



Classification: Official

Publication approval reference: PAR1621\_xi

National shared care protocol:

# Hydroxycarbamide for myeloproliferative disorders and sickle cell disease for patients within adult services

4 July 2022, Version 1

Review date: January 2025

Document Control		
Date	Version	Action
14/05/2024	V1	New national shared care protocol adapted by NCL. Contact details from NCL Clinical team added. Document control and sign-off boxes included.

Groups / Individuals who have overseen the development of this guidance:	NHSE and SPS
Groups which were consulted and have given approval:	NCL Shared Care Group NCL ICB NCL Provider Trusts
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Available on:	<a href="https://nclhealthandcare.org.uk/our-working-areas/medicines-optimisation/shared-care-guidelines-and-factsheets/">https://nclhealthandcare.org.uk/our-working-areas/medicines-optimisation/shared-care-guidelines-and-factsheets/</a>
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**The content of this shared care protocol was correct as of January 2022. As well these protocols, please ensure that [summaries of product characteristics](#) (SPCs), [British national formulary](#) (BNF) or the [Medicines and Healthcare products Regulatory Agency](#) (MHRA) or [NICE](#) websites are reviewed for up-to-date information on any medicine.**



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## 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.

## 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.
- 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 GP 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

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<sup>‡</sup>
- Unclassified myeloproliferative disorders<sup>‡</sup>
- Psoriasis<sup>‡</sup>

<sup>‡</sup> 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. 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  $2.5 \times 10^9/L$ ), thrombocytopenia (less than  $100 \times 10^9/L$ ) 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.

## **4. 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 initial dose may be lower in elderly patients.

**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.

## 5. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	<p>Hydroxycarbamide 500mg capsules</p> <p>Hydroxycarbamide 100mg/ml oral solution (Xromi®) – only for patients who are unable to swallow or open and disperse capsules.</p> <ul style="list-style-type: none"> <li>Hydroxycarbamide 100mg &amp; 1000mg tablets - only preparation licensed for sickle cell disease. NB: tablet formulation is more expensive than other solid oral dosage forms.</li> </ul>
Administration details:	<p>Capsules should be swallowed whole.</p> <p>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.</p> <p>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.</p>

	<p>For patients who are not able to swallow the tablets, these can be disintegrated <u>immediately before use</u> in a small quantity of water in a teaspoon. Adding a drop of syrup or mixing with food can mask a possible bitter taste.</p> <p>To assist accurate and consistent dose delivery to the stomach, water should be taken after each dose of hydroxycarbamide oral solution.</p>
Other important information:	Hydroxycarbamide should be handled according to local procedures for handling and disposal of cytotoxic agents.

## 6. 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.



## 7. 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
- Urea and electrolytes (U&Es)
- LFTs
- 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

### Initial monitoring:

To be repeated every 2 weeks until dose has been optimised and all test results are stable (minimum of 8 weeks).

- FBC
- U&Es
- LFTs
- Reticulocyte count (sickle cell disease only)

### 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.



## 8. 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
<ul style="list-style-type: none"> <li>FBC</li> <li>U&amp;Es</li> <li>LFTs</li> <li>Reticulocyte count (for sickle-cell disease patients)</li> </ul>	<p>Every 8-12 weeks</p> <p><b>The exact frequency of monitoring to be communicated by the specialist in all cases.</b></p>
<ul style="list-style-type: none"> <li>Patients aged 70-79 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 input may be required. Refer to <a href="#">Green Book Chapter 6 (Contraindications and special considerations)</a> and <a href="#">Green Book Chapter 28a (Shingles)</a> for further details.</li> <li><b>Annual</b> influenza (<a href="#">The Green Book, Chapter 19</a>) vaccinations are recommended.</li> <li>COVID-19 vaccination (<a href="#">The Green Book, Chapter 14a</a>) is safe and recommended.</li> <li>Repeat pneumococcal vaccine may be indicated. See <a href="#">Green Book Chapter 25</a> for advice.</li> </ul>	<ul style="list-style-type: none"> <li>Shingles vaccination: single course</li> <li>Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.</li> </ul> <p>Other vaccinations as per national schedule.</p>

**(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.**

## 9. 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](http://www.mhra.gov.uk/yellowcard)**

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

Result	Action for primary care
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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	
<b>Full blood count:</b> <ul style="list-style-type: none"> <li>White blood cells less than <math>2.5 \times 10^9/L</math></li> <li>Neutrophils less than <math>1.5 \times 10^9/L</math></li> <li>Platelets less than <math>80 \times 10^9/L</math></li> <li>Reticulocytes less than <math>80 \times 10^9/L</math> (if haemoglobin greater than <math>90g/l</math>)</li> <li>Haemoglobin less than <math>45g/L</math> (sickle cell patients only) or dropped by over <math>30g/L</math> from baseline</li> </ul>	Consider withholding and discuss urgently with specialist team.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat or mouth ulcers	Consider withholding. Check FBC immediately and discuss with the specialist team. See haematological monitoring above.
<b>Renal function</b> Serum creatinine greater than 2x upper limit of normal (ULN) or serial rise over a number of visits.	Consider withholding and discuss urgently with specialist team
<b>Liver function tests:</b> ALT or AST greater than 3x ULN	Consider withholding and discuss urgently with specialist team
Leg ulcers or cutaneous vasculitic ulcerations	Consider withholding and discuss urgently with specialist team
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.

## 10. 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 GP 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>

## **11. 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.

## 12. Specialist contact information

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### UCLH:

Leukaemia and MPN queries: [uclh.leukaemiacns@nhs.net](mailto:uclh.leukaemiacns@nhs.net)

Red cell queries: [uclh.redcell.cnsteam@nhs.net](mailto:uclh.redcell.cnsteam@nhs.net)

Haematology helpline (Monday – Friday 9am-5pm): 02034477359

Out of hours contact details: 07852220900

## 13. 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.

## 14. References

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- eBNF accessed via <https://bnf.nice.org.uk/drug/hydroxycarbamide.html> on 06/10/2021.
- 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. 2018. Guidelines for the use of hydroxycarbamide in children and adults with sickle cell disease. Accessed via <https://b-s-h.org.uk/guidelines/guidelines/guidelines-for-the-use-of-hydroxycarbamide-in-children-and-adults-with-sickle-cell-disease/> on 06/10/2021.
- British Society for Haematology. 2019. A guideline for the diagnosis and management of
- Polycythaemia vera. Accessed via <https://b-s-h.org.uk/guidelines/guidelines/diagnosis-and->

[management-of-polycythaemia-vera/](#) on 06/10/2021

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

## 15. 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/>

## 16. 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**

APC board date:  
Last updated:

## 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.



## 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/or address]*

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/or address]*

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

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

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

		Tick which apply
1.	<p><b>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</b></p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. 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.</p> <p><b>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.</b></p>	
2.	<p><b>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</b></p> <p>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.</p> <p><b>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</b></p>	

3.	<p><b>A minimum duration of supply by the initiating clinician</b></p> <p>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.</p> <p><b><i>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</i></b></p>	
4.	<p><b>Initiation and optimisation by the initiating specialist</b></p> <p>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.</p> <p><b><i>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</i></b></p>	
5.	<p><b>Shared Care Protocol not received</b></p> <p>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.</p> <p>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.</p> <p><b><i>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</i></b></p>	
6.	<p><b>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)</b></p>	

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

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

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

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

Yours sincerely

**Primary Care Prescriber signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Primary Care Prescriber address/practice stamp**