University Hospital of North Staffordshire NHS
NHS Trust

NHS
Stoke on Trent

North Staffordshire Combined Healthcare NHS
NHS Trust

NHS
North Staffordshire

Effective Shared Care Agreement for the **prevention of rejection following renal transplantation**

Mycophenolate mofetil capsules / tablets and oral solution (Cellcept®)

These forms (1 and 2) are to be completed by both the Consultant initiating the therapy and the GP who is continuing care. A copy of the completed form should be retained by the GP and a copy should be returned to the Consultant, for filing in the patient's notes.

Form 1: - Consultant Copy*

Patient Name: **NHS Number:**

Date of Birth: **Telephone Number:**

Address:

(Or attach Addressograph label)

Patients Signature: **Date:**

And / or on behalf of the patient

Carer's Name: **Telephone Number:**

Address:

Carer's Signature: **Date:**

And:

Consultant Name: **Directorate:**

Address:

Telephone Number: **Fax Number:** **Email:**

Signature: **Date:**

And:

GP Name:

Address:

Telephone Number: **Fax Number:** **Email:**

Signature: **Date:**

Approved by Area Prescribing Committee on: 02/12/2009 Version: v1
Review date: 02/12/2011

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Form 2: - GP Copy*

Patient Name: **NHS Number:**

Date of Birth: **Telephone Number:**

Address:

(Or attach Addressograph label)

Patients Signature: **Date:**

And / or on behalf of the patient

Carer's Name: **Telephone Number:**

Address:

Carer's Signature: **Date:**

And:

Consultant Name: **Directorate:**

Address:

Telephone Number: **Fax Number:** **Email:**

Signature: **Date:**

And:

GP Name:

Address:

Telephone Number: **Fax Number:** **Email:**

Signature: **Date:**

Effective Shared Care Agreement for the **prevention of rejection following renal transplantation**

This shared care agreement outlines the ways in which the responsibilities for managing the prescribing of mycophenolate mofetil for the prevention of rejection following renal transplantation will be shared between the specialist and general practitioner (GP). If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition will remain with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practical.**

Sharing of care assumes communication between the specialist, GP and patient / carer. The intention to share care should be explained to the patient / carer by the doctor initiating treatment. It is important that patients / carers are consulted about treatment and are in agreement with it. Patients who have undergone a renal transplant are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

Specialist responsibilities
Initiation
1 Initiate treatment with mycophenolate mofetil.
2 Discuss the benefits, side effects of treatment and warning signs that need to be reported with the patient.
3 Check for possible drug interactions with mycophenolate and avoid prescribing interacting drugs.
4 Assess likelihood of compliance.
5 Ask the GP whether he or she is willing to participate in shared care and explain the intention to share care with the patient/ carer.
6 Perform monitoring of FBC in accordance with local protocol.
7 Record results of baseline tests.
8 Prescribe medication until care is transferred to GP.
Follow-up assessments
8 Review immunosuppressant therapy including mycophenolate dose
9 Monitor patients Creatinine / eGFR at required intervals
10 Check for side effects and report adverse events to the CSM and GP where appropriate.
Support to GP
11 Provide copy of effective shared care agreement and supporting information.
12 Promptly communicate with GP, advising of blood test results if requested, any dosage adjustments required and when to refer the patient back to specialist care.
13 Advise when and how to adjust the dose/ stop treatment or consult the specialist.
14 Inform GP if patient does not attend specialist appointments.
15 Have a mechanism in place to receive rapid referral of a patient from the GP in event of deteriorating clinical condition.
16 Ensure clear backup arrangements exist for GPs to obtain advice and support.
17 Advise the GP when the patient should receive the pneumococcal vaccine.

General Practitioner responsibilities
1 Reply to the request for shared care as soon as practical.
2 Prescribe mycophenolate mofetil, as directed by the specialist.
3 Contact the specialist if you suspect the patient is not complying with their medication.
4 Adjust the dose as advised by the specialist.
5 Check for possible drug interactions when prescribing new medication and avoid prescribing interacting drugs.
6 Ensure the patient understands which warning symptoms to report.
7 Recommend that female patients attend for a cervical smear annually.
8 Recommend the patient receives an influenza vaccine yearly and pneumococcal vaccine as required.
9 Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
10 Refer the patient to the specialist if his/ her condition deteriorates.
11 Report any suspected adverse events to specialist team and any severe adverse events to CSM.
12 Stop treatment on advice of specialist.

Patient's role	
1	Consent to treatment with mycophenolate mofetil.
2	Take medication according to doctors' instructions.
3	Attend follow up and other appointments.
4	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
5	Ensure Cellcept® brand of mycophenolate is taken and question any differences in supply received.
6	Share any concerns in relation to treatment or their condition.
7	Inform specialist if you feel you are having problems taking your medication or have stopped taking it.
8	Inform specialist or GP of any other medication being taken, including over-the-counter products.
9	Do not take any herbal remedies without checking with the specialist.
10	Alert physician prior to any vaccine administration that you are taking mycophenolate.
11	Ensure that you receive the influenza vaccine annually from your GP.
12	Take adequate precautions to avoid exposure to ultraviolet light i.e. wear sunscreen / protective clothing.
13	Report any adverse effects or warning symptoms to the specialist or GP.

SUPPORTING INFORMATION FOR MYCOPHENOLATE MOFETIL (CELLCEPT®) EFFECTIVE SHARED CARE AGREEMENT

This information should be read in conjunction with the Summary of Product Characteristics for Mycophenolate mofetil (Cellcept®) available from www.medicines.org.uk

Licensed indications

Prophylaxis of acute transplant rejection in patients receiving allogenic renal transplants.

Dosage and Administration

Oral mycophenolate mofetil should be initiated within 72 hours following transplantation. The recommended dose is 1g twice daily.

An alternative preparation mycophenolic acid (as mycophenolate sodium) (Myfortic®) is also available. However the two preparations are **not interchangeable**, and any change in formulation should be made by the specialist with appropriate monitoring. The usual starting dose is 720mg twice daily, which corresponds to 1g twice daily of mycophenolate mofetil.

Contraindications

Patients with a known hypersensitivity to mycophenolate mofetil, mycophenolic acid or mycophenolate sodium. Mycophenolate mofetil should not be given to breast-feeding mothers. In addition it is not recommended during pregnancy and should be reserved for cases where no more suitable alternative treatment is available. Patients attempting to conceive should discuss this with their specialist.

Therapeutic Use

- Refer to NICE technology appraisal guidance 85 (September 2004) – Immunosuppressive therapy for renal transplantation in adults, available from **www.nice.org.uk**
- Midland Therapeutic Review Advisory Committee (MTRAC). Verdict & Summary: - Mycophenolate Mofetil (Cellcept®), March 2003.

Monitoring

Patients taking mycophenolate mofetil should be monitored for neutropenia, which may be related to the mycophenolate mofetil itself, concomitant medications, viral infections, or some combination of these causes. Patients receiving mycophenolate mofetil should have complete blood counts weekly during the first month, twice monthly for the second and third months of treatment, then monthly though the first year. If neutropenia develops (absolute neutrophil count < 1.3 x 10^3/µl), it may be appropriate to interrupt or discontinue mycophenolate mofetil; these amendments should be decided by the specialist.

Side Effects

Very common (≥1/10): Sepsis, gastrointestinal candidiasis, urinary tract infection, herpes simplex, herpes zoster, leucopenia, thrombocytopenia, anaemia, vomiting, abdominal pain, diarrhoea and nausea.

Common (≥1/100, <1/10): Pneumonia, influenza, respiratory tract infection, respiratory moniliasis, gastrointestinal infection, candidiasis, gastroenteritis, infection, bronchitis, pharyngitis, sinusitis, fungal

skin infection, skin candida, vaginal candidiasis, rhinitis, skin cancer, benign neoplasm of skin, pancytopenia, leucocytosis, acidosis, hyperkalaemia, hypokalaemia, hyperglycaemia, hypomagnesaemia, hypocalcaemia, hypercholesterolaemia, hyperlipidaemia, hypophosphataemia, hyperuricaemia, gout, anorexia, agitation, confusional state, depression, anxiety, abnormal thinking, insomnia, convulsions, hypertonia, tremor, somnolence, myasthenic syndrome, dizziness, headache, paraesthesia, dysgeusia, tachycardia, hypotension, hypertension, vasodilatation, pleural effusion, dyspnoea, cough, gastrointestinal haemorrhage, peritonitis, ileus, colitis (including cytomegalovirus colitis), gastric ulcer, duodenal ulcer, gastritis, oesophagitis, stomatitis, constipation, dyspepsia, flatulence, eructation, hepatitis, jaundice, hyperbilirubinaemia, skin hypertrophy, rash, acne, alopecia, arthralgia, renal impairment, oedema, pyrexia, chills, pain, malaise, asthenia, increased hepatic enzymes, increased blood creatinine, increased blood lactate dehydrogenase, increased blood urea, increased blood alkaline phosphatase, weight decreased, gingival hyperplasia, pancreatitis and intestinal villous atrophy.

Patients should be advised to avoid excess ultraviolet light exposure or limit it by wearing protective clothing and using a sunscreen with a high protection factor. Vaccinations may be less effective during treatment with mycophenolate mofetil and the use of live attenuated vaccines should be avoided.

Drug Interactions

Aciclovir- increased plasma concentrations of aciclovir
Ganciclovir- plasma concentrations of ganciclovir possibly increased
Drugs which reduce absorption of mycophenolate mofetil- antacids with magnesium and aluminium hydroxides, cholestyramine and oral iron
Rifampicin- may reduce plasma concentration of the active metabolite of mycophenolate mofetil and increase the levels of the metabolite associated with the adverse effects of mycophenolate
Sevelamer- may reduce plasma concentration of mycophenolate mofetil. It is recommended to administer Cellcept® at least 1 hour before or three hours after sevelamer intake to minimise the impact on absorption of the active metabolite of mycophenolate.
Metronidazole and norfloxacin- may reduce the bioavailability of mycophenolate mofetil
Probenecid- may increase plasma concentrations of the active metabolite of mycophenolate mofetil
Antipsychotics- increased risk of agranulocytosis with clozapine
Azathioprine-should not be administered with mycophenolate, both drugs have the potential to cause bone marrow suppression
Ciclosporin- reduces the levels of the active metabolite of mycophenolate

Primary Care Costs (emims August 2009)

Cellcept®	
250mg capsules	£83.92 / 100 capsules
1g per 5ml powder for oral suspension,	£117.48 / 175ml
500mg tablets	£83.92 / 50 tablets

References

Joint Formulary Committee. British National Formulary. 57th ed. London: British Medical Association and Royal Pharmaceutical Society of Great Britain; 2009

Summary of Product Characteristics – Cellcept® 250mg capsules. Roche. Last revised 8th June 2009. Accessed via www.medicines.org.uk

Baxter, K. Stockley's Drug Interactions. Pharmaceutical Press 2009. Accessed via www.medicinescomplete.com

BACK-UP ADVICE AND SUPPORT

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