FULL SHARED CARE AGREEMENT FOR

SIROLIMUS (RAPAMUNE®)

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
**Full** Shared Care Policy for the prescribing of sirolimus in the treatment of maintenance immunosuppression after renal transplantation

**Introduction and purpose**

This shared care agreement has been produced following classification of sirolimus 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**

Sirolimus inhibits T-cell activation by blocking calcium-dependent and calcium-independent intracellular signal transduction. Sirolimus inhibits the activation of the mammalian Target Of Rapamycin (mTOR), a critical kinase for cell cycle progression. The inhibition of mTOR results in blockage of several specific signal transduction pathways. The net result is the inhibition of lymphocyte activation, which results in immunosuppression.

Sirolimus is not routinely used in the immediate post-transplant period. Sirolimus is normally used when a switch from a calcineurin inhibitor (e.g. tacrolimus or ciclosporin) is necessary to prevent further deterioration in graft function. There is also evidence that suggests that the use of sirolimus is associated with reduced risk of recurrent skin malignancy and therefore a switch to sirolimus can be considered in these cases. Any switch to sirolimus will be initiated and monitored in secondary care. After starting sirolimus blood levels are monitored regularly until a stable dose is achieved to give a sirolimus level of 8 – 12ng/mL.

**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.
- Supply sirolimus until the patient is clinically stable.
- 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](#).

<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>
Patients taking sirolimus should have sirolimus levels checked at least every 10 to 14 days during initiation of therapy until target levels have been achieved (specified above). Subsequent sirolimus levels monitoring should be at least every 3 to 6 months.

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*. Minor dose adjustments may be made by secondary care in response to clinical need throughout the course of treatment.
- 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.
- Avoid prescribing any medicines known to interact with sirolimus (e.g. clarithromycin, erythromycin, diltiazem).

**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 to the specialist or GP whilst taking sirolimus.
- Share any concerns in relation to treatment with sirolimus or their condition.
- Inform specialist if they have any problems taking sirolimus 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>
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>

Date of preparation | Date of last review | Date of next review | Approved by LMSG | Version
-------------------|---------------------|---------------------|------------------|--------
February 2013      | March 2013          | April 2016          | April 2013       | 2      |