Shared Care Agreement: Hydroxycarbamide for myeloproliferative disorders and sickle cell disease in adult services

This Shared Care Protocol sets out details for the sharing of care for patients prescribed Hydroxycarbamide for myeloproliferative disorders and sickle cell disease for patients within adult services. This protocol is for use within haematology, indications listed in section 2.

It should be read in conjunction with the latest Summary of Product Characteristics (SPC) available at www.medicines.org.uk/emc/.

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 primary care clinician 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.

Introduction

This shared care guideline sets out details to support the transfer of responsibility for prescribing hydroxycarbamide for any of the indications listed in section 2, from specialist to primary care. For further information please click on the links below:

British National Formulary

http://www.medicines.org.uk/emc/

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Cambridgeshire & Peterborough Integrated Care System

NHS Cambridgeshire & Peterborough

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The content of this shared care protocol was correct as of May 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. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- 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.
- Provide advice to primary care on the management of adverse effects if required.
- Advise patients on the need for highly effective contraception.

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. Acceptance will be assumed if no response was received within this time period.
- Check local formulary status and, 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 hydroxycarbamide 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 hydroxycarbamide and make an urgent referral to the specialist if bone marrow suppression is suspected.
- 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 hydroxycarbamide 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 prescriber and be aware they should discuss the use of hydroxycarbamide with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if hydroxycarbamide affects their ability to do so safely.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or primary care clinician immediately if they become pregnant or wish to become pregnant

1. Background

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Hydroxycarbamide is an oral cytoreductive agent used in the management of myeloproliferative neoplasms to control the blood count and reduce the incidence of vascular complications.

Hydroxycarbamide is also used to prevent acute chest syndrome, reduce the frequency of painful crises, and reduce transfusion requirements in sickle-cell disease. The beneficial effects of hydroxycarbamide may not become evident for several months.

Hydroxycarbamide is not licensed for all the conditions it is used to treat. However its use for the indications below is established and supported by various sources and bodies including the BNF, British Society for Haematology (BSH) and British Association of Dermatologists (BAD).

2. Indications

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The licensed indications for hydroxycarbamide include:

- Chronic myeloid leukaemia
- Essential thrombocythaemia
- Polycythaemia vera
- Sickle-cell disease (Siklos only)

This shared care protocol also includes the treatment of other myeloproliferative disorders and inflammatory conditions where off-label use of hydroxycarbamide is appropriate, including:

- Primary myelofibrosis‡
- Unclassified myeloproliferative disorders‡
- Psoriasis‡

‡ Off-label indications. (Please note licensed indications vary by manufacturer). The 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.

The local formulary status of hydroxycarbamide may vary. Before accepting this shared care primary care prescribers should ensure their local formulary supports the transfer of prescribing to primary care.

3. Locally agreed off-label use

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See above.

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 hydroxycarbamide or to any of the excipients in the preparation
- Severe bone marrow depression, leukocytopenia (less than 2.5 x 10^9/L), thrombocytopenia (less than 100 x 10^9 /L) or severe anaemia.

- Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
- Pregnancy and breastfeeding, or patients who are not using effective contraception during treatment
- Severe renal impairment in sickle cell disease (creatinine clearance [CrCl] less than 30mL/min)
- Severe hepatic impairment in sickle cell disease (Child-Pugh classification C)
- Concomitant treatment with first generation antiretroviral medicinal products for the treatment of HIV, including didanosine, stavudine, and indinavir.

Cautions:

- Live vaccines (e.g. oral typhoid, MMR, BCG, yellow fever) should be avoided in patients taking hydroxycarbamide.
- Renal Impairment
- Hepatic impairment
- Skin cancer has been reported in patients receiving long-term hydroxycarbamide. Patients should be advised to protect skin from sun exposure. In addition, patients should conduct self-inspection of the skin during the treatment and after discontinuation of hydroxycarbamide and be screened for secondary malignancies during routine follow-up visits.
- Secondary leukaemias have been reported in patients taking long-term hydroxycarbamide for myeloproliferative disorders
- Patients who have received irradiation therapy in the past may have an exacerbation of post irradiation erythema when hydroxycarbamide is given.
- Leg ulcers – review treatment if cutaneous vasculitic ulcerations develop
- Hydroxycarbamide treatment may increase serum uric acid concentrations and potentiate gout. Monitoring of uric acid level and maintaining a high fluid intake is recommended.
- Hydroxycarbamide causes macrocytosis, which may mask the incidental development of folic acid and vitamin B12 deficiency.

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.

Doses are based on real or ideal body weight whichever is less.

Initial stabilisation:

Chronic myeloid leukaemia: 20-40mg/kg daily then may be reduced to 20mg/kg daily and adjusted according to response. Alternatively, 80 mg/kg once every 3 days.
Essential thrombocythaemia: 15mg/kg daily adjusted according to response
Polycythaemia vera: 15-20mg/kg daily adjusted according to response
Sickle-cell disease: 15 mg/kg daily, increased in steps of 5 mg/kg daily, dose to be increased every 8-12 weeks according to response
The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Initial doses above are subsequently adjusted according to haematological response. The selected dose will be tailored to the individual patient and decided by the specialist.
In sickle-cell disease, the maintenance dose varies from 15-30mg/kg daily; max 35mg/kg daily
The initial maintenance period must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Lower doses may be required in elderly patients and should be considered in patients with renal impairment.
In patients with sickle cell disease and CrCl 60 mL/min or lower, the starting dose should be reduced by 50%.
If myelotoxicity occurs a dose reduction may be considered by the specialist.

6. Pharmaceutical aspects

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Route of administration:	Oral

Formulation:	Hydroxycarbamide 500mg capsules Hydroxycarbamide 100mg/ml oral solution (Xromi®) – only for patients who are unable to swallow or open and disperse capsules. • Hydroxycarbamide 100mg & 1000mg tablets - only preparation licensed for sickle cell disease. NB: tablet formulation is more expensive than other solid oral dosage forms.
Administration details:	Capsules should be swallowed whole. The manufacturer of the brand Hydrea® advises that for patients with swallowing difficulties, the contents of the capsules may be emptied into a glass of water and taken immediately. Capsule contents should not be inhaled or allowed to come into contact with skin or mucous membranes. Spillages must be wiped immediately. Hydroxycarbamide tablets, or the half or quarter of the tablet, should be taken once daily, preferably in the morning before breakfast and, when necessary, with a glass of water or a very small amount of food. For patients who are not able to swallow the tablets, these can be disintegrated *immediately before use* in a small quantity of water in a teaspoon. Adding a drop of syrup or mixing with food can mask a possible bitter taste. To assist accurate and consistent dose delivery to the stomach, water should be taken after each dose of hydroxycarbamide oral solution.
Other important information:	Hydroxycarbamide should be handled according to local procedures for handling and disposal of cytotoxic agents.

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.

- **Myelosuppressive agents or radiation therapy**: previous or concurrent use with hydroxycarbamide may increase the risk of bone marrow depression. See BNF for more information on specific drugs.

- **Antiretrovirals**: Hydroxycarbamide may potentiate side effects of nucleoside reverse transcriptase inhibitors such as hepatotoxicity, pancreatitis and peripheral neuropathy. Concomitant use should be avoided.
- **Laboratory monitoring**: Studies have shown that there is an analytical interference of hydroxycarbamide with the enzymes (urease, uricase, and lactic dehydrogenase) used in the determination of urea, uric acid and lactic acid, rendering falsely elevated results of these in patients treated with hydroxycarbamide. Caution is advised when interpreting these test results, for further guidance contact local laboratory services.
- ***Live vaccines***: There is an increased risk of severe or fatal infections with the concomitant use of live vaccines. Live vaccines are not recommended in immunosuppressed patients and should be avoided for at least six months after treatment with hydroxycarbamide has finished.
- ***Interference with Continuous Glucose Monitoring Systems***: Hydroxyurea may falsely elevate sensor glucose results from certain continuous glucose monitoring (CGM) systems. This may lead to missed hypoglycaemic episodes and can also cause hypoglycaemia if sensor glucose results are relied upon to dose insulin. If a patient using a CGM is to be prescribed hydroxyurea, consult with the CGM prescriber about appropriate glucose monitoring methods.

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:

- FBC
- Estimated glomerular filtration rate
- LFTs
- Uric acid
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- Screening for lung disease, including interstitial lung disease and 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)

Additional baseline investigations for patients with sickle-cell disease:

- Reticulocyte count

- Lactate dehydrogenase (LDH)
- Urea and electrolytes (U&Es)

Initial monitoring:
To be repeated weekly for 4 weeks, then every 2 weeks for 8 weeks:

- FBC

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 • Glomerular filtration rate • LFTs • Uric Acid Additional for sickle cell disease: • U&Es • Reticulocyte count (for sickle-cell disease patients)	Every 8-12 weeks **The exact frequency of monitoring to be communicated by the specialist in all cases**.
• Patients aged 60-79 years old could be eligible for the shingles vaccine (herpes zoster). For patients taking hydroxycarbamide and/or doses of prednisolone exceeding 20mg daily, a non-live vaccine should be used. Specialist	• Shingles vaccination: single course • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. Other vaccinations as per national schedule.

input may be required. Refer to Green Book Chapter 6 (Contraindications and special considerations) and Green Book Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended. • COVID-19 vaccination (The Green Book, Chapter 14a) is safe and recommended. • Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	

(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

Results	Action for primary care

Full blood count: • White blood cells less than $2.5x10^9$/L • Neutrophils less than $1.5x10^9$/L • Platelets less than $80x10^9$/L • Reticulocytes less than $80x10^9$/L (if haemoglobin greater than 90g/l) Haemoglobin less than 45g/L (sickle cell patients only) or dropped by over 30g/L from baseline	Contact specialist team urgently for advice, and withhold only on advice of a specialist.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat or mouth ulcers	Check FBC immediately and discuss with the specialist team. Only withhold on the advice of a specialist. See haematological monitoring above.
Renal function Serum creatinine greater than 2x upper limit of normal (ULN) or serial rise over a number of visits.	discuss urgently with specialist team and only withhold on the advice of a specialist.
Liver function tests: ALT or AST greater than 3x ULN	discuss urgently with specialist team and only withhold on the advice of a specialist.
Leg ulcers or cutaneous vasculitic ulcerations	discuss urgently with specialist team and only withhold on the advice of a specialist.
GI disturbances including; nausea, vomiting or diarrhoea	Review for reversible causes. Discuss with specialist team if persistent or severe.
Alopecia, skin rash, or hyperpigmentation of nails.	Stop if patient requests and discuss with specialist

Development of gout symptoms	Monitor uric acid levels regularly, but be aware that hydroxycarbamide may affect results. Advise patient to maintain a high fluid intake during treatment. Treat symptoms appropriately. Discuss with specialist for advice if required.

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:

- Signs or symptoms indicating haematological toxicity, e.g. sore throat, mouth ulcers, infection, unexplained or abnormal bruising or bleeding.
- Signs or symptoms of hepatic toxicity e.g. jaundice
- Symptoms of chickenpox, or contact with a person with chickenpox or shingles.
- Suspected or confirmed pregnancy.

The patient should be advised:

- To drink plenty of fluids to reduce the risk of gout symptoms.
- Tell anyone who prescribes them a medicine that they are taking hydroxycarbamide. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- To wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine to protect the skin from sun exposure. 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.
- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or primary care clinician immediately if they become pregnant. All patients, both male and female, should inform their specialist well in advance if they are planning a pregnancy so that changes can be made to their treatment regime.

- That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.

Patient information:
https://www.mpnvoice.org.uk/about-mpns/treatments/hydroxycarbamide/

https://www.macmillan.org.uk/cancer-information-and-support/treatments-and-drugs/hydroxycarbamide

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.

Pregnancy:
Hydroxycarbamide is contraindicated in pregnancy. It is recommended that patients of childbearing potential use effective contraception before starting and during treatment with hydroxycarbamide.

***Breastfeeding*:**
Hydroxycarbamide is excreted in human milk. Due to the potential for serious adverse effects in infants, breastfeeding should be discontinued during hydroxycarbamide treatment.
Information for healthcare professionals: https://www.sps.nhs.uk/medicines/hydroxycarbamide/

Paternal exposure:

Men are advised to use effective contraception during and for at least 3 months after therapy. They should be informed about the possibility of sperm conservation before the start of therapy. Fertility in males might be affected by treatment. Reversible oligo- and azoospermia are very commonly observed.

13. Specialist contact information

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Cambridge University Hospitals NHS Foundation Trust

Name	Role	Contact details
Dr Anna Godfrey	Consultant Haematologist	01223 216616
Phyllis Paterson	Clinical Nurse Specialist	01223 596279
Medicines Information helpline for patients		01223 217502

North West Anglia NHS Foundation Trust

Role	Contact details
Clinical Nurse Specialist	01490 847532
Haematologist on call (Hinchingbrooke)	01480 416416 (bleep 2268)
Haematologist on call (Peterborough)	01733 678000 (bleep 1876)

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 primary care clinician or their contact details.

15. References

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- Hydroxycarbamide medac 500mg capsules. Medac GMbH. Date of revision of the text: August 2019. Accessed via https://www.medicines.org.uk/emc/product/254/smpc on 06/10/2021.
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- British Society for Haematology. 2019. A guideline for the diagnosis and management of

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- Specialist Pharmacy Service. Lactation Safety Information: hydroxycarbamide. Reviewed September 2020. Accessed via https://www.sps.nhs.uk/medicines/hydroxycarbamide/ on 06/10/2021.

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.

If there are any concerns in relation to the patient or their condition changes, primary care prescribers should contact the relevant initiating specialist using the **Specialist contact information** detailed above.

Specialist teams should contact primary care prescribers via the usual communication routes agreed 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
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. Acceptance will be assumed if no response is received within 14 days.