

Shared Care Agreement: Sulfasalazine

This Shared Care Protocol sets out details for the sharing of care for patients prescribed oral Sulfasalazine. This protocol is for patients within adult services.

It should be read in conjunction with the latest Summary of Product Characteristics (SPC) available at [electronic medicines compendium](#).

As outlined in [NHS England Guidance 2018 "Responsibility for Prescribing between Primary & Secondary/Tertiary Care"](#). When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the consultant and primary care clinician concerned. The primary care clinician may accept or decline shared care. If shared care is declined the primary care clinician practice must discuss the reason for refusal with the consultant within 14 days. Where appropriate, the clinical responsibility will then remain with the consultant.

This shared care guideline sets out details to support the transfer of responsibility for prescribing Sulfasalazine for any of the indications listed on page 5, from specialist to primary care. For further information please click on the links below:

[British National Formulary](#)
[electronic medicines compendium](#)

Document Ratification Table

Ratification Process	Details
Authored by:	Cambridgeshire and Peterborough Integrated Care System
Ratified by:	Cambridgeshire and Peterborough Joint Prescribing Group
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Version number:	1

The content of this shared care protocol was correct as of April 2025. 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](#). 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 formulation, 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 annual reviews and 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.
- 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 account any potential drug interactions in [section 7](#).
- Adjust the dose of sulfasalazine prescribed as advised by the specialist.

- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop sulfasalazine and make an urgent referral to the specialist if signs of myelosuppression, hepatic or renal dysfunction develop or a serious skin reaction or oral ulceration is observed.
- Seek advice from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take sulfasalazine as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- 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 primary care prescriber and be aware they should discuss the use of sulfasalazine with their pharmacist before purchasing any OTC medicines.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Sulfasalazine is a disease modifying antirheumatic drug (DMARD) used to treat a number of rheumatological conditions, and to induce and maintain remission in certain inflammatory gastrointestinal diseases.

This shared care protocol does not cover the treatment of people less than 18 years old.

2. Indications

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The licensed indications for sulfasalazine are:

- Rheumatoid arthritis (EC tablets only)
- Ulcerative colitis
- Active Crohn's disease

Sulfasalazine is also used off-label for other chronic inflammatory disorders including:

- Seronegative spondyloarthropathies such as psoriatic arthritis
- Sarcoidosis

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

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:

- Known hypersensitivity to sulfasalazine, its metabolites or any of the excipients as well as sulfonamides or salicylates.
- Porphyria.

Cautions:

- Hepatic or renal impairment.
- Pre-existing blood dyscrasias.
- Severe allergy or bronchial asthma.
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency due to risk of haemolytic anaemia.
- Folic acid deficiency.
- Adequate fluid intake should be maintained during treatment to avoid crystalluria and kidney stone formation.
- Slow acetylator status increases the risk of sulfapyridine-related adverse drug reactions (ADRs) which can present as a drug-induced lupus-like syndrome.
- Transfer of monitoring and prescribing to primary care is normally after the patient has been treated for 3 months, the 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.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been treated for 3 months, the 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:

Treatment of acute attacks of ulcerative colitis and Crohn's disease:

Oral: 1-2g four times daily until remission. The night-time interval between doses should not exceed 8 hours.

Rheumatoid arthritis (using enteric coated (EC) tablets):

500mg daily, increasing by 500mg each week until 2-3g per day in divided doses is reached according to response. Only the enteric coated tablets are licensed in rheumatoid arthritis; use of other formulations is off-label.

For other indications take specialist advice.

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Ulcerative colitis and Crohn's disease:

Oral: Usual maintenance dose 500mg four times daily.

Rheumatoid arthritis and other indications (using EC tablets):

2-3g daily in 3-4 divided doses.

The initial maintenance period must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

In patients with GFR <10 mL/min, start at very low dose and monitor.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	500mg tablets 500mg enteric coated (EC) tablets 250mg/5mL oral suspension (contains ethanol, see below) Licensed indications vary with formulation. See relevant summary of product characteristics for full details.
Administration details:	EC tablets should be swallowed whole and not crushed or broken.
Other important information:	Plain tablets are only licensed for use in ulcerative colitis or active Crohn's disease. The oral suspension contains 4.7 mg of alcohol (ethanol) in each 5ml, equivalent to less than 1ml of beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects. EC tablets are licensed for use in rheumatoid arthritis as well as ulcerative colitis and active Crohn's disease. Their use in ulcerative colitis and Crohn's disease is usually recommended if the patient experiences gastro-intestinal intolerance with the plain tablets. Sulfasalazine may cause a yellow-orange discolouration of body fluids and skin. Certain types of extended wear soft-contact lenses may be permanently stained. Sulfasalazine or its metabolites may interfere with ultraviolet absorbance, particularly at 340 nm, and may cause interference with some laboratory assays that use NAD(H) or NADP(H) to measure ultraviolet absorbance around that wavelength. Examples of such assays may include urea, ammonia, LDH, α-HBDH and glucose. It is possible that alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatine kinase-muscle/brain (CK-MB), glutamate dehydrogenase (GLDH), or thyroxine may also show interference when sulfasalazine treatment is given at high doses. Consult with the testing laboratory regarding the methodology used. Caution should be exercised in the interpretation of these laboratory results in patients who are receiving sulfasalazine. Results should be interpreted in conjunction with clinical findings.

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.

- **Digoxin:** Reduced absorption may be seen when used concomitantly with sulfasalazine.

- Sulfonamides are chemically similar to some **oral hypoglycaemic agents** and may cause hypoglycaemia. Patients receiving sulfasalazine and hypoglycaemic drugs should closely monitor blood glucose.
- **Azathioprine and 6-mercaptopurine:** Possible risk of bone marrow suppression and leucopenia
- **Folate** absorption and metabolism may be reduced by sulfasalazine.
- **Darolutamide and voxilaprevir** may increase exposure to sulfasalazine, manufacturer advises avoid.

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:

- Urea and electrolytes (U&Es) including creatinine and creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), & albumin
- Full blood count (FBC)
- Weight
- Height and blood pressure
- Assess for co-morbidities which may influence DMARD choice
- Screening for HIV and hepatitis B and C
- 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, influenza, COVID-19).

Initial monitoring and at dose change:

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for three months. After which, the transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 4 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine, but may be sooner in some indications.

- FBC
- U&Es, including creatinine and CrCl
- AST and/or ALT, albumin, and bilirubin
- Rheumatology patients: C-reactive protein (CRP) &/or erythrocyte sedimentation rate (ESR)

Following a dose change 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	Frequency
- FBC - U&Es including creatinine and CrCl - ALT and/or AST and albumin - Rheumatology patients: CRP &/or ESR	3 Monthly After 12 months no routine monitoring is required for the majority of patients. Annual serum creatinine or eGFR may be considered. The decision to discontinue monitoring should be following advice from the specialist for the individual patient.
Vaccines are safe and recommended for this patient group and should be offered in line with the standard schedule. Refer to Green Book Chapter 6 for further details. Annual influenza (The Green Book, Chapter 19) vaccinations are recommended.	- Shingles vaccination: one course. - Other vaccinations as per national schedule. - Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.

(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.

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.

Result	Action for primary care
Full blood count - WCC less than $3.5 \times 10^9/L$ - Lymphocytes less than $0.5 \times 10^9/L$ - Neutrophils less than $1.6 \times 10^9/L$ - Platelets less than $140 \times 10^9/L$ - Unexplained eosinophilia; greater than $0.5 \times 10^9/L$ Unexplained fall in albumin; less than 30g/L	Withhold treatment and discuss with specialist.

MCV >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, purpura, mouth ulcers.	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.
Acute infection	During serious infections (e.g. requiring intravenous antibiotics or hospitalisation) temporarily withhold sulfasalazine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.
Liver function tests: ALT and/or AST greater than 100units/L And/or a sudden increase (e.g. doubling of baseline) Jaundice	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 increase of greater than 30% from baseline in the last 12 months or CrCl reduces to less than 60mL/min	Use clinical judgement and repeat in 1 week If still more than 30% from baseline, withhold and discuss with specialist.
Gastrointestinal disorders Nausea, vomiting, diarrhoea or unintentional weight loss	Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team.
Other symptoms • Skin/mucosal reaction, e.g. serious rash • Diffuse alopecia • Breathlessness or cough • Peripheral neuropathy	Consider withholding treatment and discussing with specialist. For widespread rash, discontinue and discuss with specialist urgently.

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:

- Sore throat, mouth ulcers, fever, malaise, swollen lymph nodes, or unexplained bleeding or bruising
- Progressive skin rash with blisters or oral ulcerations – see below
- Nausea, vomiting, diarrhoea, jaundice, dark urine and unintentional weight loss.
- Hair loss
- Breathlessness, infection or cough
- Symptoms of peripheral neuropathy e.g. pins and needles, numbness or burning pain in extremities

The patient should be advised:

- Life-threatening skin reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of sulfasalazine. The highest risk for occurrence is within the first weeks of treatment. Patients should be advised to report a progressive skin rash often with blisters or mucosal lesions, or any other sign of hypersensitivity.
- During a serious infection, sulfasalazine should be temporarily discontinued until the patient has recovered from the infection.
- Tell anyone who prescribes them a medicine that they are taking sulfasalazine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.
- Sulfasalazine may cause a harmless yellow-orange discolouration of body fluids and skin. Certain types of extended wear soft-contact lenses may be permanently stained.
- To maintain adequate fluid intake during treatment to reduce the risk of crystalluria and kidney stones.
- Sulfasalazine oral suspension contains 4.7 mg of alcohol (ethanol) in each 5ml, equivalent to less than 1ml of beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Patient information:

General information: [Sulfasalazine](#)

General information: [Sulfasalazine Salazopyrin Sulazine](#)

[Rheumatology](#)

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.

The [BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding](#) advises the following:

Pregnancy:

Sulfasalazine, with folate supplementation (5 mg/day), is compatible throughout pregnancy.

[Information for healthcare professionals](#)

[Information for patients and carers](#)

Breastfeeding:

Sulfasalazine is compatible with breastfeeding in healthy, full-term infants.

There have been reports of bloody stools or diarrhoea in infants who were breastfeeding from mothers on sulfasalazine. In cases where the outcome was reported, bloody stools or diarrhoea resolved in the infant after discontinuation of sulfasalazine in the mother.

[Information for healthcare professionals](#)

Paternal exposure:

Men taking sulfasalazine may have reduced fertility, due to oligospermia and impaired mobility, which may take 2-3 months to return to normal following treatment cessation.

13. Specialist contact information

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Cambridge University Hospitals NHS Foundation Trust

Medicines Information department (patient helpline) - 01223 217478

CUH Rheumatology Department

Decisions to alter or discontinue treatment are usually discussed via the Rheumatology Helpline on 01223 254933. The on-call rheumatology specialist registrar (SpR) may also be contacted via the Addenbrooke's Contact Centre.

Specialist	Post	Telephone
Jill Bloxham; Julie Isaacson; Tracey Nash, Jane How	Rheumatology Practitioners	01223 254933, option 2 (nurse advice line)
Dr Nick Shenker	Clinic lead, Consultant Rheumatologist)	01223 256883
Dr Kenneth Poole	Consultant Rheumatologist	01223 216774
Dr Gavin Clunie	Consultant Rheumatologist	01223 216774
Dr Andra Negoescu	Consultant Rheumatologist	01223 216774
Dr Mark Lillicrap	Consultant Rheumatologist	01223 217316
Dr Frances Hall	Consultant Rheumatologist	01223 256883
Dr Natasha Jordan	Consultant Rheumatologist	01223 256883
Dr Anshuman Malaviya	Consultant Rheumatologist	01223 217716
Dr Christopher Chan	Consultant Rheumatologist	01223 586563
Dr Gaaffar Massawi	Locum Consultant Rheumatologist	-
Dr Carmel Stober	Locum Consultant Rheumatologist	01223 586563
Dr Anoop Kuttikat	Locum Consultant Rheumatologist	-

NWAFT Rheumatology Department

Specialist	Post	Telephone
Dr Sandeep Dahiya	Consultant Rheumatologist	01733 676764
Dr Maeve Fifield	Consultant Rheumatologist	01733 676762
Dr Wiranthi Gunasekera	Consultant Rheumatologist	01733 676762
Dr Poonam Sharma	Consultant Rheumatologist	01733 676763
Dr John Pradeep	Consultant Rheumatologist	01733 676764
Rheumatology nurses	-	01733 676766

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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- 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](#).
- [eBNF](#) – accessed on 19.08.21.
- [UK Teratology Information Service. Use of sulfasalazine in pregnancy](#). Version 3 October 2020. Accessed on 19.08.21.
- [Best Use of Medicines in Pregnancy](#). Last updated September 2020, accessed on 18.08.21.
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- Menter, MD et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. [Guidelines of care for the management and treatment of psoriasis with traditional systemic agents](#). JAAD: 2009; 61: 3: 451-485. DOI:
- Briggs G. Drugs in Pregnancy and Lactation, Ninth Edition. Sulfasalazine Monograph

16. Other relevant national guidance

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- [Shared Care for Medicines Guidance – A Standard Approach \(RMOC\)](#).

- [NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care.](#)
- [General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care.](#)
- [NICE NG197: Shared decision making.](#) Last updated June 2021.

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.

To be agreed and completed locally

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

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.