenolate.
- Share any concerns in relation to treatment with mycophenolate or their condition.
- Inform specialist if they have any problems taking mycophenolate or they have stopped taking it.
- Inform specialist or GP of any other medication being taken, including over-the-counter products.

### Prescribing & Clinical Information Summary


BNF prescribing information. Available at [http://bnf.org/bnf/](http://bnf.org/bnf/)

<table>
<thead>
<tr>
<th>Date of preparation</th>
<th>Date of last review</th>
<th>Date of next review</th>
<th>Approved by LMSG</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2013</td>
<td>March 2013</td>
<td>April 2016</td>
<td>April 2013</td>
<td>2</td>
</tr>
</tbody>
</table>

Review date extended to January 20 –see LMSG minutes September 19.
Contact for support and advice

Professor M Nicholson – Consultant transplant surgeon
Tel – 0116 2584658

Professor S Carr – Consultant nephrologist
Tel – 0116 2588013

Dr P Topham – Consultant nephrologist
Tel – 0116 2588013

Professor J Feehally – Consultant nephrologist
Tel – 0116 2584132

Maria Martinez Martinez – Renal transplant specialist pharmacist
Tel – 0116 2588177

<table>
<thead>
<tr>
<th>Version</th>
<th>Section</th>
<th>Description of amendments</th>
<th>Date</th>
<th>Author / amended by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Agreement changed from simple to full amber to provide more detail for GPs on monitoring</td>
<td>April 2013</td>
<td>MM/HH</td>
</tr>
</tbody>
</table>

Review date extended to January 20 – see LMSG minutes September 19