Western Locality Shared care information ~ Mycophenolate Mofetil, Transplant patients

April 2013

- Mycophenolate Mofetil
- Prophylaxis of acute rejection in renal and cardiac transplant recipients

Specialist: The Dermatology Team will communicate with the GP when they wish Shared Care to be commenced completing and sending the appropriate form

GP: Please indicate whether you wish to share patient's care by completing letter and return to specialist

Aim of Treatment

Mycophenolate mofetil is used for prophylaxis of acute rejection in renal and cardiac transplant recipients in combination with other agents. It is used as a 2nd line treatment in liver transplantation to avoid toxicity from tacrolimus or ciclosporin.

Specialist responsibilities

1. To initiate treatment. Patients will have received at least 3 months of treatment, and have been stabilised on a suitable dose.
2. To monitor full blood counts, and urea and electrolytes as an indicator of renal function and communicate these results to the GP. If a dose change is necessary, to communicate to the patient in person or by telephone with additional written information. The letter informing of the dose change will also be sent to the GP.
3. To send a letter to the GP requesting Shared care for a particular patient. This letter will contain the following information:
    a. Diagnosis
    b. Results of blood tests
    c. Results of any other appropriate investigations
    d. Dose and name of treatment
    e. Advice on dose alterations where appropriate
4. To periodically review the patient.

General practitioner responsibilities

If GP has agreed to share care:

1. To contact the referring consultant without delay if they do not wish to enter into a Shared care agreement
2. To monitor the patient's overall health and well being
3. To prescribe treatment according to the dose directed by the secondary care physician
4. To monitor side effects of treatment, and seek urgent advice as necessary
5. To contact the appropriate secondary care physician as appropriate
6. To check for possible drug interactions when newly prescribing or stopping concurrent medication
7. **N.B** Cardiac transplant patients remain under the care of Harefield Hospital, London.

Monitoring

Monitoring will be performed within secondary care and consists of FBC to exclude myelosuppression.

Patients must report immediately any evidence of infection, unexpected bruising/bleeding or other manifestations of bone marrow suppression.

Back-up advice and support

Renal

- Dr P Rowe 01752 792463
- Dr R McGonigle 01752 792462
- Dr W Tse 01752 517580
- Dr I Saif 01752 792467
- Dr H Cramp 01752 245119

Hepatology

- Dr M Cramp 01752 793405
- Dr J Mitchell 01752 792725

Derriford Medicines Information: 01752 439976

Medicines Optimisation Teams

- NEW Devon CCG, Western Locality 01752 398800
- Kernow CCG 01726 627953

Supporting Information

Preparations

Mycophenolate Mofetil is available as 250mg capsules, 500mg tablets, 1g /5ml oral suspension and as an intravenous infusion. The intravenous infusion should not be prescribed in primary care.

Dose

1-1.5 gram twice daily. Locally, in renal transplantation initial doses of 1g twice daily are used titrated within the range 250mg – 1g twice daily. In liver transplantation doses may be titrated within the range 500mg-1.5g twice daily. Mycophenolate levels are not performed routinely but are sometimes useful. Such levels are usually ordered through secondary care services.

Contraindications

- Pregnancy: The use of mycophenolate is not recommended during pregnancy and should be reserved for cases where no more suitable alternative treatment is available. Mycophenolate should be used in pregnant women only if the potential benefit outweighs the potential risk to the foetus. There is limited data from use in pregnant women. However, congenital malformations including ear malformations i.e. abnormally formed or absent external/middle ear, have been reported in children of patients exposed to mycophenolate in combination with other immunosuppressants during pregnancy. Cases of spontaneous abortions have been reported in patients exposed to mycophenolate. Studies in animals have shown reproductive toxicity.
- Breast-feeding
- Hypersensitivity to the parent compound or metabolites

Cautions

- Elderly – increased risk of infection, gastro-intestinal haemorrhage and pulmonary oedema
- Active serious Gastro-intestinal disease – risk of haemorrhage, ulceration and perforation
- Increased susceptibility to skin cancer – avoid exposure to strong sunlight
- Children – higher incidence of side effects
- **Bone Marrow Suppression**: Patients should be warned to report immediately any signs or symptoms of bone marrow suppression e.g. infection and inexplicable bruising or bleeding

Side effects

(Refer to SPCs for further information)

- Gastrointestinal disturbances such as diarrhoea, abdominal discomfort, gastritis, nausea, vomiting and constipation. GI side effects may frequently be transient.
- Cough, influenza-like syndrome
- Headache
- Infections (viral, bacterial and fungal)
- Increased blood creatinine
- Blood dyscrasias - leucopenia, anaemia and thrombocytopenia

- Pure red cell aplasia

Less commonly – gastro-oesophageal reflux, gastro-intestinal ulceration and bleeding, pancreatitis, abnormal liver function tests, hepatitis, tachycardia, blood pressure changes, oedema, dyspnoea, tremor, insomnia, dizziness, hyperglycaemia, increased risk of malignancies, disturbances of electrolytes and blood lipids, renal tubular necrosis, arthralgia, alopecia, acne.

Interactions

(Refer to the BNF for further information)

The following drugs interact with Mycophenolate and caution must be used when prescribing concurrently:

Absorption of Mycophenolate reduced by:

- Antacids
- Colestyramine

Mycophenolate increases plasma concentration of:

- Aciclovir and Ganciclovir (both drugs also increase the plasma level of inactive metabolite of Mycophenolate)

Mycophenolate possibly reduces the absorption of:

- Phenytion

Increased risk of agranulocytosis:

- Clozapine – avoid concomitant use

With other immunosuppressants:

- Ciclosporin has been reported to lower mycophenolate levels
- Tacrolimus may increase mycophenolate levels

Vaccines may be less effective in immunocompromised patients. Live vaccines should be avoided.

Please note: The prescribing of mycophenolate mofetil for the prevention of rejection in renal transplant patients has been repatriated to secondary care. Heart and lung transplantation services are not provided by the acute trusts in NEW Devon CCG; these are provided by Highly Specialist Heart and Lung Transplant Centres. Specialist services provide assessment of patients who are eligible for a heart transplant; the transplant operation; and lifelong follow up. Guidance should be provided to GPs by those institutions when requests are made to share care. This shared care guideline has been archived.

Shared Care Agreement Letter – Consultant Request

To: Dr.....

Practice Address.....

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Patient Name:	
NHS Number:	
Date of birth:	
Address:	

Diagnosed condition: .....

I recommend treatment with the following drug: .....

At the following dosage: .....

I request your agreement to sharing the care of this patient according to the Western Locality Shared Care Information guidelines for this drug. The patient has been initiated on treatment and stabilised in accordance with the appropriate Shared Care Information.

Principles of shared care:

GPs are invited to participate, but **if the GP is not confident to undertake these roles then they are under no obligation to do so.** If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked 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. The intention to share care should be explained to the patient and accepted by them.

Remember: the doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Signed:			Date:
Consultant name:			
Telephone number:		Fax number	
Email address			

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Please sign below and return promptly. Remember to keep a copy of this letter for the patient's records. If this letter is not returned shared care for this patient will not commence.

GP Response

I agree / do not agree* to share the care of this patient in accordance with the Shared Care Guideline.

Signed: ..... Date: .....

GP name: ..... *Delete as appropriate.