SHARED CARE AGREEMENT

Name of medicine	Hydroxycarbamide
Indication	Myeloproliferative neoplasms including essential thrombocythaemia, polycythaemia vera, myelofibrosis and chronic myelomonocytic leukaemia

Version: **3.0** Approval date: **December 2024** Review date: **December 2027**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant/ Clinical nurse specialist

- Explain to the patient about indication, aim and duration of hydroxycarbamide use.
- Issue the patient with an Edinburgh Cancer Centre approved medication information leaflet and discuss any points raised by the patient/relative or carer.
- Counsel patients about potential side effects and the necessary precautions when taking hydroxycarbamide, including 1% risk of skin cancer.
- Advising the patient regarding fertility, pregnancy and the need for contraception due to potential teratogenicity (completed during consent process).
- Initiate hydroxycarbamide in the haematology clinic and obtain informed consent from the patient.
- Titrate the dose of hydroxycarbamide to optimal clinical response.
- Monitoring of treatment response and adverse drug reactions.
- Request Shared Care when the patient achieves a stable response to hydroxycarbamide (typically after 6 months of treatment). Advise that prescriptions must be issued as generic Hydroxycarbamide 500mg capsules.
- Send a letter to the GP after each clinic consultation to advise hydroxycarbamide dose.
- Arrange regular blood tests through non-attendance clinics and inform the patient and the GP about blood results and dose changes, if required.
- Review patient in the haematology clinic at appropriate intervals.
- Evaluate any reported adverse effects by the GP or the patient.
- Switch patients with intolerable side effects to an alternative treatment.

General Practitioners and primary care non-medical prescribers

- Prescribe hydroxycarbamide dose as recommended by the haematology consultant or his/her representatives e.g. specialist registrar, clinical nurse specialist when the patient is on a steady dose of hydroxycarbamide. This is typically 6 months after the patient has been initiated on treatment in the haematology clinic.
- *Please note prescriptions must be issued as generic Hydroxycarbamide 500mg capsules.
- Arrange for blood tests to be taken as advised by the specialist team.
- Refer patients with suspected skin cancer to the dermatology clinic (as per standard practice).

Patient, relatives, carers

- Patients must take hydroxycarbamide at prescribed dose.
- Patients who are unable to administer their own dose and a relative/carer is required to handle hydroxycarbamide will be issued with purple nitrile 'cytotoxic' gloves by the specialist team in order to safely do so. The CNS will continue to liaise with patient/relative/carers to ensure continued supply.
- Return all unused stock to community pharmacy.
- Patients must report any adverse effects related to hydroxycarbamide.

Support and Advice for the GP and primary care non-medical prescribers

On call haematology registrar, via switchboard 0131 537 1000

Clinical nurse specialist - Alexis.Thomson@nhs.scot

Consultant haematologists
- Dr Ioannis Koutsavlis Ioannis.Koutsavlis@nhs.scot
- Dr Katrina Dodds Katrina.dodds@nhs.scot

Key Information on the Medicine

Refer to current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication

Most patients are diagnosed with a myeloproliferative neoplasm when they are older than 60, a significant proportion will be older than 80. Myeloproliferative neoplasms are chronic bone marrow disease associated with increased risk of thrombosis, bleeding and splenomegaly. Patients will be taking hydroxycarbamide indefinitely.

The aims of hydroxycarbamide treatment are as follow:

1. To reduce the risk of arterial and venous thrombo-embolic complications
2. To reduce the risk of bleeding in patients with extreme thrombocytosis, e.g. platelet count >1500 x 10^9/l
3. To reduce spleen size in patients with symptomatic splenomegaly

Hydroxycarbamide is a well-tolerated form of oral systemic anti-cancer therapy used in the treatment of myeloproliferative neoplasms. Hydroxycarbamide has been used since 1960s and therefore has long safety record. It has also been used in non-cancerous conditions such as sickle cell anaemia.

Indication

Essential thrombocythaemia, polycythaemia vera, myelofibrosis and chronic myelomonocytic leukaemia.

Please note that not all indications are listed on the manufacturers patient information leaflet. Patient will be issued with a Macmillan Cancer Support information leaflet by specialist team prior to initiation.

Dosage and administration

Variable dose depending on clinical response and full blood count.
Typical dose ranges from 500 mg up to 2000 mg once daily. Please note some patients may be taking hydroxycarbamide on specified days of the week only.

Monitoring

Monitoring will be directed by the haematology consultant or clinical nurse specialist in charge of the patient. Patients will be monitored through a combination of face to face haematology clinic and virtual/non-attendance clinic. Patients will receive a letter asking them to arrange blood tests through their practice nurse prior to Systemic AntiCancer Therapy (SACT) All results done through virtual clinic will be reviewed by consultant in charge.

Patients with **high platelet count** may get spuriously high potassium level ie pseudohyperkalaemia. To reduce the risk of pseudohyperkalaemia, **lithium heparin (orange top) blood tubes** may be used for biochemistry tests.

Test	Frequency	Abnormal result	Action if abnormal result
Full blood count	Every 3 to 6 months	Hb <80 g/L	Check history of bleeding and symptoms of anaemia. Request blood film, reticulocyte count, ferritin, B12, folate and serum protein electrophoresis. Advise patient to stop hydroxycarbamide and contact consultant in charge via e-mail for further advice.
		Neutrophil <0.5 x10^9/L	Check history of fever/infection. If febrile or showing signs of infection, discuss with the oncall haematology registrar. Advise patient to stop hydroxycarbamide. If the patient is well, contact consultant in charge for further advice.
		Platelet count <50 x10^9/L	Advise patient to stop hydroxycarbamide and contact consultant in charge via e-mail for further advice.
		MCV >100	No action if Hb within normal range. If Hb reduced, check Vit B12/folate and thyroid function.
Urea and creatinine	Every 3 to 6 months	Creatinine: note trend	Exclude other causes of kidney dysfunction. Inform consultant in charge if creatinine increased by 50%.
LFTs	Every 3 to 6 months	ALT >100	Exclude other causes of transaminitis. If no alternative cause identified, inform consultant in charge.
		Bilirubin >50	Exclude other causes of hyperbilirubinaemia. If no alternative cause identified, inform consultant in charge.

Cautions, contraindications - Refer to current Summary of Product Characteristics: www.medicines.org.uk

Fertility, Pregnancy and Lactation

Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

- Male patients should not father a child whilst taking hydroxycarbamide. It is known to cause azoospermia, oligospermia and is considered to be teratogenic.
- Women must not conceive while receiving hydroxycarbamide as hydroxycarbamide affects DNA synthesis, it is considered a potent mutagenic agent and can also have teratogenic effects due to cytotoxicity.
- A reliable form of contraception should be used by men and women (avoid prescribing oral contraceptive pill) whilst taking hydroxycarbamide and for 3 months after treatment.
- Nursing mothers should not breast feed if taking hydroxycarbamide as it is excreted in human breast milk.
- Women and men who are on hydroxycarbamide and planning to conceive should be referred to the specialist service for further advice and management.

Vaccination

Live vaccines e.g. shingles vaccine, should not be offered to patients taking hydroxycarbamide.

Please see the Edinburgh Cancer Center haematology policy: Vaccination in Patients with Haematological Disease.pdf

Adverse effects - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Over 90% patients do not experience any side effects.

Common: Bone marrow suppression e.g. anaemia, leucopenia, thrombocytopenia. Raised MCV is an expected effect of hydroxycarbamide, no action will be required if serum B12 and folate are otherwise normal and the patient is asymptomatic.

Less common: Rash, leg ulcers, nausea, diarrhoea. Hydroxycarbamide has been reported to be associated with 1% risk of non-melanoma skin cancer.

If the patient reports leg ulceration, please stop hydroxycarbamide and inform the consultant haematologist in charge of the patient.

Drug interactions - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Hydroxycarbamide may enhance the antiretroviral activity of nucleoside reverse transcriptase inhibitors like didanosine and stavudine.

Hydroxycarbamide may also enhance potential side effects of nucleoside reverse transcriptase inhibitors such as hepatotoxicity, pancreatitis and peripheral neuropathy.

The presence of this Shared Care Agreement does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 10th December 2024