Central Manchester University Hospitals NHS
NHS Foundation Trust

Greater Manchester Interface Prescribing Group Shared Care Template

Shared Care Guideline for **Mycophenolate Mofetil for Rheumatological Conditions**		**Reference Number** **CMFT-SCG-007**
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Date approved by Commissioners: **January 2013**	**Review Date:** **January 2015**	

Please complete all sections

1. Licensed Indications	Mycophenolate Mofetil for Rheumatoid Arthritis, this is an unlicensed indication.	
2. Therapeutic use & background	*Mycophenolate mofetil is a pro-drug of the active metabolite of mycophenolic acid. It is a suppressor of T and B cell proliferation and adhesion and inhibits inosine monophosphate dehydrogenase and eventually blocks the progression to DNA synthesis and proliferation.*	
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	*Contraindicatons: Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking mycophenolate. Localised or systemic infections.* *Cautions: Localised or systemic infection, very frail and elderly, patients with suspected lymphoproliferative disorder or unexplained anaemia, leucopenia and thrombocytopenia.*	
4. Prescribing in pregnancy and lactation	This drug *should not* be prescribed *during* pregnancy *and or while* breastfeeding patient. *Mycophenolate is contra-indicated during pregnancy or via breastfeeding. Contraception should be used for 6 weeks after stopping the drug.*	
5. Dosage regimen for continuing care	Route of administration	*oral*
	Preparations available (include in this section any necessary information relating to availability of special preparations for children or those with swallowing difficulties) *Mycophenolate is now available in generic form. To be prescribed as mycophenolate mofetil and not as the brand cellcept.* *Suspension available for swallowing difficulties and enteral feeding.*	

	Insert dose to be prescribed including units, frequency and duration of treatment. Please prescribe*: 500mg/day* increased by *500mg every week* to a maintenance dose of between *1.5gram/day* to *3gram/day* according to Consultant.		
	Is titration required	**Yes (complete the following section) Yes**	
	Titrate dosage up by *500mg* / *every week* according to response. Maintenance dosage up to a maximum *3gram daily*.		
	Adjunctive treatment regime *No adjunctive treatment*		
	Conditions requiring dose reduction *Renal and hepatic impairment discuss with Consultant.*		
	Usual response time *6 weeks to 3 months*		
	Duration of treatment *ongoing*		
	Treatment to be terminated by *healthcare professional in consultation with Rheumatology Team.*		
	NB. All dose adjustments will be the responsibility of the initiating specialist care unless directions have been specified in the medical letter to the GP.		
6.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs must <u>not</u> be prescribed without consultation with the specialist: *Plasma concentration of active metabolite of mycophenolate reduced by rifampicin.* *Avoid use of clozapine as increased risk of agranulocytosis.*		
	The following drugs may be prescribed with caution: *Antacids containing aluminium and magnesium hydroxide cause a decrease in the absorption of mycophenolate by 33% and bioavailability by 17%.* *Colestyramine may decrease the absorption of mycophenolate and bioavailability by 40%.* *Aciclovir causes increase in the concentration of both mycophenolate and aciclovir, significant only in renal impairment.* *Probenecid prevents tubular secretion and causes an increase in plasma concentration of mycophenolate*		
7. Adverse drug reactions *For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF*	**Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.**		
	Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
	WBC<3.5 x 10^9/l *Neutrophils< 2.0 x 10^9/l* *Platelets<150 x 10^9/l*	*Withhold until discussion with Rheumatology Team*	*GP*

	Bruising with or without sore throat	*Check FBC immediately and discuss with Rheumatology Team as risk of bone marrow suppression*	*GP*
	The patient should be advised to report any of the following signs or symptoms to their GP without delay: *Infection, or inexplicable bruising or bleeding.*		
	Other important co morbidities (e.g. Chickenpox exposure). Include advice on management and prevention and who will be responsible for this in each case: *Pneumovax and annual 'flu vaccine should be given. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.*		
	Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.		
8.Baseline investigations	*List of investigations / monitoring undertaken by secondary care* *FBC* *U&E* *LFTs* *Chest X-Ray*		
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?**	**Yes or No (if yes complete following section)** *Yes*	

Monitoring	Frequency	Results	Action	By whom
FBC, LFTs, U&E (ESR is desirable but not essential)	***During dose titration**: Every week whilst increasing dose then once weekly for the 1st month until stable* ***Maintenance**: when stable every 2 weeks for 2nd and 3rd month and then once monthly*	*See Section 7: Adverse drug reactions above*		*GP*

10. Pharmaceutical aspects	*e.g. special storage requirements, washout periods Or where there are "no special considerations"* *Mycophenolate is now available in generic form. To be prescribed as mycophenolate mofetil and not as the brand cellcept.*
11. Secondary care contact information	**If stopping medication or needing advice please contact:**
	To contact The Kellgren Centre Rheumatology Manchester Royal Infirmary: **Enquiries regarding blood monitoring and results please contact the specialist nurses below:** **Specialist Nurse Jane Hawthorne 0161 276 4688** **Specialist Nurse Melissa Aris 0161 701 1454** **Specialist Nurse Carole Hill 0161 701 1454** **Fax number for GP blood results 0161 276 8690**

	Consultant contact details below: **Professor Ian Bruce 0161 276 4626** **Professor Ann Barton 0161 276 4626** **Dr Kimme Hyrich 0161 276 4627** **Dr Pauline Ho 0161 276 4397** **Dr Rachel Gorodkin 0161 276 4628** **To contact Rheumatology Department Trafford General Hospital:** **Trafford Rheumatology helpline number 0161 746 2162** **Consultant contact details below:** **Dr Frank McKenna 0161 746 2395** **Dr Preeti Shah 0161 746 2395**
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been initiated and established by the secondary care specialist. ▪ The patient's initial reaction to and progress on the drug is satisfactory. ▪ The GP has no objection in each individual case that shared care is appropriate ▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements
13. Responsibilities of initiating specialist	Initiate treatment and prescribe for the 1st 3 months of treatment. Undertake baseline monitoring. Advice GP of any dose adjustments. Monitor patient's initial reaction to and progress on the drug. Ensure that the patient has an adequate supply of medication unless a GP supply can be arranged. Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review. Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient *or* inform GP if the patient repeatedly does not attend appointment. Provide GP with advice on when to stop this drug. Provide patient with relevant drug information to enable Informed consent to therapy. Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action. Provide patient with relevant drug information to enable understanding of the role of monitoring. Provide patient with monitoring booklet.

14. Responsibilities of the GP	Provide patient with rheumatology nurse helpline contact number. --- Continue treatment as directed by the specialist. Ensure no drug interactions with concomitant medicines. To monitor and prescribe in collaboration with the specialist according to this protocol. To ensure that the monitoring and dosage record is kept up to date in the shared care booklet. To ensure blood monitoring is carried out once dose stable and responsibility transferred from secondary care. To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring. To undertake vaccination as directed by the initiating consultant, the BNF or Green Book. Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary. ---
15. Responsibilities of the patient	To take medication as directed by the prescriber, or to contact the GP if not taking medication. To attend hospital and GP clinic appointments, bring monitoring booklet. Failure to attend will result in medication being stopped (on specialist advice). To report adverse effects to their Specialist or GP.
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet. Patient Information Leaflet EMC medicines Mycophenolate Mofetil Arthritis Research UK Patient information Leaflet Mycophenolate Mofetil
18. Patient monitoring booklet	The patient must receive a monitoring booklet from the specialist upon initiation of treatment. The patient must bring this booklet to all specialist and GP appointments where it will be updated by the health professional conducting the appointment. The patient must also produce the booklet to any health professional involved in other aspects of their care e.g. pharmacists and dentists.