

## Hydroxycarbamide Shared Care Guideline

### Introduction

<p><b>General Statements</b></p>	<ul style="list-style-type: none"> <li>• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and GP</li> <li>• The GP must reply in writing to the request for shared care as soon as practicable if <u>unwilling</u> to participate.</li> <li>• The responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and GP notes</li> <li>• The agreement to consider the use of a shared care guideline is only considered when the patient's clinical condition is stable or predictable</li> </ul>
<p><b>Indication</b></p>	<ul style="list-style-type: none"> <li>• Hydroxycarbamide (Medac<sup>®</sup> brand) is licensed to treat Chronic Myeloid Leukaemia (CML). It will also be used, off license, within this shared care guideline to treat chronic myelo-proliferative disorders (CMPD), chronic myelomonocytic leukaemia (CMML), and atypical CML.</li> <li>• Hydroxycarbamide (Siklos<sup>®</sup> brand) is licenced to treat sickle cell disease</li> </ul>

### Individuals Responsibilities

<p><b>Hospital Specialist's Responsibilities</b></p>	<ul style="list-style-type: none"> <li>• Ask the GP whether he or she is willing to participate in shared care.</li> <li>• Diagnose MPD and initiate treatment after discussion with patient of benefits/side effects.</li> <li>• Obtain baseline FBC, U&amp;E's, LFT's and folic acid levels. To continue to monitor in haematology clinic until CMPD is well controlled and stable.</li> <li>• Assess and monitor patient's response to treatment, make dosage adjustments and inform the GP of dosing schedule, monitoring measurements and progress of treatment after each appointment.</li> <li>• Provide the patient with information about CMPD, CMML, sickle cell disease and atypical CML (available from: <a href="http://www.leukaemialymphomaresearch.org.uk">www.leukaemialymphomaresearch.org.uk</a>.)</li> </ul>
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- Explain the risks and benefits associated with hydroxycarbamide therapy, including the requirement for continued blood monitoring and the action to be taken in the event of adverse events – particularly any unexplained bleeding, bruising, purpura (or other skin changes), sore throat, fever or malaise.
- Ensure that patients who fail to attend the hospital clinic or otherwise fail to supply a blood sample at the GP are contacted in order to try to arrange this, and reinforce the importance of monitoring. Should the specialist decide that it is unsafe for treatment to continue due to lack of monitoring this will be communicated by letter to the GP.
- Patients who are stabilised on treatment may also be contacted by the hospital haematology clinical nurse specialist and may undergo a telephone appointment/consultation. GP's will be informed of the telephone consultation frequency.
- The process for telephone appointments is as follows:
  - An appointment letter is sent out to the patient with a blood form attached.
  - The patient then books an appointment with the phlebotomist at the GP surgery or comes to the hospital for bloods taking.
  - The Clinical Nurse Specialist (CNS) rings the patient at the stipulated appointment time and discusses the blood results with the patient and if necessary will adjust the dose.
  - A letter will be faxed to the GP and a copy sent to the patient detailing the conversation and the dose.
  - The G.P. practice will be contacted to confirm receipt of the fax.
- The process for patients who attend hospital appointments is as follows:
  - Patients have their bloods done in the hospital and are reviewed in the clinic.
  - A letter will be faxed to the GP and a copy sent to the patient detailing the conversation and the dose.
  - The G.P practice will be contacted to confirm receipt of the fax.
- If there are any changes to the dosage of hydroxycarbamide at any point in a patient's treatment, these changes will be communicated to the GP by fax within 24 so that the GP can amend their records in time for the patient's next supply of hydroxycarbamide. The G.P. practice will be contacted to confirm receipt of the fax.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.

## Hydroxycarbamide Shared Care Guideline

	<ul style="list-style-type: none"> <li>Report adverse events to MHRA, as per the Yellow Card Scheme</li> </ul>
<b>General Practitioner's Responsibilities</b>	<ul style="list-style-type: none"> <li>Prescribe hydroxycarbamide as per the written dosage supplied by the hospital specialist after stabilisation in secondary care.</li> <li>Acknowledge receipt of faxes sent from Hospital specialists detailing doses or dosage changes of hydroxycarbamide.</li> <li>Arrange for blood samples to be taken as per hospital specialist's request (see "Hospital Specialists Responsibilities" above). All interpretation and monitoring of blood results will occur in hospital setting.</li> <li>Monitor the patient's overall health and well being.</li> <li>Monitor side effects of treatment, and seek urgent advice as necessary.</li> <li>To check for possible drug interactions when newly prescribing or stopping concurrent medications.</li> <li>Ensure that the patient requesting a repeat prescription has been reviewed by the hospital specialist; i.e. there is a recent clinic letter.</li> <li>Stop treatment promptly if advised by specialist.</li> <li>Report to and seek advice from the Consultant Haematologist if any aspects of patient care are of concern to the GP or are affecting treatment.</li> <li>Report adverse events to MHRA, as per the Yellow Card Scheme</li> </ul>

### Product Information

<b>Dosage</b>	<p>Treatment regimens can be continuous or intermittent. An adequate trial period for determining the antineoplastic effect of hydroxycarbamide is <b>six weeks</b>. Therapy is continued indefinitely where there is a significant clinical response, provided that the patient is adequately monitored.</p> <p><b>Dose is determined by the haematology specialist based on the FBC.</b></p>
<b>Monitoring</b>	<p>Monitoring will be individualised to each patient.</p> <p>This will be advised by the Hospital Specialist</p>

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<p><b>Adverse Effects</b></p>	<p><b>Common (1-10%):</b> Bone marrow depression, leucopenia, megaloblastosis, diarrhoea, constipation.</p> <p><b>Uncommon (0.1-1%):</b> Thrombocytopenia, anaemia, nausea, vomiting, anorexia, stomatitis. Drug fever, chills, malaise, maculopapular rash, facial erythema, erythema affecting peripheral parts, elevation of liver enzymes, bilirubin and transient impairment of the renal tubular function (accompanied by elevation in serum uric acid, urea and creatinine).</p> <p><b>Very rare (&lt; 0.0001%):</b> Hydroxycarbamide can induce painful leg ulcers which are usually difficult to treat. <b>Stop Drug and discuss</b> (the ulcers usually resolve over some weeks).</p> <p>Patients who develop mouth or leg ulcers need to be monitored very closely. If lesions worsen or do not improve within 7 days then the treatment may need to be withheld temporarily. In all cases the management should be discussed with the Consultant Haematologist on-call.</p>
<p><b>Precautions and Contra-indications</b></p>	<p><b>Precautions</b> If neutrophils <math>&lt; 2 \times 10^9/L</math> or platelet count <math>&lt; 100 \times 10^9/L</math>, therapy should be interrupted. Counts should be rechecked after 3 days and treatment resumed when they rise significantly towards normal.</p> <p>If severe anaemia present when hydroxycarbamide is to be commenced, then anaemia requires urgent intervention first. If, during treatment, anaemia occurs, correct without interrupting Hydroxycarbamide therapy (but a reduction in dose may be necessary).</p> <p>Erythrocytic abnormalities; (raised MCV) megaloblastic erythropoiesis, which is self-limiting, is often seen early in the course of hydroxycarbamide therapy. The morphologic change resembles pernicious anaemia, but is not related to vitamin B12 or folic acid deficiency.</p> <p>Hydroxycarbamide should be used with caution in patients with marked renal dysfunction.</p> <p>Hydroxycarbamide is not licensed for use in combination with antiretroviral agents for HIV disease and it may cause treatment failure and toxicities (in some cases fatal) in HIV patients.</p> <p><b>Contra-indications</b></p> <ul style="list-style-type: none"> <li>• Marked leucopenia (WCC <math>&lt; 2.5 \times 10^9/L</math>),</li> <li>• Thrombocytopenia (Platelets <math>&lt; 100 \times 10^9/L</math>),</li> <li>• Severe anaemia</li> </ul>

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	<ul style="list-style-type: none"> <li>• Those who have previously shown hypersensitivity to Hydroxycarbamide.</li> <li>• Live vaccines must be avoided during treatment and for at least six months after treatment has stopped. Examples of live vaccines could include oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster – for full details check the latest SPC before administration</li> </ul>
<b>Clinically relevant Drug Interactions and their management</b>	<ul style="list-style-type: none"> <li>• Hydroxycarbamide may delay plasma iron clearance and decrease rate of iron utilization by erythrocytes but it does not appear to alter the red blood cell survival time.</li> <li>• Hydroxycarbamide should not be given during pregnancy or lactation.</li> <li>• Hydroxycarbamide + Clozapine – increased risk of agranulocytosis.</li> <li>• Hydroxycarbamide + Didanosine and stavudine – enhanced side effects (pancreatitis &amp; peripheral neuropathy).</li> </ul> <p>Refer to the current BNF and <a href="http://www.medicines.org.uk/emc/">www.medicines.org.uk/emc/</a> for complete and up to date information</p>
<b>Contact Details</b>	Telephone numbers, bleep, email, fax numbers, out of hours and Contact details of haematology team will be included in the specialists' letter.
<b>The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics</b>	