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Royal Cornwall Hospitals NHS Trust

# Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline

## V3.0

## February 2019

# 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. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 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 can't rely on Opt out, it must be Opt in.

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team 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

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.

2.3.1. 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 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

Any patient who presents with skin ulceration or severe mouth ulcers should have hydroxycarbamide stopped immediately and the haematology team be notified.
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.

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

2.5.2. 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 shared care agreement letter.
- 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:**

- If the GP disagrees to undertake shared care he/she will notify the consultant in writing without undue delay by completing the shared care agreement letter
- 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:**

- Sign the shared care agreement letter
- 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**

# 3. Monitoring compliance and effectiveness

| | |
|---|---|
| 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 | No specific tool |
| 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

| | | | |
|---|---|---|---|
| **Document Title** | Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline V3.0 | | |
| **Date Issued/Approved:** | November 2018 | | |
| **Date Valid From:** | February 2019 | | |
| **Date Valid To:** | February 2022 | | |
| **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 | CFT | KCCG |
| | ✓ | | ✓ |
| **Executive Director responsible for Policy:** | Care Group General Manager | | |
| **Date revised:** | Nov 2018 | | |
| **This document replaces (exact title of previous version):** | Hydroxycarbamide for myeloproliferative disorders shared care guideline | | |
| **Approval route (names of committees)/consultation:** | Cornwall Area Prescribing Committee | | |
| **Divisional Manager confirming approval processes** | Karen Jarvill | | |
| **Name and Post Title of additional signatories** | Not required | | |
| **Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings** | {Original Copy Signed} | | |
| | Name: Kevin Wright | | |
| **Signature of Executive Director giving approval** | {Original Copy Signed} | | |

| | | | | |
|---|---|---|---|---|
| **Publication Location (refer to Policy on Policies – Approvals and Ratification):** | Internet & Intranet | ✓ | Intranet Only | |
| **Document Library Folder/Sub Folder** | Pharmacy | | | |
| **Links to key external standards** | | | | |
| **Related Documents:** | | | | |
| **Training Need Identified?** | No | | | |

**Version Control Table**

| Date | Version No | Summary of Changes | Changes Made by *(Name and Job Title)* |
|---|---|---|---|
| 21 Nov' 2012 | V1.0 | Original document | M Wilcock, Head of Prescribing Support Unit |
| Nov 2015 | V 2.0 | 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 |
| | | | |
| | | | |

**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. Initial Equality Impact Assessment Form

***This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.***

<table>
<tr><td colspan="6">Hydroxycarbamide for Myeloproliferative Disorders Shared Care Guideline V3.0</td></tr>
<tr><td colspan="3">Directorate and service area: Pharmacy</td><td colspan="3">Is this a new or existing Policy?<br>Existing</td></tr>
<tr><td colspan="3">Name of individual completing assessment:<br>Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow</td><td colspan="3">Telephone:<br>01726 627953</td></tr>
<tr><td>1. Policy Aim*<br><br>Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">To provide information on prescribing of hydroxycarbamide to enable General Practitioners to take over prescribing responsibility from secondary care.</td></tr>
<tr><td>2. Policy Objectives*</td><td colspan="5">To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)</td></tr>
<tr><td>3. Policy – intended Outcomes*</td><td colspan="5">Confident and competent prescribers, enabling medicines to be access in a primary care setting.</td></tr>
<tr><td>4. *How will you measure the outcome?</td><td colspan="5">Six monthly review</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">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.</td></tr>
<tr><td rowspan="3">6a Who did you consult with<br><br>b). Please identify the groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td>X</td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups<br>Cornwall Area Prescribing Committee</td></tr>
<tr><td>What was the outcome of the consultation?</td><td colspan="5">Agreed</td></tr>
</table>

**7. The Impact**
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have differential impact on:

| Equality Strands: | Yes | No | Unsure | Rationale for Assessment / Existing Evidence |
|---|---|---|---|---|
| **Age** | | **X** | | |
| **Sex** (male, female, trans-gender / gender reassignment) | | **X** | | |
| **Race / Ethnic communities /groups** | | **X** | | |
| **Disability -** Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions. | | **X** | | |
| **Religion / other beliefs** | | **X** | | |
| **Marriage and Civil partnership** | | **X** | | |
| **Pregnancy and maternity** | | **X** | | |
| **Sexual Orientation,** Bisexual, Gay, heterosexual, Lesbian | | **X** | | |

**You will need to continue to a full Equality Impact Assessment if the following have been highlighted:**

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major this relates to service redesign or development

| 8. Please indicate if a full equality analysis is recommended. | **Yes** | | **No X** | |
|---|---|---|---|---|

9. If you are **not** recommending a Full Impact assessment please explain why.

Not indicated.

| Signature of policy developer / lead manager / director | | Date of completion and submission |
|---|---|---|
| M Wilcock | | Nov 2018 |
| Names and signatures of members carrying out the Screening Assessment | 1. M Wilcock<br>2. Human Rights, Equality & Inclusion Lead |  |

**Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead**
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

**This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.**

A summary of the results will be published on the Trust's web site.

Signed M Wilcock

Date 28/11/18