Hydroxycarbamide for patients in adult services

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and communicated to primary care.
- Discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions and interactions.
- Conduct required baseline investigations and initial monitoring.
- Initiate and optimise treatment as outlined below. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information.
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in and communicate the results to primary care. After a review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined below remains appropriate.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing within 14 days.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request , taking into any account potential drug interactions listed below.
- Adjust the dose prescribed as advised by the specialist.
- Conduct the required monitoring as outlined below. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed below and discuss with specialist team when required.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take the medication as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed below.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of the medication with their pharmacist before purchasing any OTC medicines.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Indications

The licensed indications for hydroxycarbamide include:

- Chronic myeloid leukaemia
- Essential thrombocythaemia
- Polycythaemia vera
- Sickle-cell disease

This shared care protocol also includes the treatment of other myeloproliferative disorders and inflammatory conditions where off-label use of hydroxycarbamide is appropriate, including:

- Primary myelofibrosis
- Unclassified myeloproliferative disorders
- Psoriasis

This shared care protocol applies to adults aged 18 and over.

2. Initiation and ongoing dose regime

- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist.

Doses are based on real or ideal body weight whichever is less.

Initial stabilisation:

Chronic myeloid leukaemia: 20-40mg/kg daily then may be reduced to 20mg/kg daily and adjusted according to response. Alternatively, 80 mg/kg once every 3 days.

Essential thrombocythaemia: 15mg/kg daily adjusted according to response

Polycythaemia vera: 15-20mg/kg daily adjusted according to response

Sickle-cell disease: 15 mg/kg daily, increased in steps of 5 mg/kg daily, dose to be increased every 8-12 weeks according to response

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Initial doses above are subsequently adjusted according to haematological response. The selected dose will be tailored to the individual patient and decided by the specialist.

In sickle-cell disease, the maintenance dose varies from 15-30mg/kg daily; max 35mg/kg daily

The initial maintenance period must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

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

In patients with sickle cell disease and CrCl 60 mL/min or lower, the starting dose should be reduced by 50%.

If myelotoxicity occurs a dose reduction may be considered by the specialist.

3. Contraindications and cautions

Please see BNF & SPC for comprehensive information.

Live vaccines (e.g. oral typhoid, MMR, BCG, yellow fever) should be avoided in patients taking hydroxycarbamide.

4. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Baseline investigations:

- FBC
- Urea and electrolytes (U&Es)
- LFTs
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- Screening for lung disease, including interstitial lung disease and tuberculosis, should be undertaken at clinician discretion on a case by case basis
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)

Additional baseline investigations for patients with sickle-cell disease:

- Reticulocyte count

Initial monitoring:

To be repeated every 2 weeks until dose has been optimised and all test results are stable (minimum of 8 weeks)

- FBC
- U&Es
- LFTs
- Reticulocyte count (sickle cell disease only)

Ongoing monitoring to be undertaken by primary care	
• FBC • U&Es • LFTs • Reticulocyte count (for sickle-cell disease patients)	• Every 8-12 weeks • **The exact frequency of monitoring to be communicated by the specialist in all cases**.

• Patients may 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) and Green Book Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended. • COVID-19 vaccination (The Green Book, Chapter 14a) is safe and recommended. • Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	• Shingles vaccination: as per Green Book guidance • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • Other vaccinations as per national schedule.

5. Adverse effects and other management The following list is not exhaustive. Please see BNF & SPC for comprehensive information and cautions/contraindications

Result	Action for primary care
• White blood cells less than $2.5x10^9$/L • Neutrophils less than $1.5x10^9$/L • Platelets less than $80x10^9$/L • Reticulocytes less than $80x10^9$/L (if haemoglobin greater than 90g/l) • Haemoglobin less than 45g/L (sickle cell patients only) or dropped by over 30g/L from baseline	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	Stop medication and make an urgent referral to specialist if bone marrow suppressions is suspected. Check FBC immediately and discuss with the specialist team. See haematological monitoring above.
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
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.

6. Significant medicine interactions

The following list is not exhaustive. Please see BNF & SPC for comprehensive information and recommended management.

- **Myelosuppressive agents or radiation therapy**: previous or concurrent use with hydroxycarbamide may increase the risk of bone marrow depression. See BNF for more information on specific drugs.
- **Antiretrovirals**: Hydroxycarbamide may potentiate side effects of nucleoside reverse transcriptase inhibitors such as hepatotoxicity, pancreatitis and peripheral neuropathy. Concomitant use should be avoided.
- **Laboratory monitoring**: 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, for further guidance contact local laboratory services.
- **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 and should be avoided for at least six months after treatment with hydroxycarbamide has finished.

7. Pregnancy, paternal exposure and breast feeding

Pregnancy:

Hydroxycarbamide is contraindicated in pregnancy. It is recommended that patients of childbearing potential use effective contraception before starting and during treatment with hydroxycarbamide.

Breastfeeding:

Hydroxycarbamide is excreted in human milk. Due to the potential for serious adverse effects in infants, breastfeeding should be discontinued during hydroxycarbamide treatment.

Paternal exposure:

Men are advised to use effective contraception during and for at least 3 months after therapy. They 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.

8. Specialist contact information

Ipswich Hospital

Dr Ademokun: 01473 703718 Debo.ademokun@esneft.nhs.uk

Dr Whalley: 01473 703718 Ioana.whalley@esneft.nhs.uk

Dr Chalmers: 01473 703718 Isobel.chalmers@esneft.nhs.uk

Dr Hodson: 01473 703718 Andrew.hodson@esneft.nhs.uk

Dr Prahladan: 01473 703718 Mahesh.Prahladhan@esneft.nhs.uk

Dr Page 01473 703718 Catherine.page@esneft.nhs.uk

Colchester Hospital

Dr Gavin Campbell Gavin.Campbell@esneft.nhs.uk

Dr Andrew Robinson andrew.robinson@esneft.nhs.uk
Dr Khalid Saja KhalidFahad.Saja@esneft.nhs.uk
Dr Maha Mohan Mahalakshmi.Mohan@esneft.nhs.uk
Dr Joseph Padayatty Joseph.Padayatty@esneft.nhs.uk

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Templates for response to shared care guidelines are available in SNEE on DXS and Ardens. The listings are:

For Suffolk practices (DXS)

Form Name - Appendix 2 Accepting Shared Care

Form Reference - SUF2133

Folder Location - Medicines Management – Care Pathway

Form Name – SNEE Cannot Prescribe Form

Form Reference - SUF2132

Folder Location - Medicines Management – Care Pathway

For North East Essex practices (Ardens)

SystmOne

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

Form Reference - SUF2133

Folder Location - Secondary Care Referrals P – Prescribing

Form Name –Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Secondary Care Referrals P – Prescribing

EMIS

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

Form Reference - NEE2133

Folder Location - Prescribing

Form Name – Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Prescribing

The documents are also copied below for reference

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: Date:

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility***	

	for providing the patient with their medication remains with you.	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: **Date:**

Primary Care Prescriber address/practice stamp