## Mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications)

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| Version: | HNY v1.0 | Replaces version: | RDTC v1.1 |
| Clinical content last reviewed: | November 2023 | Next review date: | November 2025 |

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| **Version** | **Date published** | **Changes since previous version** |
| RDTC v1.0 | 8th March 2024 | References and hyperlinks updated to current versions. |
| RDTC v1.1 | 10th December 2024 | Advice on shingles vaccine clarified to reflect potential eligibility of patients aged 50 years or older taking immunosuppressive therapy |
| HNY v1.0 | April 2025 | * HNY Logos added
* Section 4: Transfer of monitoring and prescribing updated as per NHSE document - <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf> and following wording added: To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended.
* Section 5: Creatinine clearance removed and replaced with eGFR
* Section 5: Wording re screening for viral infections changed from "as per local policy" to "at discretion of the treating clinician"
* Section 5: Wording re checking bloods after dose change amended from "every 2 weeks" to "repeat bloods after 2 weeks and 6 weeks"
* Section 5: Ongoing monitoring – added " At initiation of shared care, communication to primary care should include current and ongoing dose, any relevant test results, and date the next monitoring is required."
* Section 6: CrCl removed and added eGFR
* Section 6: Removed monitoring of CRP & / or ESR
* Section 6: Removed monitoring of bloods monthly for 3 months as this is responsibility of specialist (section 5)
* Section 10: FBC management section – changed wording from "interruption" to "withholding treatment"
* Section 10: Changed eosinophilia to unexplained eosinophilia
* Section 10: Mean cell volume greater than 105fl – changed wording in management section from "Consider interruption in treatment if there is a significant increase from baseline" to " Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal treat, if normal discuss with specialist team"
* Section 10: Changed "calculated GFR" to eGFR
* Section 10: Changed wording in management section from "Withhold and discuss with specialist team" to "discuss urgently with specialist team"
* Section 11: Added **highly** to wording "To use effective contraception" and added see section 12
* Section 13: Contact information updated to "Details for contacting specialist must be included on clinic letter"
* Section 16: Hyperlink to Shared Care for Medicines Guidance updated
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**Local review and adoption**

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| **Local approval** | **Date** |
| Local content added | March 2025 |
| Approved for use by HNY ICB  | 2nd April 2025 |

Clinical content has been reviewed and updated by the RDTC on the date indicated above. Every effort is made to keep the content up to date. These templates are provided to the North West and North East and Yorkshire ICBs for localisation and approval through standard ICB processes. The most recent version is available on the RDTC website at <https://rdtc.nhs.uk/prescribing-support-document/shared-care-protocol-mmf-mpa-in-adults-non-transplant/>.

This document is intended for use by NHS healthcare professionals and cannot be used for commercial or marketing purposes.

**Shared Care Protocol**

## Mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications)

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| Background | Mycophenolate mofetil is a pro-drug of the active metabolite mycophenolic acid. Mycophenolic acid 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. Mycophenolate is only licensed for the prevention of acute kidney, heart or liver transplant rejection (in combination with prednisolone or ciclosporin). It is not licensed for all the conditions it is used to treat. However, its use as a disease modifying anti-rheumatic drug (DMARD) and for the indications below are well established and supported by clinical specialists. |
| Licensed and agreed off-label indications | Off-label use for the treatment of chronic inflammatory conditions where use of mycophenolate mofetil is appropriate, including but not limited to the following specialities and conditions: * Dermatology (e.g. myositis, severe psoriasis, severe atopic dermatitis/eczema, autoimmune bullous dermatoses, SLE)
* Gastroenterology (e.g. Crohn’s disease, ulcerative colitis)
* Haematology (e.g. idiopathic thrombocytopenic purpura)
* Hepatology (e.g. auto-immune hepatitis)
* Neurology (e.g. inflammatory neuropathies, myasthenia gravis)
* Ophthalmology (e.g. uveitis, scleritis)
* Oral medicine (e.g. Behçet’s disease, refractory inflammatory oral disease)
* Renal medicine (e.g. immune-mediated nephritis)
* Respiratory disease (e.g. interstitial lung disease)
* Rheumatology (e.g. rheumatoid arthritis, systemic lupus erythematosus [SLE], vasculitis)

These indications are off-label. The initiating specialist must specify the indication for each patient when initiating shared care and clearly state when use is off-label. This shared care protocol applies to adults aged 18 and over. It does not include use of mycophenolate mofetil for transplant indications. |
| Locally agreed indications | Agreed indications as per section 2 |
| Initiation and ongoing dose regime | Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 12 weeks. To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended.The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.All dose or formulation adjustments will be the responsibility of the specialist unless directions have been discussed and agreed with the primary care clinician.Termination of treatment will be the responsibility of the specialist.**Initial stabilisation:** To be determined by the specialist based on indication and disease severity. Typically mycophenolate mofetil 250mg or 500mg once or twice daily, increasing in weekly increments.**The loading period must be prescribed by the initiating specialist.****Maintenance dose (following initial stabilisation):**Typically mycophenolate mofetil 1-2 grams daily, in divided doses. Maximum dose: 3 grams daily. **The initial maintenance dose must be prescribed by the initiating specialist.****Mycophenolic acid**Mycophenolic acid 720 mg is approximately equivalent to mycophenolate mofetil 1 g, but unnecessary switching should be avoided due to pharmacokinetic differences. Switches should only be performed by, or with the advice of, the specialist team. Mycophenolic acid should usually be reserved for patients who do not tolerate mycophenolate mofetil. **Conditions requiring dose adjustment:**The maximum recommended dose in severe chronic renal impairment (GFR less than 25 mL/min/1.73m2) is: * Mycophenolate mofetil:1 gram, twice daily
* Mycophenolic acid: 720 mg, twice daily
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| Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist | Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care.**Baseline investigations:** * Full blood count (FBC).
* Urea and electrolytes (U&E), including creatinine and eGFR.
* Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), and albumin.
* Height & weight.
* Blood pressure.
* Screening for viral infections at discretion of the treating clinician , e.g. HIV and hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus.
* Before starting mycophenolate mofetil treatment, people of childbearing potential should have a negative pregnancy test. Two serum or urine pregnancy tests with a sensitivity of at least 25 mlU/mL are recommended. A second test should be done 8-10 days after the first one and immediately before starting mycophenolate mofetil, unless exceptional circumstances exist whereby a delay in the initiation of treatment would cause harm to the patient and the prescriber is satisfied that a single test is adequate to rule out pregnancy. Pregnancy tests should be repeated as clinically required (e.g. after any gap in contraception is reported). See [MHRA Drug Safety Update](https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed) for more detail.
* Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case by case basis.
* Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19).

**Initial monitoring:** To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months: * FBC
* U&Es, including creatinine and eGFR
* AST and/or ALT, and albumin

Following a dose increase repeat bloods after 2 weeks and 6 weeks, then revert to previous schedule.  **Ongoing monitoring:** At initiation of shared care, communication to primary care should include current and ongoing dose, any relevant test results, and date the next monitoring is required.The specialist will retain the responsibility for monitoring the patient’s ongoing response to treatment, and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 6](#six_monitoring) remains appropriate.  |

## Ongoing monitoring requirements to be undertaken by primary care

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

| **Monitoring** | **Frequency** |
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| * FBC
* U&Es including creatinine and eGFR
* ALT and/or AST and albumin
 | At least every 12 weeks, and more frequently in patients at higher risk of toxicity, as advised by the specialist team. **The exact frequency of monitoring to be communicated by the specialist in all cases**.  |
| * Patients aged 60-79 years old are eligible for the shingles vaccine (herpes zoster). Patients aged 50 years or older and taking immunosuppressive therapy may also be eligible. Specialist input may be required. Refer to [Green Book Chapter 6 (Contraindications and special considerations)](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) and [Green Book Chapter 28a (Shingles)](https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a) for further details.
* **Annual** influenza ([The Green Book, Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19)) vaccinations are recommended.
* COVID-19 vaccination is safe and recommended (see [The Green Book, Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).
 | * Shingles vaccination: one course (two doses).
* Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.
* COVID-19 vaccination as per national schedule.
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## Pharmaceutical aspects

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| Route of administration: | Oral |
| Formulation: | Mycophenolate mofetil Mycophenolate mofetil 250 mg capsules Mycophenolate mofetil 500 mg tablets  Mycophenolate mofetil 1g/5mL powder for oral suspension.  Mycophenolate should be prescribed generically, and not by brand name. Brands include Cellcept® and Myfenax®; generics are available and may be more cost effective.  Mycophenolic acid Mycophenolic acid gastro-resistant capsules 180 mg and 360 mg tablets Brands include Ceptava® and Myfortic®.Mycophenolic acid 720 mg is approximately equivalent to mycophenolate mofetil 1 g but unnecessary switching should be avoided, due to pharmacokinetic differences. Mycophenolic acid should usually be reserved for patients who do not tolerate mycophenolate mofetil.  |
| Administration details: | Mycophenolate mofetil can be taken with or without food. If a dose is missed it should be taken as soon as remembered, then dosing resumed at the usual times. However, a double dose should not be taken to make up for a missed dose.  |
| Other important information:  | Capsules and tablets should not be opened crushed, or chewed, to avoid inhalation or direct contact with skin or mucus membranes of the active substance. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.  |

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| Cautions and contraindications | This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.**Contraindications:** * Hypersensitivity to mycophenolate mofetil or any excipients
* Pregnancy or breastfeeding. Treatment should not be initiated without providing a negative pregnancy test.

**Cautions:*** Localised or systemic infection.
* Very frail or elderly patients.
* Patients with suspected lymphoproliferative disorder.
* Patients with unexplained anaemia, leukopenia or thrombocytopenia.
* Active gastrointestinal disease.
* Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever): should usually be avoided in patients taking mycophenolate. Live shingles vaccine should be avoided in patients taking mycophenolate 1g/day or more, or lower doses together with prednisolone 7.5 mg/day or more.  Please refer to the [Green Book Chapter 6](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) (cautions and contraindications), together with chapters for the specific vaccine under consideration, for current advice. A non-live vaccine can still be used. Contact the specialist if further guidance is required.
* As there is a potential increased risk of malignancy, any pre-malignant disease should be adequately treated before starting therapy and patients should be up to date with relevant national cancer screening programmes.
* Due to the increased risk of skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor
* Avoid if previous hepatitis B or C infection, or recurrent shingles
* Marked renal failure (eGFR below 25 mL/min).
* Paternal exposure. See [section 12](#twelve_pregnancy) and [MHRA advice](https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-updated-contraception-advice-for-male-patients).
* Patients should not donate blood during therapy or for at least 6 weeks following discontinuation of mycophenolate. Men should not donate semen during therapy or for 90 days following discontinuation of mycophenolate.

In addition, the MHRA have also issued the following Drug Safety Updates for mycophenolate: * [Mycophenolate mofetil: pure red cell aplasia](https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-pure-red-cell-aplasia) (Dec 2014)
* [Mycophenolate mofetil (CellCept) and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis](https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-cellcept-and-mycophenolic-acid-risk-of-hypogammaglobulinaemia-and-risk-of-bronchiectasis) (Jan 2015)
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| Significant drug interactions | The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drugs/mycophenolate-mofetil/) and [SPC](https://www.medicines.org.uk/emc/search?q=mycophenolate+or+mycophenolic) for comprehensive information and recommended management.* **Aciclovir / ganciclovir / valaciclovir / valganciclovir**: possible increased plasma concentration of antiviral and mycophenolate metabolite especially in patients with renal impairment; possible increased risk of haematological toxicity
* **Antacids and proton pump inhibitors**: reduced absorption of mycophenolate
* **Further immunosuppression e.g. azathioprine, ciclosporin, sirolimus**: increased risk of bone marrow suppression
* **Cholestyramine / colesevelam**: reduced absorption of mycophenolate
* **Ciclosporin**: reduced mycophenolate exposure
* **Isavuconazole**: possible increased risk of mycophenolate adverse effects due to increased exposure to mycophenolate or its metabolite
* **Telmisartan**: may reduce mycophenolate exposure
* **Live vaccines**: Increased risk of generalised infection. Consult the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) for the most up to date advice
* **Rifampicin**: decreased plasma concentration of mycophenolate
* **Sevelamer**: reduced mycophenolate exposure; separate administration by 1-3 hours
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## Adverse effects and management

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance**.**

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

For information on incidence of ADRs see relevant SPCs.

**As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.**

| **Adverse effect** | **Management** |
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| * White blood cells less than 3.5x109/L
* Lymphocytes less than 0.5x109/L
* Neutrophils less than 1.6x109/L
* Platelets less than 140x109/L
* Unexplained Eosinophilia greater than 0.5x109/L
 | Discuss urgently with specialist team, and consider withholding treatment. |
| Mean cell volume greater than 105 fL  | Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal, treat, if normal discuss with specialist team.   |
| Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers  | Check FBC immediately and discuss with the specialist team. See haematological monitoring above.   |
| **Infections**:  Infection requiring antibiotics.Recurrent or opportunistic infections. | Temporarily withhold mycophenolate until the patient has recovered. Review for reversible causes. Withhold and discuss with specialist team.  |
| Exposure to chickenpox or shingles  | Contact specialist team for advice. See the [Green Book (chapter 34)](https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34) and [PHE guidance](https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles) for detailed advice on risk assessment and post exposure prophylaxis.  |
| **Liver function tests**: ALT or AST greater than 3 x upper limit of normal (ULN), or any sudden increases (e.g. double of baseline), OR Unexplained fall in serum albumin less than 30g/L  | Withhold and discuss with specialist team. Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication. |
| **Renal function**:  Creatinine rise of more than 30% over 12 months, or eGFR reduces to less than 60ml/min  | Discuss urgently with specialist team. |
| **Gastrointestinal disorders**: Very common adverse effects include nausea and vomiting, abdominal cramps, diarrhoea and dyspepsia.  | Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team.  |
| GI ulceration, bleeding and perforation   | Review for reversible causes. Withhold and discuss urgently with specialist team.  |
| Suspected pancreatitis  | Withhold and discuss with specialist team  |
| **Skin disorders**: Skin hypertrophy, acne, alopecia  | Review for reversible causes. Discuss with specialist team if symptoms become troublesome.  |
| Rash  | Review for possible causes. If cause of rash thought to be mycophenolate or immune-mediated, withhold and discuss with specialist team.  |
| **Other:** Neurological symptoms, psychiatric disorders, sudden onset or worsening of shortness of breath, cough or dyspnoea  | Review for reversible causes. Withhold and discuss with specialist team.  |
| Suspicion of malignancy  | Discuss with specialist team. Refer for diagnosis and treatment of malignancy  |

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| Advice to patients and carersThe specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs. | **The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:** * Rash
* Abdominal pain or jaundice (skin or whites of the eyes appear yellow)
* Signs and symptoms suggestive of bone marrow suppression e.g. sore throat, oral ulceration, abnormal bruising or bleeding, or signs of infection.
* Exposure to chickenpox or shingles or if the patient develops chicken pox or shingles.
* Pregnancy or they or their partner are planning to become pregnant.

**The patient should be advised:** * During a serious infection (requiring antibiotics) mycophenolate mofetil should be temporarily discontinued until the patient has recovered from the infection.
* If exposed to chickenpox or shingles patient must alert their primary care prescriber or specialist team and seek advice.
* That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.
* Tell anyone who prescribes them a medicine that they are taking mycophenolate. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
* Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin.
* Mycophenolate mofetil may cause somnolence, confusion, dizziness, tremor or hypotension, and therefore patients are advised to use caution when driving or using machines.
* To use highly effective contraception (see section 12), and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they or their partner become pregnant or are planning a pregnancy.
* Not to donate blood during treatment or for 6 weeks after stopping, and not to donate semen during treatment or for 90 days after stopping.
* To avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:
	+ the [Green Book (Chapter 34)](https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34)
	+ UKHSA guidance: [Guidelines on post exposure prophylaxis (PEP) for varicella/shingles](https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles).

Patient information leaflets: General information: [Patient.info](https://patient.info/medicine/mycophenolate-mofetil-cellcept-myfenax)  Rheumatology: [Versus Arthritis](https://www.versusarthritis.org/about-arthritis/treatments/drugs/mycophenolate/)  Dermatology: [British Association of Dermatologists](https://www.bad.org.uk/pils/mycophenolate-mofetil/)  Patient information leaflets are also available from [electronic medicines compendium](https://www.medicines.org.uk/emc/search?q=mycophenolate) |
| Pregnancy, paternal exposure and breastfeeding | It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.**All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.**  **Pregnancy:** **Mycophenolate is contraindicated during pregnancy or breastfeeding. Contraception should be used for 6 weeks after stopping the drug.** Treatment should not be initiated without providing a negative pregnancy test.  Because of the genotoxic and teratogenic potential of mycophenolate mofetil, people of childbearing potential must use at least one highly effective form of contraception before and during treatment and for six weeks after stopping mycophenolate unless abstinence is the chosen method of contraception.  Two forms of contraception used simultaneously are preferred. See [MHRA Drug safety update](https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-new-pregnancy-prevention-advice-for-women-and-men) and [letter sent to healthcare professionals](https://assets.publishing.service.gov.uk/media/566aefec40f0b6036600002d/Cellcept_II-121_DHPC_UK__1__LETTER_PROOF__3_.pdf). See also more recent advice: * [MHRA Drug Safety Update: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?](https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed#need-for-pregnancy-testing)
* [Faculty of Sexual and Reproductive Healthcare statement on contraception for women using known teratogenic drugs or drugs with potential teratogenic effects](https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-contraception-for-women-using-known/).

Methods of contraception which are considered ‘highly effective’ in this context include the long-acting reversible contraceptives (LARC) copper intrauterine device (Cu-IUD), levonorgestrel intrauterine system (LNG-IUS) and progestogen-only implant (IMP) and male and female sterilisation, all of which have a failure rate of less than 1% with typical use. (Note that patients using IMP must not take any interacting drugs that could reduce contraceptive effectiveness). * Information for healthcare professionals: [UK Teratology Information Services (UKTIS)](https://uktis.org/monographs/use-of-mycophenolate-mofetil-in-pregnancy/)
* Information for patients and carers: [Best Use of Medicines in Pregnancy (BUMPs)](https://www.medicinesinpregnancy.org/Medicine--pregnancy/Mycophenolate/)

 **Breastfeeding:** Mycophenolate should not be prescribed for people who are breastfeeding.Information for healthcare professionals: [UK Drugs in Lactation Advisory Service (UKDiLAS)](https://www.sps.nhs.uk/medicines/mycophenolate-mofetil/)   **Paternal exposure**: Limited evidence does not indicate an increased risk of malformations or miscarriages in pregnancies where the father is taking mycophenolate.  However, mycophenolate is genotoxic and the risk cannot be fully excluded.  It is therefore recommended that male patients or their female partners use reliable contraception during treatment, and for at least 90 days after stopping mycophenolate.See MHRA Drug Safety Update: [Mycophenolate mofetil, mycophenolic acid, updated contraception advice for male patients (Feb 2018)](https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-updated-contraception-advice-for-male-patients)  |
| Specialist contact information and arrangements for referral | Details for contacting specialist must be included on the clinic letter. |
| Additional information | Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. |
| References | 1. British National Formulary. Accessed via https://bnf.nice.org.uk/ on 30/11/23
2. Mycophenolate mofetil 250 mg capsules (CellCept®). Date of revision of the text 22/07/22. Accessed via <https://www.medicines.org.uk/emc/product/1102> on 30/11/23.
3. Mycophenolate mofetil 500 mg film-coated tablets (Cellcept®). Date of revision of the text 22/07/22. Accessed via <https://www.medicines.org.uk/emc/product/1103> on 30/11/23.
4. Package leaflet: Information for the patient. CellCept 500 mg film-coated tablets. May 2023. Accessed via <https://www.medicines.org.uk/emc/files/pil.1103.pdf> on 23/02/24.
5. Mycophenolate mofetil 1g/5 mL powder for oral suspension (CellCept®). Date of revision of the text 22/07/22. Accessed via <https://www.medicines.org.uk/emc/product/1569> on 30/11/23.
6. Mycophenolate mofetil 250 mg hard capsules (Myfenax®). Date of revision of the text 30/06/23. Accessed via <https://www.medicines.org.uk/emc/product/9293> on 30/11/23.
7. Mycophenolate mofetil 500 mg tablets (Myfenax®). Date of revision of the text 30/06/23. Accessed via <https://www.medicines.org.uk/emc/product/9294> on 30/11/23.
8. Mycophenolic acid 360 mg gastro-resistant tablets (Ceptava®). Date of revision of the text 21/12/22. Accessed via <https://www.medicines.org.uk/emc/product/8508/smpc> on 23/02/24.
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11. British Society for Rheumatology 2023. Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids. Accessed via <https://academic.oup.com/rheumatology/article/62/4/e48/6783012>.
12. Renal Drug Database. Mycophenolate. Reviewed 10/08/20. Accessed via <https://renaldrugdatabase.com/> on 30/11/23.
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| To be read in conjunction with the following documents | * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.medicinesresources.nhs.uk/shared-care-for-medicines-guidance-a-standard-approach-rmoc.html>
* NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
* General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
* NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.
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