

SHARED CARE AND NEAR PATIENT TESTING

DRUG: MYCOPHENOLATE MOFETIL Protocol number CV 53

INDICATIONS: Various conditions, which characteristically respond to immunosuppressive therapy.

General guidance

This protocol sets out details for the shared care of patients taking **Mycophenolate Mofetil** and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribed the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Mycophenolate is used as second line disease modifying therapy for treatment of various conditions (*unlicensed conditions*) which characteristically respond to immunosuppressive therapy.

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care/ Near Patient Testing request form with Shared Care Protocol to GP.
2. Initiate therapy following full discussion with the patient of benefits and risks, including provision of written patient information. The patient will be informed to contact their GP immediately if any of the following occur: nausea, vomiting, diarrhoea, rash, mouth ulcers, bruises, itching, bleeding, fever, sore throat, jaundice or other infection.
3. Check patient's immune status to *Herpes Zoster* and notify GP to enable coding to occur.
4. To counsel female patients to take contraceptive precautions during treatment and for 6 weeks after treatment has ceased (refer to special precautions). Record in letter to GP that contraceptive advice has been given.
5. Baseline and continued monitoring until haematological parameters are stable on the chosen final dose of mycophenolate (see next page) (If Near Patient Testing not agreed then monitoring will be continued after patient is stabilised)
6. Appropriate monitoring of clinical effectiveness of treatment.
7. When a GP positive response to SC/NPT has been received and patient has been stabilised send a letter to GP "handing over" the Shared Care/Near Patient Testing of the patient to the GP.
8. Respond to any request from GP to review patient due to adverse effects of therapy.
9. Advise GP on continuing or stopping mycophenolate therapy, following medical review of the patient and associated drug therapy.
10. Ensure clear arrangements in place for prompt back up advice and support.

11. If Near Patient Testing not agreed notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care/Near Patient Testing request form to indicate whether or not willing to undertake Shared Care/ Near Patient Testing.
2. Prescribe **mycophenolate mofetil** as part of the shared care agreement.
3. Where Near Patient Testing is agreed monitor the parameters indicated (see below) and report to and seek advice from the consultant on any aspect of patient care which is of concern.
4. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
5. Monitor the general health of the patient.
6. Stop treatment on advice of specialist.
7. Report to and seek advice from the consultant on any aspect of patient care which is of concern.
8. Recommend that patient receives pneumococcal vaccination and annual influenza vaccination.
9. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with mycophenolate mofetil.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst taking mycophenolate mofetil.

Dosage Regimen

Typical dose: 1 – 2g/day

Typical starting dose: 500mg daily for the first week, 500mg twice daily for the second week and increased gradually by 500mg each week until the optimum or maximum tolerated dose is reached. In severe or resistant cases a maximum of 1500mg twice daily may be used.

Initial monitoring in secondary care

Before treatment

FBC, Creatinine and electrolytes, LFTs

During treatment

Initial monitoring in secondary care

FBC weekly until the dose stable for 4 weeks and then every 2 weeks for 2 months.

Monitoring by GP when patient is stable

FBC monthly

Following changes in dose

Repeat FBC 2 weeks after dose change and then monthly

Withhold mycophenolate and discuss with specialist if any of the following occurs:

WBC	$< 4.0 \times 10^9 /L$
Neutrophils	$< 1.5.0 \times 10^9 /L$
Platelets	$< 150 \times 10^9 /L$
Abnormal bruising with or without sore throat (check FBC immediately)	

* patients may continue treatment if WBC is $3.0 - 4.0 \times 10^9 /L$ if the neutrophil count is above $1.5 \times 10^9 /L$

Please note that in addition to absolute values for haematological indices a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance

Adverse effects

Gastrointestinal: Commonest dose-limiting adverse effects, particularly dyspepsia (~40%), diarrhoea (21%), nausea and vomiting, abdominal cramps.

Haematological: Abnormal bruising with or without sore throat may indicate bone marrow failure. Severe neutropenia occurs in 0.5% patients receiving mycophenolate in the full dose. Most commonly seen within the first 6 months. Temporary suspension of mycophenolate for 10-14 days will usually result in recovery of the cell count. Once the cell count recovers the drug can be re-administered in half the previous dose and gradually increased until a stable dose is attained without any toxic effect.

Uro-genital: Sterile haematuria, urinary tract infection, renal tubular necrosis

Malignancy: Lymphomas caused by oncogenic viruses and skin tumours

Notable drug interactions (refer to BNF & SPC)

Antacids – containing aluminium and magnesium hydroxide reduce the absorption and bioavailability of mycophenolate

Cholestyramine – may decrease the absorption and bioavailability of mycophenolate

Probenecid – prevents renal tubular secretion and causes an increase in plasma concentration of mycophenolate.

Aciclovir – causes increase in the concentration of both mycophenolate and acyclovir, however increase only significant in renal impairment.

Special Recommendations

Live vaccines should be avoided in patients taking mycophenolate.

It is important that patients are warned to be observant about any symptoms of infection as the reported incidence of cytomegalovirus infection is slightly higher.

Mycophenolate is contra-indicated in pregnancy and during breast-feeding. Women of child-bearing age should have a negative pregnancy test and be using adequate contraception prior to starting mycophenolate therapy. Contraception should be continued for six weeks after stopping mycophenolate therapy.

Women treated with mycophenolate should not breast feed

Patients should be advised to wear protective clothing and use sunscreen in direct sunlight due to the increased risk of skin cancer with mycophenolate treatment.

In patients receiving mycophenolate exposed to chickenpox or shingles, whose immune status to *Herpes Zoster* is unknown or negative, aciclovir (po) (unlicensed use) should be prescribed 40mg/kg daily in four divided doses for 7 days starting one week after exposure.

If a patient on mycophenolate mofetil develops chickenpox, aciclovir should be started urgently. If the rash is severe and extensive and the patient is systemically unwell then he/she will need to be admitted urgently via the medical assessment unit as intravenous acyclovir and possibly other support will be required. If the patient is well however and the rash is no worse than would usually be seen then there is no indication for urgent admission or referral. The patient can be treated at home with oral aciclovir and advised to seek medical advice if there is any worsening of their condition

Contact information

Please refer to contact information details on the Shared Care/Near Patient Testing request form

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