Azathioprine for patients within adult services (non-transplant indications)
- Rotherham Place (Dermatology)

Adapted from national shared care protocol, published 4 July 2022, Version 1

Authors: Dr Saurabh Mittal (Lead), Nurse Consultant Tara Lees
Eloise Summerfield, Prescribing Advisor, Rotherham Place

Approval date: Jan 2024
Review date: Jan 2029

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 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.
- 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, 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.
- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant or breastfeed.
- 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 received by the GP practice, 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 azathioprine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Assess for possible interactions with azathioprine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop azathioprine and discuss urgently with the specialist if bone marrow suppression is suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (see section 10).
- Contact the specialist team for advice if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take azathioprine 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 azathioprine.
- 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 azathioprine with their pharmacist before purchasing any OTC medicines.

Inform the specialist or primary care prescriber as soon as possible if they become pregnant or wish to become pregnant.

1. Background

Back to top

Azathioprine is a disease modifying anti-rheumatic drugs (DMARDs). It is used as an immunosuppressant anti-metabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) to influence the immune response.

Therapeutic effect may be evident only after weeks or months and can include a steroid sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids.

Azathioprine is not licensed for all the conditions they are used to treat, as noted below. However, its use for the indications below is established and supported by various sources and bodies including the BNF, NICE, British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), British Association of Dermatologists (BAD), British Thoracic Society (BTS), Association of British Neurologists (ABN) and British Society of Gastroenterology (BSG).

2. Indications

Back to top

The licensed indications for azathioprine, in dermatology, include:

- Dermatomyositis
- Inflammatory bowel disease (IBD)

- Pemphigus vulgaris
- Pyoderma gangrenosum
- Systemic lupus erythematosus (SLE)
- Pemphigus vulgaris
- Severe refractory eczema

Licensed indications vary with brand. See relevant summary of product characteristics (see SPC) for full details.

This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of azathioprine is appropriate. 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 azathioprine for transplant or oncology indications.

3. Locally agreed off-label use

Back to top

NONE

4. Contraindications and cautions

Back to top

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:

- Known hypersensitivity to the active substance or any excipients.
- Hypersensitivity to 6-mercaptopurine (6-MP) should alert the prescriber to probable hypersensitivity to azathioprine.
- Absent or very low thiopurine methyltransferase (TPMT) activity – risk of life-threatening pancytopenia.

Cautions:

- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever): should be avoided in patients taking azathioprine at a dose greater than 3 mg/kg/day. Please refer to the Green Book Chapter 6 for current advice regarding the use of live vaccines in patients taking immune modulators. Contact the specialist if further guidance is required.
- Concomitant prescribing of allopurinol: A 75% dose reduction of azathioprine is required, see section 7.
- Patients receiving azathioprine are at an increased risk of developing lymphoproliferative disorders and other malignancies, notably skin cancers, sarcomas and uterine cervical cancer in situ. Exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity
- Patients with low thiopurine methyltransferase (TPMT) activity are at increased risk of myelosuppression. Substantial dose reduction is generally required.
- Severe infection.
- Severely impaired hepatic or bone marrow function.
- Pregnancy and breastfeeding (see section 12).

Treatment may need to be monitored more frequently in the following:

- Elderly patients
- Impaired renal function
- Mild/moderately impaired hepatic function
- Mild/moderately impaired bone marrow function

5. Initiation and ongoing dose regimen

Back to top

- 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.

There is a wide dose range depending on the indication. The selected dose will be tailored to the individual patient and decided by the specialist.
The initial stabilisation period must be prescribed by the initiating specialist.
Transfer of monitoring and prescribing to primary care is usually after 3 months. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

Maintenance dose (following initial stabilisation):
Usual dose range**:**

- **Azathioprine: 0.5–3 mg/kg daily**, adjusted according to response.

Some patients may respond to lower doses. Please note patients may be initiated on more than one DMARD.
The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:
Lower doses may be required if there is significant renal or hepatic impairment, in elderly patients, and in patients with mild/moderately impaired bone marrow function, TPMT deficiency or NUDT15 mutation (see SPC) .

6. Pharmaceutical aspects

Back to top

Route of administration:	Oral
Formulation:	Azathioprine 25mg and 50mg tablets Azathioprine 10 mg/mL oral suspension (Jayempi®)
Administration details:	The tablets should be swallowed whole and not split / crushed. Can be taken either with or without food, but patients should standardise which method is chosen. Tablets should be taken at least 1 hour before or 2 hours after milk or dairy products. Taking with or after food may relieve nausea, however the oral absorption of azathioprine may be reduced. Consideration should be given to monitoring

	therapeutic efficacy more closely if patient is taking azathioprine consistently with food. For azathioprine oral suspension, the bottle should be shaken vigorously for at least 30 seconds to ensure the suspension is well mixed.
Other important information:	Providing the film coating of azathioprine tablets remains intact, there is no risk or additional precautions required when handling tablets. Azathioprine is cytotoxic. It is recommended that they are handled following local recommendations for the handling and disposal of cytotoxic agents.

7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following drugs must not be prescribed without consultation with the specialist:

- **Allopurinol** has the potential to cause thiopurine toxicity and should be avoided, except with specialist input. Allopurinol may be recommended in combination with thiopurines by the specialist for IBD patients, particularly in those who are unable to tolerate to or do not respond to treatment with a thiopurine alone. The dose of azathioprine should be reduced by 75% if used concurrently with allopurinol. If considering prescribing allopurinol, discuss with the specialist for advice and a dose adjustment.
- **Febuxostat** has the potential to cause thiopurine toxicity; avoid in combination with azathioprine.
- **Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever) can be given to patients on stable long term low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for >14 days) alone or in combination with low dose non-biological oral immune modulating drugs (e.g. azathioprine up to 3mg/kg/day). Clinician discretion is advised. Please refer to the Green Book Chapter 6 for current advice, and advice for patients taking higher doses.
- **Warfarin** – thiopurines may reduce anticoagulant effects of warfarin.
- **Co-trimoxazole / trimethoprim** – possible increased risk of haematological toxicity, however evidence is conflicting and this combination is often used in practice.
- **Clozapine** - avoid due to increased risk of agranulocytosis.
- **Ribavirin** - increased risk of haematological toxicity when azathioprine given concurrently and this combination should be avoided.
- **Aminosalicylates** (sulfasalazine, mesalazine or olsalazine) - increased risk of haematological toxicity with concomitant thiopurine due to TPMT inhibition. Dose adjustment of azathioprine and additional monitoring of FBC may be required.

The following drugs may be prescribed with caution:

- **ACE inhibitors** - increase the risk of anaemia and or leukopenia.
- **Cimetidine and indomethacin** - concomitant administration of thiopurines may increase the risk of myelosuppression.

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

Back to top

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:

- Height and weight
- Blood pressure
- Full blood count (FBC)
- Urea and electrolytes (U&Es) & creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST),and albumin
- Baseline thiopurine methyl transferase (TPMT) status
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster.
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case by case basis
- Confirm cervical screening is up to date
- Complete skin check and lymph node examination

Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)

Initial monitoring and at dose change:

Weekly. For 1st 4 weeks, then monthly until dose stabilisation and then every 3 months:

- FBC
- U&Es, including creatinine and CrCl
- LFTs, including 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. More frequent monitoring is appropriate in patients at higher risk of toxicity.

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, along with an annual skin check and lymph node examination.
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

Back to top

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

Monitoring and actions	Frequency
• FBC • U&Es including creatinine and CrCl • ALT and/or AST, and albumin • Rheumatology patients: CRP &/or ESR	Monthly for three months, unless already completed in secondary care. Thereafter 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 70-79 years old could be eligible for the shingles vaccine (varicella zoster). For patients taking prednisolone exceeding 20mg daily or azathioprine exceeding 3mg/kg/day 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 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). Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	• 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

Back to top

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	

Full blood count: • 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. NB: Isolated lymphopenia or eosinophilia is often a feature of the underlying autoimmune indication, and is rarely an indication to discontinue azathioprine.
Mean cell volume >105 fl NB: Reversible, dose-related increases in mean corpuscular volume are a known effect of thiopurines.	Consider interruption in treatment if there is a significant increase from baseline. 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	Consider interruption in treatment. Check FBC immediately and discuss with the specialist team. See haematological monitoring above.
Infections: Infection requiring antibiotics	Temporarily withhold thiopurine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.
Liver function tests: ALT or AST >100 units/L, or any sudden increases (e.g. double of baseline), OR Unexplained fall in serum albumin <30g/L Jaundice	Withhold and discuss with specialist team. When used for hepatology indications, continue treatment and discuss with specialist urgently. 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: Nausea	Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team.
Suspected pancreatitis	Withhold and discuss with specialist team.

11. Advice to patients and carers

Back to top

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:

Signs or symptoms indicating haematological toxicity, e.g. sore throat, infection, unexplained or abnormal bruising or bleeding.
Signs of symptoms of hepatic toxicity, e.g. Jaundice (yellowing of the skin or whites of the eyes)

The patient should be advised to:

- During a serious infection azathioprine should be temporarily discontinued until the patient has recovered from the infection.
- 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 azathioprine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- To inform their specialist or primary care prescriber promptly if pregnancy occurs or is planned.
- All women aged 25-64 years old should be encouraged to participate in national cervical cancer screening programmes. There is no need to attend more frequently than recommended.
- 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.
- Patients taking azathioprine at a dose of 3 mg/kg or more should be advised 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)
  UKSHA guidance: Guidelines on post exposure prophylaxis (PEP) for varicella/shingles April 2022

Patient information:

- General information: https://www.nhs.uk/medicines/azathioprine/
- General information: https://patient.info/medicine/azathioprine-azapress-imuran
- Rheumatology: https://www.versusarthritis.org/about-arthritis/treatments/drugs/azathioprine/
- Dermatology: https://www.bad.org.uk/for-the-public/patient-information-leaflets/azathioprine
- Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=azathioprine

Gastroenterology:

- https://www.crohnsandcolitis.org.uk/about-crohns-and-colitis/publications/azathioprine-mercaptopurine
- https://gutscharity.org.uk/advice-and-information/conditions/crohns-disease/
- https://gutscharity.org.uk/advice-and-information/conditions/ulcerative-colitis/

12. Pregnancy, paternal exposure and breast feeding

Back to top

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:
The BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding advises that azathioprine is compatible throughout pregnancy at doses ≤2mg/kg/day.

The British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease advises that both maintenance and flares can be treated as normal with thiopurines (azathioprine) during pregnancy.

Information for healthcare professionals:
https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AZATHIOPRINE-OR-MERCAPTOPURINE-IN-PREGNANCY/

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Azathioprinemercaptopurine/

Breastfeeding:
Azathioprine is compatible with breastfeeding, although the active metabolite mercaptopurine is present in breast milk. A risk versus benefit assessment is advised. If used during breastfeeding, monitor for signs of infection or immunosuppression. If high doses of azathioprine are used, monitor infant blood counts. If mercaptopurine is used, monitor infant's blood count and liver function.

Information for healthcare professionals:

- https://www.sps.nhs.uk/medicines/azathioprine/

Paternal exposure:
Azathioprine is compatible with paternal exposure. There is currently no evidence of adverse fetal effects relating to paternal use.

- Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/PATERNAL-USE-OF-AZATHIOPRINE-OR-MERCAPTOPURINE/

13. Specialist contact information

Back to top

Department Contact Details:

Nurse Station	01709 424436

Consultants

Dr Saurabh Mittal	(Mon- Friday)	01709 424161
Dr Samanthi Paranavithane	(Mon-Friday)	01709 424161

Email address: rgh-tr.dermatologysecretaries@nhs.net

14. Additional information

Back to top

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

Back to top

- eBNF accessed via https://bnf.nice.org.uk/ on 05/10/2021.
- Azathioprine 50mg tablets (Imuran®). Aspen. Date of revision of the text: April 2021. Accessed via https://www.medicines.org.uk/emc/product/3823 on 08/07/2021.
- Azathioprine 50mg tablets (Azapress®). Ennogen. Date of revision of the text: 29/06/2016. Accessed via www.medicines.org.uk/emc on 01/10/2020.
- British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Accessed 01/10/2020.
- British Society of Rheumatology and British Health Professionals in Rheumatology. 2016. Guideline on prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. Accessed 01/10/2020.
- British Association of Dermatologists. 2011. Guidelines for the safe and effective prescribing of azathioprine (update in progress). Accessed 01/10/2020.
- British Association of Dermatologists. 2007 (updated 2016). Patient information leaflet: azathioprine. Accessed 01/10/2020.
- British Thoracic Society in collaboration with the Thoracic Society of Australia and New Zealand and the Irish Thoracic Society. 2008. Interstitial lung disease guideline (archived). Accessed 01/10/2020.
- British Society of Gastroenterology. 2019. Consensus guidelines on the management of inflammatory bowel disease in adults. Accessed 01/10/2020.
- British Society of Gastroenterology. 2011. Guidelines on the management of autoimmune hepatitis. Accessed 01/10/2020.
- Association of British Neurologists. 2015. Myasthenia gravis: management guidelines. Accessed 01/10/2020.
- Public Health England. Immunisation against infections disease: The Green Book. Accessed 01/10/2020.
- Specialist Pharmacy Service. Lactation Safety Information: azathioprine. Reviewed September 2020. Accessed via https://www.sps.nhs.uk/medicines/ on 08/07/2021.
- UK Teratology Information Service. Toxbase monograph: Azathioprine or mercaptopurine in pregnancy. December 2019. Accessed via www.toxbase.org on 06/10/2021.
- UK Teratology Information Service. Toxbase monograph: Paternal use of azathioprine or mercaptopurine. December 2019. Accessed via www.toxbase.org on 06/10/2021.
- NICE Guidance: Crohn's disease: management (NG129) May 2019. Accessed via: https://www.nice.org.uk/guidance/ng129 on 09/12/21

- NICE Guidance: Ulcerative colitis: management (NG130) May 2019. Accessed via: https://www.nice.org.uk/guidance/ng130 on 09/12/21

16. Other relevant national guidance

Back to top

- 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/.

GP to contact the dermatology secretaries email address with a letter with a rationale of why the patient requires a dermatology appointment outside of the annual review. This may include drug lost efficiency, side effects from treatments and concerns with deranged blood monitoring.

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 *[insert APC name]*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 the 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: The date must be at least 1 month from the initiation of treatment.

The next blood monitoring is due on *[insert date]. It* should be continued according to the shared care guidelines.

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

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 responsibility for prescribing to this patient.
In the interest of patient safety, NHS *[insert CCG name]*, in conjunction with local acute trusts, has classified *[insert medicine name]*as a Shared Care drug and requires a number of conditions to be met before transfer 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)**	

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

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. I hope to receive more information about this shared care agreement as soon as possible.

Yours sincerely

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp