

Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline

V4.0

April 2022

1. Aim/Purpose of this Guideline

- 1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of hydroxycarbamide when used in myeloproliferative disorders.
- 1.2. Treatment of adults with hydroxycarbamide (also known as hydroxyurea) for myeloproliferative disorders (Essential Thrombocythemia, Polycythemia Rubra Vera and Myelofibrosis). These patients will normally be managed and monitored by the Haematology department but may obtain repeat prescriptions for hydroxycarbamide from their General Practitioner.
- 1.3. This shared care guideline sets out details for the sharing of care of patients with myeloproliferative disorders prescribed hydroxycarbamide. These guidelines provide additional limited information necessary to aid in the treatment these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.
- 1.4. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

- 2.1. Some patients may be managed by a (hospital) nurse-led telephone dosing service. Patients are referred by their haematology consultant when their condition is stable. Instead of attending the haematology clinic several times a year, patients will be given forms to have an FBC at their GP surgery. They will then be telephoned by the nurse to advise them on the dose to be taken. Supplies of hydroxycarbamide will either be dispensed by the pharmacy and sent to the surgery for patients to collect, or patients may have a repeat prescription issued by their GP. A letter will be sent from the haematology clinic to the GP after each telephone consultation. Patients who are managed by the telephone service will normally attend the haematology clinic annually for consultant review and assessment of organomegaly.

2.2. Preparations and Dosage

Hydroxycarbamide is prescribed as a 500mg capsule (NOT the tablet formulation). The dose will be adjusted based on the full blood count. A usual starting dose may be 500mg-1g daily. The patient will have received at least 4-6 month's treatment, been shown to respond to the treatment and the dosage stabilised before being considered for transfer to the nurse-led telephone dosing service.

2.3. Contraindications and Precautions

- 2.3.1. Patients should not breastfeed whilst receiving hydroxycarbamide. Live vaccines should be avoided by patients receiving hydroxycarbamide. Female patients must be advised not to conceive whilst receiving hydroxycarbamide. A reliable form of contraception should be used by men and women whilst on hydroxycarbamide and for at least 3 months afterwards.
- 2.3.2. Hydroxycarbamide contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.
- 2.3.3. Hydroxycarbamide should be used with caution in patients with:
 - Myelosuppression (reduced dose may be required)
 - Renal impairment (reduced dose may be required).
 - Skin ulceration.

2.4. Monitoring

For patients commencing hydroxycarbamide regular FBC will be checked (usually in the RCHT Haematology clinic) e.g. weekly, until on a stable dosage. Monitoring frequency will then reduce to 3-4 monthly. After a change in dose a repeat FBC should be checked after 4-8 weeks. Monitoring carried out at the request of the haematology team will be acted upon by them. If there are any GP concerns about blood counts done at other times the haematology team should be contacted for advice. NB It is normal for a patient taking hydroxycarbamide to have a raised MCV.

2.5. Side Effects

- 2.5.1. Any patient who presents with skin ulceration or severe mouth ulcers should have hydroxycarbamide stopped immediately and the haematology team be notified.
- 2.5.2. Bone-marrow suppression is the major serious side effect of hydroxycarbamide, including leucopenia, thrombocytopenia and anaemia. Patients must report sore throat, fever, epistaxis, unexpected bruising or bleeding and any unexplained illness/infection. They should be seen urgently and full blood count checked.

2.5.3. Due to the possibility of increased serum uric acid levels, patients should be instructed to maintain a high fluid intake.

2.5.4. Other side effects are rare but can include

- Anorexia, nausea, vomiting, diarrhoea, constipation, abdominal pain
- Headache, drowsiness, dizziness, disorientation
- Alopecia, skin rash

2.6. Significant Drug Interactions

Not to be used in combination with antiretroviral treatments for HIV. Treatment failure and fatal toxicities have been seen in HIV patients

2.7. Handling and Disposal

The contents of capsules should not be inhaled or allowed to come into contact with the skin or mucous membranes. Spillages must be wiped immediately. Capsules should only be handled by the patient taking them.

2.8. References:

Summaries of Product Characteristics

2.9. Areas of Responsibility for the Sharing of Care

2.9.1. These are suggested ways in which the responsibilities for the management of adult patients with who are prescribed **hydroxycarbamide** can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

2.9.2. In the NHS E guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

2.9.3. Referral criteria

- A full diagnostic assessment will have taken place under the specialist's care.

- The patient will have received two to three months of treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

2.9.4. **Specialist:**

- Decision to start treatment.
- Discussion with the patient regarding the benefits and side effects of treatment and gain consent to treatment. Refer patient to specialist nurse service where appropriate (e.g. new patient) for advice on taking/administering the drug, its cautions, side effects associated with treatment, monitoring requirements and the timing of reassessment and by whom.
- Start drug treatment by providing the first prescription and ensuring the patient's condition is stabilised (usually requires 2-3 months treatment prescribed by the specialist).
- Ask the GP whether they are willing to participate in shared care using the suggested wording template (Appendix 3).
- Conducting baseline tests (FBC, LFTs, U&Es) and reviewing results of ongoing monitoring (FBC).
- Prompt communication with GP of any changes in treatment, results of monitoring undertaken and assessment of adverse events.
- Specify review dates at clinically relevant time intervals for both the GP and the consultant.
- Ensure clear arrangements for back-up advice and support.
- Reporting adverse events to the MHRA.

2.9.5. **General Practitioner:**

- To respond to the shared care request from the consultant in writing without undue delay.
- The general practitioner will prescribe the medicine in consultation with, and receiving advice from, the specialist service. Repeat prescriptions should be issued for a maximum of one month's treatment.
- Monitoring the patient's overall health and well-being, conducting ongoing monitoring (FBC) and checking and acting upon the results communicated by the specialist.
- Adverse drug reaction / interaction monitoring.
- Inform the Specialist team if treatment is stopped for any reason.

2.9.6. Patient / parent / guardian / carer:

- Report any adverse effects to their GP and/or specialist.
- Ensure they attend for monitoring requirements as per shared care guideline.
- Safe storage of the hydroxycarbamide in the home.

2.9.7. BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM:

2.9.7.1. In office hours:

- **On call consultant haematologist 01872 252501 or via RCH switchboard 01872 250000**
- **Haematology Clinical Nurse Specialists 07824 866491**
- **Pharmacy Cancer Team 07876 217568**

2.9.7.2. Out of hours:

- **On call consultant haematologist via RCH switchboard 01872 250000**
- **On call pharmacist via RCH switchboard 01872 250000** Equality and Diversity

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process on a Word or Excel template specific to the topic.
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Inclusion & Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline V4.0
This document replaces (exact title of previous version):	Hydroxycarbamide for myeloproliferative disorders shared care guideline V3.2
Date Issued/Approved:	23 March 2022
Date Valid From:	April 2022
Date Valid To:	April 2025
Directorate / Department responsible (author/owner):	Cancer Team / Pharmacy - Head of Prescribing Support Unit
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists
Suggested Keywords:	Hydroxycarbamide
Target Audience:	RCHT: Yes CFT: No KCCG: No
Executive Director responsible for Policy:	Medical Director
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None
Related Documents:	None
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
21 Nov' 2012	V1.0	Original document	M Wilcock, Head of Prescribing Support Unit
Nov 2015	V2.0	Minor text alterations	M Wilcock, Head of Prescribing Support Unit
Nov 2018	V3.0	New format and slight text amendments to 2.9 and inclusion of shared care agreement letter	M Wilcock, Head of Prescribing Support Unit
March 2020	V3.1	Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request	Demi Louise Kent, Corporate Records Manager
Sept 2021	V3.2	Replacement of shared care agreement letter with suggested wording template instead (Appendix 3)	M Wilcock, Head of Prescribing Support Unit
March 2022	V4.0	Minor text amendment 2.3.2 and 2.4	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity & Inclusion Team richt.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline V4.0
Directorate and service area:	Pharmacy, Clinical Support
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01726 627953

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of hydroxycarbamide to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	<ul style="list-style-type: none"> • Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Cornwall Area Prescribing Committee
6c. What was the outcome of the consultation?	Agreed
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys: No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dan Thomas,
Pharmaceutical Services Contracting Team, NHS Kernow

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:

[Section 2. Full Equality Analysis](#)

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.