Classification: Official

Publication approval reference: PAR1621_xiv

National shared care protocol for mycophenolate mofetil and mycophenolic acid for patients within adult services (non-transplant indications)	
Adapted and adopted for use in NHS Frimley	
Agreed by NHS Frimley Medicines Optimisation Group	March 2025
Ratified by NHS Frimley Medicines Board	April 2025
Review date	April 2030

National shared care protocol:

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

The content of this shared care protocol was correct as of January 2022. As well these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).

- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose and form, baseline and most recent test results, confirm the monitoring schedule, and when the next monitoring is required. Include contact information (section 13).
- Conduct the required monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Review treatment and reassume prescribing responsibility if a patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into any account potential drug interactions in section 7.
- Adjust the dose of mycophenolate mofetil prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Assess for possible interactions with mycophenolate mofetil when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop mycophenolate mofetil and discuss urgently with the specialist if gastrointestinal bleeding or perforation is suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (see section 10).
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take mycophenolate mofetil as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist. Tell anyone who prescribes them a medicine that they are taking mycophenolate.
- Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of mycophenolate mofetil with their pharmacist before purchasing any OTC medicines.
- Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service, and to inform their prescriber as soon as possible if they or their partner become pregnant or wish to become pregnant.

1. Background

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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.

2. Indications

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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.

3. Locally agreed off-label use

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Nil

4. Contraindications and cautions

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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

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 (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.
- Dose reduction or discontinuation should be considered for patients in cases of clinically significant COVID-19.

- 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 15.
- 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 (Dec 2014)
- Mycophenolate mofetil (CellCept) and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis (Jan 2015)

5. Initiation and ongoing dose regimen

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- 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 4 weeks.
- 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 initiating 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 initial 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 <25 mL/min/1.73m^2) is:

- Mycophenolate mofetil:1 gram, twice daily
- Mycophenolic acid: 720 mg, twice daily

6. 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 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.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC 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 for the most up to date advice
- **Rifampicin**: decreased plasma concentration of mycophenolate
- **Sevelamer**: reduced mycophenolate exposure; separate administration by 1-3 hours

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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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 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 creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), and albumin
- Height & weight
- Blood pressure
- Screening for viral infections as per local policy, 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 mIU/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 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 CrCl
- AST and/or ALT, and albumin

Following a dose increase repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

Ongoing monitoring:

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 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
• FBC • U&Es including creatinine and CrCl • ALT and/or AST and albumin	Monthly for three months, unless already completed in secondary care. Thereafter at least every 12 weeks, and more frequently in

• Rheumatology patients: CRP &/or ESR	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 70-79 years old could be eligible for the shingles vaccine (herpes zoster). For patients taking mycophenolate 1g/day or more, or lower doses together with prednisolone 7.5 mg/day or more, a non-live vaccine should be used. Specialist input may be required. If patient is taking additional DMARDs, check advice for all drugs. Please refer to Green Book Chapter 6 (cautions and contraindications) and Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended. • COVID-19 vaccination is safe and recommended (see The Green Book, Chapter 14a).	• Shingles vaccination: one-off. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • COVID-19 vaccination as per national schedule.
(If relevant) 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.	

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
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	

• White blood cells less than $3.5x10^9$/L • Lymphocytes less than $0.5x10^9$/L • Neutrophils less than $1.6x10^9$/L • Platelets less than $140x10^9$/L • Eosinophilia greater than $0.5x10^9$/L	Discuss urgently with specialist team, and consider interruption
Mean cell volume >105 fL	Consider interruption in treatment. Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.
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) and PHE guidance for detailed advice on risk assessment and post exposure prophylaxis.
Liver function tests: ALT or AST > 3 x upper limit of normal (ULN), or any sudden increases (e.g. double of baseline), OR Unexplained fall in serum albumin <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 >30% over 12 months, or calculated GFR reduces to <60ml/min	Withhold and discuss 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

11. Advice to patients and carers

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The 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 medicines.

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 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 effective contraception, 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 partners 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)
    - UKHSA guidance: Guidelines on post exposure prophylaxis (PEP) for varicella/shingles.

Patient information leaflets:

General information: https://patient.info/medicine/mycophenolate-mofetil-cellcept-myfenax

Rheumatology: https://www.versusarthritis.org/about-arthritis/treatments/drugs/mycophenolate/

Dermatology: https://www.bad.org.uk/for-the-public/patient-information-leaflets/mycophenolate-mofetil

Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=mycophenolate

12. Pregnancy, paternal exposure and breast feeding

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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.

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 and letter sent to healthcare professionals. See also more recent advice:

- MHRA Drug Safety Update: Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?
- Faculty of Sexual and Reproductive Healthcare statement on contraception for women using known teratogenic drugs or drugs with potential teratogenic effects.

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: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MYCOPHENOLATE-MOFETIL-IN-PREGNANCY/
Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Mycophenolate/

Breastfeeding:

Mycophenolate should not be prescribed for people who are breastfeeding
Information for healthcare professionals: 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)

13. Specialist contact information

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Please obtain specialists details via the associated clinic letters for individual cases.

Alternatively, the following contact details can be used:

- Gastroenterology consultants: Dr Sarah Langlands (sarah.langlands1@nhs.net) and Dr Tom Shephard (tom.shepherd@nhs.net) cross-site
- Rheumatology consultants: Dr Mark Lloyd for Frimley Park (mark.lloyd1@nhs.net) and Dr Francesca Demetriadi for Wexham Park (francesca.demetriadi@nhs.net)
- Dermatology consultant: Dr Synclare D'Souza (synclare.dsouza1@nhs.net) cross-site
- Respiratory consultants: Dr Natalie Stolagiewicz for Frimley Park (n.stolagiewicz@nhs.net) and Dr Sharon Power (sharon.power4@nhs.net) for Wexham Park

14. Additional information

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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.

15. References

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16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- 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/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed Frimley shared care protocol for *[insert medicine name]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS Frimley**,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	

3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and

the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp