Effective Shared Care Agreement (ESCA)

DRUG NAME : **MYCOPHENOLATE MOFETIL**

Indication/s Covered: **Immunosuppression in autoimmune diseases as defined below**

East Sussex Health Economy Formulary Traffic Light system classification: Specialist Drug / Orange

NOTES to the primary care prescriber

Specialist drugs - These are drugs where the need for specialist input has been identified. A specialist is not necessarily a consultant, rather a practitioner with specialist skills e.g. GP with Specialist Interest, Community Psychiatric nurse, Tissue Viability nurse.

Drugs will have “orange” status when:

* A specialist starts treatment
* A specialist provides advice for a specific patient

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| Version: | V2.0 |
| Ratified by: | Area Prescribing Committee |
| Date ratified: | 7/6/17 |
| Name of author and title: | Janki Patel -Lead Pharmacist Specialist Medicine Stephanie Butler-Principal Pharmacist MSK |
| Date Written: | 09/03/2017 |
| Name of responsible committee/individual: | Area Prescribing Committee |
| Date issued: | June 2017 |
| Issue number: | 2017123 |
| Review date: | 3 Years (June 2020) |
| Target audience: | Rheumatology, neurology and dermatology consultants and specialist nurses and GPs responsible for ongoing patient care |

# Version Control Table

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| --- | --- | --- | --- | --- |
| **Version number**  **and issue number** | **Date** | **Author** | **Reason for**  **Change** | **Description of**  **Changes Made** |
| V1.0 | 10/12/2015 | Janki Patel | New document |  |
| V2.0 | 7/6/2017 | Stephanie Butler | Update | Update and |
|  |  | Janki Patel |  | include new BSR |
|  |  |  |  | DMARD |
|  |  |  |  | guidelines 2017 |
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**Consultation Table**

### This document has been developed in consultation with the groups and/or individuals in this table:

|  |  |  |
| --- | --- | --- |
| **Name of Individual or group** | **Title** | **Date** |
| Area Prescribing Committee | Area Prescribing Committee | 27/4/2017 |
| Dr Anita Amin,  Dr Von der Werth | Consultant Dermatologist | 27/4/2017 |
| Dr Sathianathan Panthakalam  Dr Andrew Pool | Consultant Rheumatologist | 27/4/2017 |
| Dr Muhammad Chowdhury,  Dr Monika Lipnicka-Khan, Dr Yuankai Lee | Consultant Neurologists | 27/4/2017 |

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| **INFORMATION** |
| This information sheet does not replace the Summary of Product Characteristics (SmPC), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.  **Link to SmPC** [http://www.medicines.org.uk](http://www.medicines.org.uk/) |
| **Background to use for the indication/s, including licence status**   * Mycophenolate is a potent immunosuppressant. * Mycophenolate is a licensed medicine with marketing authorisation for the use in severe eczema and blistering skin diseases including pemphigus and pemphigoid. Unlicensed indications include; thrombocytopenic purpurea, ANCA +ve & ANCA –ve vasculitis, inflammatory rheumatic disease and connective tissue diseases, second line therapy for myasthenia gravies, inflammatory myopathies and neuropathies, CNS vasculitis and other immune-mediate peripheral and central nervous system disease. |
| **Dose and administration**   * The recommended adult dose is between 1g and 3g daily, taken in 2 divided doses. * Gastrointestinal adverse-effects (most commonly diarrhoea and nausea) may be limited by increasing dose frequency (e.g. 500mg four times a day). |
| **Cautions (including for pregnancy & lactation where relevant)**   * Avoid excessive unprotected sun exposure, and advise the patient to use a high factor sunscreen. * Decreased resistance to infection- including opportunistic infection. * Progressive multifocal leukoencephalopathy (PML) should be considered as a differential diagnosis in patients reporting neurological symptoms on treatment with mycophenolate. * Use with caution in patients with active serious digestive system disease.   **Pregnancy and Lactation**   * Pregnancy/contraception. Women AND men of childbearing potential receiving mycophenolate mofetil should be advised to use effective contraception prior to, during and for six weeks after stopping treatment. * All patients contemplating becoming pregnant must be seen by a Consultant at the earliest opportunity to discuss the complex issues surrounding therapy with mycophenolate. * Breastfeeding: women being treated with mycophenolate mofetil should not breastfeed. |
| **Contraindications**   * Hypersensitivity to mycophenolate. |
| **Side effects**   * Very common: Increased infections, blood dyscrasia, GI disturbances. |
| **Interactions – Prescribers are advised to check the BNF or ask a pharmacist for advice where required. This is not a comprehensive list**   * Plasma concentration of the active metabolite of mycophenolate is reduced by rifampicin.   **Vaccines**   * Severe or fatal infections may occur if a live vaccine is given concurrently. **AVOID LIVE VACCINES** * Inactivated vaccines such as influenza vaccine are safe to use although they may elicit a lower response. * Also consider appropriate washout period after stopping therapy before administering live vaccines if required. |
| **Criteria for use**   * Chronic inflammatory conditions as determined by the appropriate specialist. |
| **Any further information (e.g. supporting therapies)**  N/A |

**ROLES and RESPONSIBILITIES**

**Specialist responsibilities:**

* Identify patients requiring mycophenolate and counsel patients appropriately.
* Undertake pre-treatment testing/assessment as per speciality guidelines 1,3 and record Varicella status.
* Record other medications and address possible drug interactions before starting therapy.
* Monitor and prescribe according to speciality guidelines until handover is appropriate, a minimum of 6 weeks (including when dose changes are made).
* Provide patient with hand-held information on mycophenolate, and explain ongoing monitoring requirements
* Review efficacy of treatment at regular intervals and ensure drug treatment changes are communicated to the patient and GP. This will include at least an annual review whilst on treatment.
* Report any adverse events to the MHRA and GP.
* Dose increases should be monitored by FBC, creatinine/ calculated GFR, ALT and / or AST and albumin every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.

Note: this shared care guideline applies to several different specialities and pre prescribing checks will vary according to local practice. GP will be informed of any relevant findings.

### Primary care prescriber responsibilities:

* Subsequent prescribing of mycophenolate at the dose recommended.
* In static doses, monitoring of FBC, creatinine/ calculated GFR, ALT, and / or AST and albumin at monthly intervals from handover to end of 3 months, and 3 monthly thereafter.
* Monitor for adverse effects throughout treatment and check for drug interaction on initiating new treatments.
* Provide patient with pneumococcal polysaccharide vaccine and flu vaccination unless contra-indicated.
* Perform an urgent FBC on any patient on mycophenolate who becomes unwell to check for myelosuppression.
* If shared care is declined, the practice should inform the named consultant within 14 days of receipt of the request
* Report any adverse events to the MHRA and specialist team.

### Patient’s/Carer’s role – these will be explained to the patient by the specialist team on initiation

* Ask the specialist or primary care prescriber for information, if any aspects of treatment are not fully understood.
* Tell the specialist or primary care prescriber of any other medication being taken, including over-the-counter products.
* Read the patient information leaflet included with the medication and report any side effects or concerns to the specialist or primary care prescriber.
* Be aware of monitoring requirements, book blood test appointments with the GP and attend when required to do so.

Note: this shared care guideline applies to several different specialities and pre prescribing checks will vary according to local practice. GP will be informed of any specific additional requirements.

Dose reduction required in CKD stage 4 or 5, discuss with specialist service.

This list is not exhaustive; refer to the Summary of Product Characteristics (SMPC) or BNF for further guidance.

More frequent monitoring is appropriate in patients at higher risk of toxicity.

**Contact specialist team urgently and consider interruption in treatment if any of the following develop:**

**Monitoring schedule**

**MONITORING REQUIREMENTS**

**OTHER WARNING SIGNS**

|  |  |  |
| --- | --- | --- |
| Test | Frequency Duration | |
| FBC  Creatinine/ calculated GFR  ALT and / or AST Albumin | Every 2 weeks | For first three months until on stable dose for 6  weeks |
| Monthly | For three months |
| 12 weekly | To continue |

|  |  |
| --- | --- |
| White Cell Count <3.5x109/l | Mean cell volume >105 f/l |
| Neutrophils <1.6 x109/l | Creatinine increase >30% over 12 months and/or calculated GFR <60ml/min/1.73m2 |
| Unexplained eosinophilia >0.5 x 109/l | ALT and/or AST >100 U/l |
| Platelet count <140 x109/l | Unexplained reduction in albumin <30 g/l |

* During a serious infection, mycophenolate should be temporarily discontinued until the patient has recovered from the infection. It can be considered appropriate to continue this drug in patients with minor infections (e.g. uncomplicated urinary tract infection treated with a short course of oral antibiotics).3
* Rapid falls or downwards trends in any of the monitored parameters: Monitor closely and discuss with specialist team.
* Abnormal bruising or severe sore throat: Check FBC and withhold treatment until results available.
* New or increasing dyspnoea or dry cough: Withhold treatment and discuss with specialist service.

This list is not exhaustive; refer to the Summary of Product Characteristics (SMPC) or BNF for further guidance.

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| **Specialist team:**  Address:  Contact Number: | Patient Details |
| **Primary care Prescriber:**  Address:  Contact Number: |
| **Main Carer if appropriate:**  Contact Number: |
| **Key Worker if appropriate:**  Contact Number |

**A further letter will be sent with specific dosing instructions and contact details for stable doses, prior to handover**

### References

1. Chakraverty, K., Mcdonald, H., Pullar, T. Et al. (2008) BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists. Rheumatology 47(6), 924-925.
2. Immunisation of individuals with underlying medical conditions<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/566853/Green_Book_Chapter7.pdf>(accessed 09/03/2017)
3. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Jo Ledingham et al.<http://www.rheumatology.org.uk/includes/documents/cm_docs/2017/f/full_guideline_dmards.pdf>(accessed 9/3/17)

4Handbook of systemic drug treatment in dermatology 2nd edition (2015) S Wakelin et al

# Shared care prescribing handover sheet

Effective Shared Care Agreement (ESCA)

DRUG NAME: **Mycophenolate Mofetil**

Indication:

**Agreement for transfer of prescribing to PRIMARY CARE PRESCRIBER Patient details:**

## This patient is being handed over on the following dose: Date treatment initiated:

**Name: Address: DoB: NHS No:**

**Hospital No:**

**The results of any relevant tests are attached to this letter.**

**The patient will be reviewed regularly under their named consultant team. Approximate date of next clinic appointment:**

**If the practice declines shared care the named consultant should be informed within 14 days of receipt of this request**

**BACK- UP ADVICE AND SUPPORT**

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| --- | --- | --- | --- |
|  | **Name / position** | **Telephone** | **Email** |
| **Named consultant:** |  |  |  |
| **Alternative specialist (e.g. departmental contact or Shared care**  **co-ordinator):** |  |  |  |
| **Hospital Pharmacy:** |  |  |  |
| **Out of hours (e.g.**  **medical team on call):** |  |  |  |