**Request to Share Care and Agreement Form**

**Shared Care Protocol: Hydroxycarbamide for patients within adult services**

**Guideline No 9; Version 1.1**

**This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 6 onwards).**

**GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 5.**

**For Completion by Specialist (with page 5 Shared Care Agreement Form)**

Addressograph label

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| **Patient name** |  |  |
| **DOB** |  | **OR** |
| **NHS number** |  |  |

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| **Drug(s) Dose and Route at handover:** |  |
| **Indication:** |  |
| **Date of first prescription by specialist:** |  |
| **Estimated date for prescribing to be continued by the GP:** |  |
| **Next monitoring tests due and dates if not at 12 weekly monitoring:** |  |
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| **Total monitoring period:** |  |

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| **Key Primary Care Information (refer to Full Shared Care Protocol for further information)**  **GP RESPONSIBILITIES**   * Consider request to shared care arrangements and prompt completion. Email return of signed response to the specialist using the Shared Care Agreement Form **within 14 days** of its receipt * If shared care accepted, prescribe hydroxycarbamide for stable patients in line with protocol and consider any drug interactions. * Prescribe medication until the patients next blood tests. This should not be longer than 3 months, unless specified by the specialist team. * Conduct monitoring as outlined and communicate any abnormal blood results to the specialist. * Liaise with the specialist if there are delays in receiving clinic letters by the time the patient’s blood tests are scheduled. * Adjust the doses of hydroxycarbamide as advised by the specialist. * Help patients manage with hydroxycarbamide related adverse effects and refer to specialists if required. Report adverse events via the yellow card scheme to the MHRA. * Liaise with and follow specialist advice if patients miss an appointment or blood test. * 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.  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **MONITORING AND ACTIONS TO BE TAKEN**  **Monitoring Table**  Monitoring at baseline and during initiation is the responsibility of the specialist. Care should only be transferred once the patient is optimised on hydroxycarbamide with no anticipated further changes expected in the immediate future.  *Baseline investigations:*   * FBC * Urea and electrolytes (U&Es) * Liver function tests (LFTs) * Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus should be undertaken at clinical discretion on a case-by-case basis * Screening for lung disease, including interstitial lung disease and tuberculosis, should be undertaken at clinical discretion on a case-by-case basis * Appropriate vaccinations, including pneumococcal, influenza, shingles and COVID-19, are recommended prior to treatment initiation   *Initial monitoring:*  Repeat every 2 weeks (or as indicated by specialist) until dosage is optimised and all test results are stable (minimum of 12 weeks).   * FBC * Urea and electrolytes (U&Es) * Liver function tests (LFTs)   *Ongoing monitoring:*  The specialist will retain responsibility for monitoring the patient’s ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. After each review, primary care should be advised whether treatment cessation is appropriate.   |  |  | | --- | --- | | **Monitoring and advice** | **Frequency** | | * FBC * U&Es * LFTs | Every 8-12 weeks  **The exact frequency of monitoring to be communicated by the specialist in all cases**. | | * Patients aged 65-79 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 [Green Book Chapter 6 (Contraindications and special considerations)](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) and [Green Book Chapter 28a (Shingles)](https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a) for further details. * **Annual** influenza ([The Green Book, Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19)) vaccinations are recommended. * COVID-19 vaccination ([The Green Book, Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) is safe and recommended. * Repeat pneumococcal vaccine may be indicated. See [Green Book Chapter 25](https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25) for advice. | * 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. | | **(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.** | |   **Action to be taken if Abnormal Result**  Normal reference range may vary slightly between labs. Results should be recorded in the patient’s shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.   |  |  | | --- | --- | | **Abnormal Result** | **Action to be taken by GP** | | **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** | | | **Full blood count**:   * White blood cells less than 2.5x109/L * Neutrophils less than 1.5x109/L * Platelets less than 80x109/L | 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. | | **Renal function**  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 | | **Liver function tests:**  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 | Discuss with specialist team if persistent or severe. | | Alopecia, skin rash, or hyperpigmentation of nails. | Consider withholding and discuss urgently with specialist team. | | 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. | | |

* The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
* Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
* Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
* Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
* Specialist and patient have completed and signed the shared care agreement form (page 5).

**Shared Care Agreement Form**

**This form is used to agree shared care between the specialist, patient and GP.**

**Specialist and patient agreement**

**By signing below we accept:**

* the Herts and West Essex Area Prescribing Committee [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c) (HWE APC) and
* the requirements and responsibilities defined in this drug specific shared care protocol

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| **Specialist name:** | **Patient name or addressograph label:** |
| **Role and specialty:** |
| **Provider Trust:** |
| **Direct telephone number:** |
| **Email address:**  **Email (for use by GP to respond to request to share care):** |
| **Alternative contact:** |
| **Out of hours contact details:** |
| **Date:** | **Specialist Signature:** |
| **Date:** | **Patient signature or specialist confirmation of patient agreement to shared care arrangement:** |

**GP response to shared care**

**Please return to specialist within two weeks of receipt of request to share care.**

***This form is to be completed by the GP who is requested to share care.***

I agree to accept shared care for this patient as set out in this shared care protocol and HWE [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)

I do not accept shared care for this patient

My reason(s) for not prescribing are given below:       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

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| **GP name:** | **Practice address /stamp:** |
| **Direct telephone number:** |
| **Email:** |
| **Date:** | **GP Signature:** |

**Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).**

1. Specialist to retain copy in patient’s hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient’s notes.

**Full Shared Care Protocol**

**Shared Care Protocol: Guideline No 9; Version 1.1**

**HYDROXYCARBAMIDE FOR THE TREATMENT OF MYELOPROLIFERATIVE NEOPLASMS (ESSENTIAL THROMBOCYTHAEMIA AND POLYCYTHAEMIA VERA)**

**This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with APC shared care principles,** [**Summary of Product Characteristics (SPC)**](https://www.medicines.org.uk/emc) **and the** [**BNF**](http://www.bnf.org/bnf/index.htm)**.**

**BACKGROUND AND INDICATION(S) FOR USE**

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

*Essential Thrombocythaemia (ET)* Is characterised by a persistently elevated platelet count. *Polycythaemia vera* is characterised by in an increase in red blood cell production and increased haematocrit (Hct) due to mutations in a gene called JAK2.

This shared care agreement outlines the individual responsibilities for managing the prescribing and monitoring of hydroxycarbamide for the stated myeloproliferative neoplasms. Responsibilities are expected to be shared between the haematology specialist and the GP. A haematology specialist can be a non-medical prescriber. GP participation in shared care involves full prescribing responsibility in primary care. If the GP is unable to undertake this role for any reason, they are under no obligation to do so. However, they must notify the specialist in writing within 14 days of receiving a prescribing request otherwise shared care will automatically be assumed to have been accepted. Medication cost is not an acceptable reason for refusing to take on shared care.

Haematology specialists will have clinical responsibility for the medication and the consequences of its use. Shared care necessitates effective and efficient correspondence between the specialist, the GP and the patient. GPs take responsibility to check the blood results in conjunction with the clinic letter and prescribe hydroxycarbamide following the advice documented by the specialist. Shared care principles must be explained to the patient by the doctor initiating treatment. Patients will obtain hydroxycarbamide from their community pharmacy under the shared care plan.

**Indications:**

Hydroxycarbamide for the treatment of myeloproliferative neoplasms i.e. Polycythaemia vera (PV) and Essential Thrombocythaemia (ET). The adequate trial period for determining the anti-neoplastic effect of hydroxycarbamide is SIX weeks.

The protocol applies to adults aged 18 and over and does not cover hydroxycarbamide for sickle cell.

**DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT**

Doses are based on actual or ideal bodyweight of the patient (whichever is the less). Hydroxycarbamide is available and can be supplied as either capsules or as solution for oral administration.

Lower doses may be required in elderly patients and should be considered in patients with renal impairment.

*(Note: All dose and formulation adjustments will be the responsibility of the initiating specialist based on clinical response and tolerability unless agreed with the primary care clinician. Termination of treatment is also the responsibility of the specialist).*

In Essential thrombocythaemia, hydroxycarbamide is usually given at starting doses of 15mg/kg/day with doses adjusted to maintain platelet counts below 600 x 109/l without lowering white blood cell counts below 4 x 109/l.

In Polycythaemia vera, hydroxycarbamide should be started at a dose of 15 – 20 mg/kg/day. The hydroxycarbamide dose should be adjusted individually to maintain the haematocrit below 45% and platelet count below 400 x 109/l. In most patients this can be achieved with hydroxycarbamide given continuously at average daily doses of 500 to 1000mg.

Treatment is continued indefinitely, according to clinical response i.e. if haematocrit and platelet count can be sufficiently controlled.

Capsules should be swallowed whole.

Swallowing difficulties

Please refer to the [‘specials’ alternative guidance](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hweclinicalguidance.nhs.uk%2Fall-clinical-areas-documents%2Fdownload%3Fcid%3D2274%26checksum%3D95f8d9901ca8878e291552f001f67692&data=05%7C02%7Cheernamehta%40nhs.net%7Ccba67ac584344a90298108dcafcc3bcd%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638578538908037976%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=drWPIVzT4RkMn0VJJa96%2F2dIm19xPNtqcc0yghL%2FsEA%3D&reserved=0) for a list of commonly prescribed medicines and alternative methods of administration for patients with swallowing difficulties, feeding tubes or for patients prescribed unlicensed ‘specials’ medication. Each entry takes into account alternative medicines, formulations, cost and licensing. This list is not exhaustive. As not all medicines are listed, please contact the initiating specialist if required for individual patient advice if a patient has a swallowing difficulty.

Haematological toxicity

If neutrophils < 1.5 x 109/L and/or platelets < 100 x 109/L, interrupt treatment until counts rise above these levels.

Renal Impairment

Although in practice the dose will be titrated according to response, impaired renal function may affect clearance.

Clinical decision: discuss with specialist consultant

Hepatic Impairment

Clinical decision: discuss with specialist consultant

Please note that in addition to absolute values for haematological indices, a rapid fall or consistent downward trend in any values should prompt caution and extra vigilance.

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| **SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT**   * Assess the patient and provide a diagnosis, within the scope of shared care protocol and communicated to primary care. * Assess for contraindications, interactions and cautions. * Use a shared decision making approach, provide patient information leaflets illustrating risks and benefits associated with hydroxycarbamide therapy to enable the patient to reach an informed decision. Explain the requirement for continued blood monitoring and actions to be taken if patients display adverse reactions. * Ensure pre-chemotherapy counselling completed in line with national safety recommendations and chemotherapy measures. * Gain consent to initiate treatment and confirm patient understanding regarding therapy. * Initiate and optimise treatment following baseline blood tests and supply prescriptions for the first 3 months of treatment. * Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care. * To request shared care protocol for patients who have been stabilised on at least 3 months of treatment under the specialist team (THIS CANNOT BE REQUESTED FOR PATIENTS WHO ARE NOT STABLE). Outline the shared care protocol criteria. * Respond to concerns raised regarding accepting shared care and continue prescribing until resolution of such concerns. If no objections are raised within 14 days, shared care will be assumed as accepted and patients with collect the following prescriptions from the GP. * Undertake and review blood tests, monitor responses to treatment, adjust doses when necessary. * Once treatment is optimised, complete the shared care documentation. * Relay information to the GP in a clinic letter/shared care documentation specifying:   + Results of blood tests   + Dose of hydroxycarbamide to be prescribed   + Length of hydroxycarbamide prescription   + Date of next blood test   + Stop date (if treatment is to be stopped)   + When next monitoring is required   + Contact information * Inform the GP if patients fail to attend appointments or blood tests and advise whether prescribing can be continued (and duration of extension) or must be stopped. * Conduct the required monitoring 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 remains appropriate. * Stop treatment when no longer appropriate and inform the GP.   Provide guidance to primary care regarding management of side effects if required. |

**GP RESPONSIBILITIES**

Refer to page 1/2 and GP Considerations for Shared Care page 15.

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| **PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP**   * Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement. * Confirm their understanding of the treatment and agreeing to contact the specialist/GP if they subsequently do not have a clear understanding of the treatment (patient to be provided with relevant contact details for GP/specialist in and out of hours). * Take hydroxycarbamide as prescribed and avoid abrupt withdrawal unless advised by the primary care team or specialist. * Attend appointments regularly for monitoring with primary care and specialist, make sure contact details are up to date. Be aware that medicines may be stopped if they do not attend. * Report adverse effects to their primary care prescriber and seek medical attention if they develop any symptoms as detailed in this SCP. * Report any use of over-the-counter medication to their prescriber. Discuss use of hydroxycarbamide with their pharmacist before obtaining any OTC medication. * Do not drive or operate heavy machinery if hydroxycarbamide affects their ability to do so. * Patients should take a pregnancy test if they believe they are pregnant and inform the GP or specialist immediately if they become pregnant or wish to become pregnant. Hydroxycarbamide is contraindicated in pregnancy. It is recommended that patients of childbearing potential use effective contraception before starting and during treatment with hydroxycarbamide. |

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| **DISPENSING PHARMACIST RESPONSIBILITIES**   * Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required. * Check the patient is being monitored regularly, e.g. using the patient held monitoring booklet where available, to ensure that it is safe before issuing or dispensing prescriptions. |

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| **MONITORING AND ACTIONS TO BE TAKEN**   * Refer to page 2-4. |

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| **SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**  GP to liaise with specialist if any side effects are a cause for concern  **Common:**   * Bone marrow depression, leukocytopenia, megablastosis, thrombocytopenia, anaemia, diarrhoea or constipation, nausea and vomiting, rash, fever, chills and malaise.   **Rare:**   * Tumour lysis syndrome, gangrene, headache, dizziness, alopecia, dysuria, leg ulcers and cutaneous vasculitis. * (NOTE: Primary care to seek advice from specialist if patient report any of above side effects) * **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  |  |  | | --- | --- | | * **Abnormal Result** | * **Action to be taken by GP** | | * **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** | | | **Full blood count**:   * White blood cells less than 2.5x109/L * Neutrophils less than 1.5x109/L * Platelets less than 80x109/L | * 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. | | **Renal function**   * 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 | | **Liver function tests:**   * 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. | |

**CONTRAINDICATIONS AND PRECAUTIONS**  **(REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

Please refer to the BNF and SPC for a more comprehensive list.

Contradictions:

* Hypersensitivity to hydroxycarbamide or to any of the excipients in preparation.
* Severe bone marrow depression, leukocytopenia (<2.5 x 109/L), thrombocytopenia (<100 x 109 platelets/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.
* 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. Advise patients to protect from sun exposure, regularly self-inspect skin during and after treatment and screen 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. Advise patients to maintain a high fluid intake.
* Hydroxycarbamide causes macrocytosis, which may mask the incidental development of folic acid and vitamin B12 deficiency.

**NOTABLE DRUG INTERACTIONS (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

Common drug interactions

This list is not exhaustive. Please see BNF and SmPC for comprehensive information and recommended management:

* Myelosuppressive agents: concurrent use with hydroxycarbamide may increase the risk of bone marrow depression.
* Antiretrovirals: Hydroxycarbamide may potentiate side effects of nucleoside reverse transcriptase inhibitors such as hepatotoxicity, pancreatitis and peripheral neuropathy. Concomitant use should be avoided.
* 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.
* Studies have demonstrated the ability of hydroxycarbamide to enhance the cytotoxicity of both cytarabine and fluoropyrimidines (e.g. 5-FU).
* 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.

**PHARMACEUTICAL ASPECTS**

Under this shared care protocol, only the 500mg capsules and the 100mg/ml oral solution are suitable to be prescribed due to safety reasons.

(Hydroxycarbamide 100mg & 1000mg tablets - only preparation licensed for sickle cell disease which is excluded from this shared care protocol. NB: tablet formulation is more expensive than other solid oral dosage forms).

For patients with swallowing difficulties, consider prescribing the Hydrea® brand. The manufacturer confirms the suitability of opening capsules and emptying contents to a glass of water for oral administration. The contents should not be inhaled or placed in contact with skin. The opening of capsules is off label and is suitable with and Hydrea® brand.

To assist accurate and consistent dose delivery to the stomach, water should be taken after each dose of hydroxycarbamide oral solution.

Hydroxycarbamide should be handled according to local procedures for handling and disposal of cytotoxic agents.

1. **PREGNANCY, FERTILITY AND BREAST-FEEDING**

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. Hydroxycarbamide should not be administered to patients who are pregnant unless the benefits outweigh the possible risks.

**Fertility:**

Hydroxycarbamide may be genotoxic, therefore, genetic consultation is recommended if a patient intends to become pregnant after therapy with hydroxycarbamide. Women of childbearing potential must use effective contraception before the start of, during treatment with hydroxycarbamide and for 6 months following completion. Men are recommended to use effective contraceptive measures and to not father a child while receiving hydroxycarbamide and for 3 months following completion of treatment. Men 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.

**Breast-feeding:**

As hydroxycarbamide is excreted into human milk, a decision should be made whether to discontinue nursing or to discontinue hydroxycarbamide, taking into account the importance of the drug to the mother and also the serious adverse reactions in nursing infants from hydroxycarbamide.

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| **ADVICE TO PATIENTS AND CARERS**  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  Patients should be asked to report:   * Signs and symptoms of haematological toxicity, e.g. sore throat, infection, unexplained or abnormal bruising and bleeding. * Signs or symptoms of hepatic toxicity e.g. jaundice. * Symptoms of chickenpox or exposure to a person with chickenpox or shingles. * Suspected or confirmed pregnancy.   Patients should be advised:   * To maintain a high fluid intake due to the possibility of increases in serum uric acid levels. * 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 could be pregnant. Patients should inform the specialist or the 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/>  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. |

**REFERENCES**

* Oxford University Hospitals NHS Foundation Trust. *Hydroxycarbamide for myeloproliferative neoplasms (polycythaemia vera and essential thrombocythaemia) for patients with adult services Shared Care Protocol.* Approved by Area prescribing committee Oxfordshire: May 2022.
* Renal drug database, Hydroxycarbamide monograph, accessed 20/03/24 <https://www.renaldrugdatabase.com>
* Patient information on hydroxycarbamide [www.cancerresearchuk.org](http://www.cancerresearchuk.org), accessed 18/09/2023
* Summary of Product Characteristics. *Hydroxycarbamide medac 500mg capsule, hard.* Medac GmBH. Last updated on 17/05/2023. Accessed online via [www.medicines.org.uk](http://www.medicines.org.uk) on 18/09/2023
* National shared care protocol: Hydroxycarbamide for myeloproliferative disorders and sickle cell disease for patients within adult services. Accessed online via <https://www.england.nhs.uk/wp-content/uploads/2022/07/B1621_xi_Hydroxycarbamide-for-myeloproliferative-disorders-and-sickle-cell-disease-for-patients-within-adult-s.docx> Accessed on 27/11/2023

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| **CONTACT DETAILS for BACK-UP INFORMATION / ADVICE**  **East and North Hertfordshire NHS Trust**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Pharmacy Team shared care admin contact** | **Out of hours contact / switchboard** | | **Haematology CNS** | 07818 588 764 | [enh-tr.haemato-oncologycns@nhs.net](mailto:enh-tr.haemato-oncologycns@nhs.net) | [sharedcare.enh-tr@nhs.net](mailto:sharedcare.enh-tr@nhs.net)  01438 284032 | 01438 314333 |   **Princess Alexandra Hospital NHS trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Haematology** | 01279 827035/ 01279 444455 Ext 2891  MI: 01279 827052 | paht.pahhaematologyconsultants@nhs.net | 01279 444 455 |   **West Hertfordshire Hospitals NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Haematology** | 01923 217628/ 01923 217571/ 01923 217084 | westherts.haematology@nhs.net | Ext 7628, 7751, 7084 |   **Communication**  For any queries relating to a patient’s treatment with hydroxycarbamide, please contact the specialist as documented at the top of this document. Read in conjunction with HWE APC shared care principles document.  For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call. |

**GP Considerations for Shared Care**

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

* Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
* Have you been provided with relevant clinical details including monitoring data?
* Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

**If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.**

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its useas well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient’s condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

**Approval Information**

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| Version | 1.1 Updating wording on swallowing difficulties September 2024  1.0 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include:   * Rebadging with HWE ICB * Review date removed and replaced with standard statement. |
| Developed by | Pharmacy and Medicines Optimisation Team, Hertfordshire and West Essex (HWE) ICB with relevant HWE ICS stakeholders. |
| Approved by | Hertfordshire & West Essex Area Prescribing Committee |
| Date approved/updated | April 2024 |
| Review date: | The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available. |
| Superseded version | Hydroxycarbamide shared care agreement – West Essex CCG, MOPB, Nov 2016 |