Shared Care Guideline for the Management of Sickle Cell Disease in Adults and Children

HYDROXYCARBAMIDE (HYDROXYUREA)

Executive Summary/ Critical Information

Indication	Route & Dose	Monitoring undertaken by specialist before requesting shared care	Ongoing monitoring to be undertaken by GP (or non-medical prescriber)	Duration of treatment	Stopping criteria	Follow up (weeks/months)
Homozygous sickle cell disease, sickle beta thalassaemia, haemoglobin sickle cell disorder with: 1. Recurrent painful crises, significantly interfering with lifestyle. In practice, this would be more than three hospital admissions with painful vaso-occlusive crises per year or frequent events managed at home. 2. Recurrent chest crises, two or more a year or 1 life threatening event e.g., requiring ventilation 3. For primary stroke prevention:	**In adults, adolescents and children older than 2 years** Starting dose: 15mg/kg per day as a single dose, orally (adults), 20mg/kg (children) - Dose can be increased by 2.5mg-5mg/kg every 8 weeks - Usual dose is 15mg-30mg/kg per day - In exceptional circumstances the dose may be increased to a maximum of 35mg/kg per day justified under	Full blood count, reticulocytes, renal, liver function, Haemoglobin (Hb) analysis, including fetal Hb level. This will be completed by hospital consultant or NELFT GPwSI and included in the communication to GPs when requesting for a shared care agreement.	The following will be completed by hospital consultant or NELFT GPwSI and communicated to GP at the following time points*: **2 weekly:** Full blood count (FBC), renal and hepatic function should be monitored every 2 weeks at treatment initiation (for the first 2 months). and 2 weekly following dose changed until established on a stable dose (to be monitored if patient lives too far from hospital)	Dependant on response to treatment which will be evaluated every 3 months by specialist service.	If blood counts are below the following range, hydroxycarbamide should be temporarily discontinued and discussed with haematology consultant: **Neutrophils** < $1x10^9$/L **Platelets** < $80x10^9$/L **Haemoglobin** < 60 g/L **Reticulocytes** < 80 x 109/L if the haemoglobin concentration < 90 g/L **(SEE SECTION 8 for further details)** Hydroxycarbamide should be temporarily discontinued and discussed with	**Specialist:** Monthly (virtual or face to face review) at initiation to 3 monthly at steady state. Annual review.

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• consider in those children with high risk transcranial Doppler (TCD) velocities where transfusions are not possible (alloantibodies, transfusion reactions) • consider in children who have normalised TCD velocities on transfusions after 2 years with no overt vasculopathy and who are > age 10.	close haematological monitoring - Increased to the dose that controls symptoms rather than maximum tolerated dose.		**<u>2 monthly:</u>** FBC, renal and hepatic function (when on stable dosage), clinical assessment for adverse effects, compliance monitoring (to be monitored if patient lives too far from hospital) **<u>3 monthly:</u>** Clinical assessment: frequency of crises, other adverse sickle events, height and weight centile, Tanner stage, adverse effects, compliance, U+Es, LFTs, reticulocyte count, Hb F as part of haemoglobin analysis (to be monitored if patient lives too far from hospital) **<u>At every contact point</u>**: Reinforce patients understanding of treatment; overall health and well-being and adverse drug reactions.		haematology consultant in the following situations: - Severe skin/nail/hair reactions - Severe CNS reactions - Severe gastrointestinal disturbances - Bone marrow suppression - Planning pregnancy or become pregnant - Patient choice - Failure to attend for blood test monitoring (>6months). In the event a patient does still not respond when treated with the maximum dose of hydroxycarbamide (35 mg/kg/day) over three to six months, permanent discontinuation of hydroxycarbamide should be considered.	

Note: For patients taking 35mg/kg (maximum dose), BNF suggests 2 weekly FBC review, however less frequent monitoring may be considered following discussion with a hospital consultant.
***If the patient lives a long distance from the hospital it maybe more convenient for the phlebotomy to be organised locally and the results sent to the hospital for monitoring if all parties agree.**

Key Safety Notice (for instance: notification if prescribing must be brand specific or BNF cautionary and advisory warnings)

- An effective method of contraception is strongly recommended in women and men of childbearing potential. Patients on hydroxycarbamide wishing to conceive should stop treatment 6 months before pregnancy if possible. If a pregnancy does occur the treating physician must be informed urgently and hydroxycarbamide stopped.

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- Hydroxycarbamide is excreted in human milk. Because of the potential for serious adverse reactions in infants, breastfeeding must be discontinued while taking hydroxycarbamide.
- Adverse effect of hydroxycarbamide on sperm count and function. These changes may be reversible on stopping hydroxycarbamide. However irreversible cases have also been reported. The potential long term risk of infertility must be considered. All post pubertal boys and men should be counselled AND SPERM STORAGE ORGANISED. This is not possible for pre-pubertal boys and parents should be made aware of this. This should be documented as part of the consent process, the specialist initiating hydroxycarbamide, in hospital. The parent/carers should be advised on the risks of treatment in pre-pubertal boys.

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1. Background

Hydroxycarbamide is a drug that is used to treat sickle cell anaemia with more than 25 years clinical experience in its use. The benefits of hydroxycarbamide are well studied and it has been shown to have proven efficacy but with considerable variation in its benefit between patients. Its effects are dose dependent. Clinical trial data has shown the potential of hydroxycarbamide to reduce the number of painful crisis and chest crisis, also to reduce the need for blood transfusions; it can also be used for primary stroke prevention. It may have a beneficial effect on chronic organ damage and improve life expectancy.

Although the mechanism of action is not certain three main effects are known to be important:

1. Increase in fetal haemoglobin content within the red cell, inhibiting sickle haemoglobin polymerisation.
2. Decreased adhesion molecule expression on the surface of the red blood cell.
3. Reduction of white cell and platelet count. This may also impair the sickle cell/endothelial interaction and reduce the inflammatory process in the microvasculature.

Indications for use:

Homozygous sickle cell disease, sickle beta thalassaemia, haemoglobin sickle cell disorder with:

1. Recurrent painful crises, significantly interfering with lifestyle. In practice, this would be more than three hospital admissions with painful vaso-occlusive crises per year or frequent events managed at home.
2. Recurrent chest crises, two or more a year or 1 life threatening event e.g., requiring ventilation
3. For primary stroke prevention:
    - consider in those children with high risk transcranial Doppler (TCD) velocities where transfusions are not possible (alloantibodies, transfusion reactions).
    - consider in children who have normalised TCD velocities on transfusions after 2 years with no overt vasculopathy and who are > age 10.

2. Important information

Procedure Prior to Starting Therapy:

The benefit and risk of using hydroxycarbamide should be considered for each patient individually and discussed with the patient and/or parents. They should be given a detailed explanation of treatment, including nature of possible side effects. Where appropriate, discussion about risks of becoming pregnant or fathering a child whilst on hydroxycarbamide should be explained and the risk of infertility in males carefully discussed.

- **Ensure that the patient is willing to attend regularly for monitoring blood tests.**
- **Give patient and/or parents the information sheet and document consent.**
- **Sperm banking should be organised in post pubertal boys and men pre-treatment. (see section: effects on spermatogenesis for further information)**

The above will be carried out by the hospital team

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3. Drug name, form, and licensed indications (unlicensed/off-label)

- **Barts Health NHS Trust use generic hydroxycarbamide for the treatment of sickle cell anaemia; Hydroxycarbamide (hydroxyurea) 500 mg capsules**
  - The Siklos brand is the only licensed formulation of hydroxycarbamide licensed for the treatment of sickle cell disease. As Siklos ® is significantly more expensive and it is the same chemical entity as the generic hydroxycarbamide, Barts Health NHS Trust will only use the generic hydroxycarbamide which is not licensed for sickle cell disease. Patients will be notified of this during initiation and this will be documented in the patient's notes as evidence of consent.
- There is now a licensed liquid formulation: Xromi® 100mg/mL by Nova Laboratories Ltd, which may be considered in young children.

4. Dose and Administration

Hydroxycarbamide will be initiated and the dose will be stabilised in hospital.
The following are guidelines, which will be adhered to for all patients initiating on hydroxycarbamide in hospital. Monitoring of effects would be conducted in these initial stages.

<u>In adults, adolescents and children older than 2 years:</u>
Starting dose: 15 mg/kg per day as a single dose, orally (adults), 20mg/kg (children)

- Dose can be increased by 2.5mg-5 mg/kg every 8 weeks
- Usual dose is 15-30 mg/kg per day
- In exceptional circumstances the dose may be increased to a maximum of 35mg/kg per day justified under close haematological monitoring.
- Increased to the dose that controls symptoms (rather than maximum tolerated) while monitoring and maintaining.
- The dose requires reduction in renal impairment. The hospital will monitor and advise on dose adjustments as required.

Responsibilities	**Tower Hamlets & Newham**	**Waltham Forest**
Prescribing Initiated by	Consultant Paediatric Haematologist/ Haematologist/ paediatrician	Consultant Paediatric Haematologist/ Haematologist/paediatrician/ GP with specialist interest (SI) under the guidance of the Haematologist as part of the NELFT Haemoglobinopathy service
Prescribing continued by	Hospital consultant / GP when dose stabilised. Changes to	Hospital consultant / GP when dose stabilised. Changes to dosage will

	dosage will be communicated by hospital consultant / haematology clinical non-medical prescriber specialist to GP.	be communicated by hospital consultant /haematology clinical non-medical prescriber specialist to GP.
Monitored by	Hospital - see details below* Or ELFT Haemoglobinopathy service	Hospital - see details below* Or NELFT Haemoglobinopathy service
Duration of treatment	Response to treatment evaluated every 3 months by responsible service	

**If the patient lives a long distance from the hospital it maybe more convenient for the phlebotomy to be organised locally and the results sent to the hospital for monitoring if all parties agree.*

5. Contraindications/Cautions

- Hypersensitivity reactions
- Severe hepatic impairment (Child-Pugh classification C).
- Severe renal impairment (CrCl < 30 ml/min)
- Bone marrow suppression

PREGNANCY

An effective method of contraception is strongly recommended in women and men of childbearing potential. Both men and women should be counselled and this documented in the notes. Patients on hydroxycarbamide wishing to conceive should stop treatment 6 months before pregnancy if possible. The evaluation of the risk-benefit ratio should be made on an individual basis outweighing the respective risk of hydroxycarbamide therapy against the switch to a blood transfusion programme. If a pregnancy does occur the treating physician must be informed urgently and hydroxycarbamide stopped. Studies in animals have shown reproductive toxicity with adverse effects on fertility. Patients on hydroxycarbamide should be made aware of the theoretical risks to the foetus.

Based on the limited amount of available information, in case of an *in utero* exposure to hydroxycarbamide, of female, or partners of male patients treated by hydroxycarbamide, a careful follow-up with adequate clinical, biological and ultrasonography examinations should be considered.

BREAST FEEDING

Hydroxycarbamide is excreted in human milk. Because of the potential for serious adverse reactions in infants, breastfeeding must be discontinued while taking hydroxycarbamide.

EFFECTS ON SPERMATOGENESIS

There is increasing evidence demonstrating an adverse effect of hydroxycarbamide on sperm count and function. These changes may be reversible on stopping hydroxycarbamide. However irreversible cases have also been reported. The potential long term risk of infertility must be considered. All post pubertal boys and men should be counselled AND SPERM STORAGE ORGANISED. This is not possible for pre-pubertal boys and parents must be made aware of this. This should be documented as part of the consent process, by the specialist initiating hydroxycarbamide. The parents/carers should be advised

on the risks of treatment in pre-pubertal boys. For complete list of contraindications and cautions, please refer to the SPC: https://www.medicines.org.uk/emc.

6. Drug interactions

Increased risk of severe or fatal infection is given concomitantly with live vaccines.

For complete list of drug interactions please refer to the SPC: https://www.medicines.org.uk/emc

7. Side effects which require managing

Adverse effects	**Symptoms/signs** *(specify what would prompt action)*	**Actions** (*what action should the GP take if identified in primary care)*
Skin /nail / hair reactions	Hypersensitivity rash, pruritus, hyperpigmentation, alopecia	Stop treatment if severe. Reassure patient if mild and discuss with consultant
CNS effects	Drowsiness, hallucinations, headache, dizziness	Stop medication, arrange for urgent assessment by consultant. Headaches alone can be monitored. Severe symptoms should be discussed with consultant.
Gastrointestinal disturbance	Persistent abdominal pain, anorexia, nausea, vomiting, diarrhoea, constipation, pancreatitis	Continue if mild and tolerated. Stop, arrange for review by consultant if severe
Bone marrow suppression	• Oral ulceration • Abnormal bruising / bleeding • Recurrent sore throat • Recurrent infections Leucopenia, thrombocytopenia, anaemia, neutropenia, reticulocytopenia, macrocytosis	Stop medication arrange for urgent review by consultant

This only lists the key important adverse drug reactions - for comprehensive information on cautions, contraindications and interactions, please refer to the current British National Formulary and Summary of Product Characteristics (link to SPC https://www.medicines.org.uk/emc).

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8. Monitoring and Responsibilities

MONITORING STANDARDS FOR MEDICATION AT BARTS HEALTH NHS TRUST

In view of the risk of marrow suppression, a full blood count and reticulocyte count should be checked 2 weeks after commencement and after every dose increment and then at least every 8–12 weeks for the entirety of treatment.

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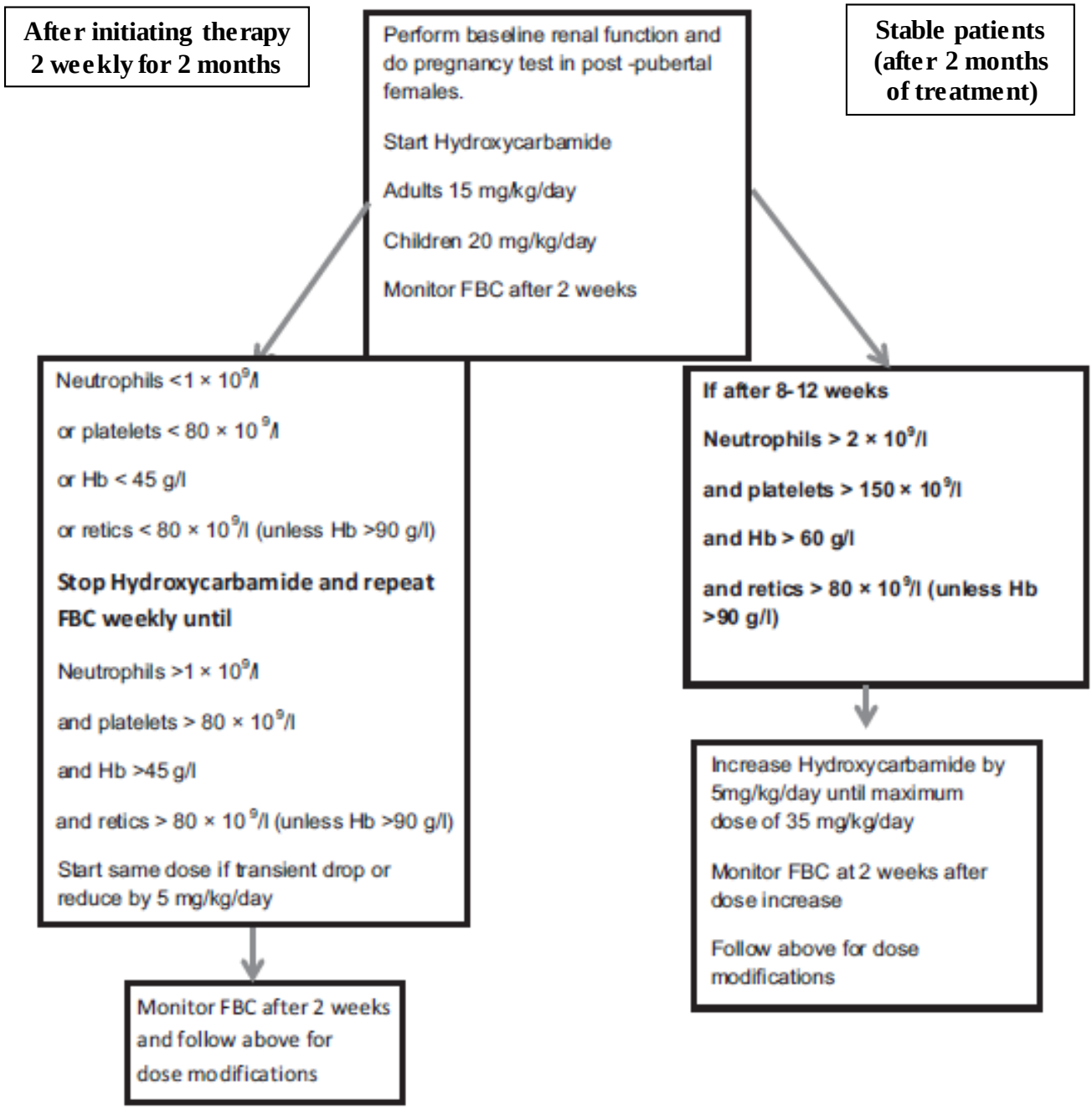

Pre-treatment	Full blood count, reticulocytes, renal, liver function, Haemoglobin (Hb) analysis, including fetal Hb level – **This will be completed by hospital consultant or NELFT GPwSI and included in the communication to GPs when requesting for a shared care agreement.**	
Monitoring	2 Weekly	**This will be completed by the hospital or NELFT GPwSI and communicated to GP when requesting for shared care agreement.** Full blood count (FBC), renal and hepatic function tests should be monitored every 2 weeks at treatment initiation (for the first 2 months). Monitor FBC 2 weekly following dose changed until established on a stable dose.

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	2 Monthly	**This will be carried out by the hospital or NELFT GPwSI and communicated to GP when requesting for shared care agreement.** FBC (when on stable dosage), renal, hepatic function, clinical assessment for adverse effects, compliance monitoring.*
	3 monthly	**This will be carried out by the hospital or NELFT GPwSI and communicated to GP when requesting for shared care agreement.** Clinical assessment: frequency of crises, other adverse sickle events, height and weight centile, Tanner stage, adverse effects, compliance, U+Es, LFTs, reticulocyte count, Hb F as part of haemoglobin analysis.
Note: For patients taking 35mg/kg (maximum dose), BNF suggests 2 weekly FBC review, however less frequent monitoring may be considered following discussion with a hospital consultant (possibly up to 3 monthly). *Less frequent monitoring (2 or 3 monthly) may be considered following discussion with hospital consultant. The maximum period between monitoring for stable patients is 3 months, unless alternative arrangements agreed with consultant haematologist/specialist centre.		

9. Shared care responsibilities

a. Hospital Consultant or GPwSI upon agreement with Haematologist in NELFT service:

- Ensure that the patient/carer is an informed recipient in therapy.
- Ensure that patient understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue patient information leaflet.
- Pre-treatment assessment and investigations. Ensure baseline investigations are normal before commencing treatment.
- Give the patient, a patient held booklet for result monitoring if appropriate. Record height and weight centile. Tanner stage (child <16), FBC, reticulocytes, renal, liver, Hb analysis, including fetal Hb level.
- Initiate treatment and prescribe until the GP formally agrees to share care, when the patient is stabilised.
- Send 'Shared Care Guideline: Prescribing Agreement' (Appendix 1) to the GP requesting shared care for this patient. If GP not willing inform of hospital based specialist nurse led service.
- Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
- Send letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
- Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP.
- Evaluation of any reported adverse effects by GP or patient.
- Advise GP on review, duration, change of dose or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
- Inform GP of patients who do not attend clinic appointments.
- Counsel the patient on contraception and what to do if pregnancy occurs. Document in the notes.
- Ensure that backup advice is available at all times.

- Ensure, where timing is appropriate, that the patient has received a flu vaccine prior to commencing
- treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given.
- Organise sperm banking following viral screen in post pubertal boys and men.

b. General Practitioner/ non-medical prescriber Specialist:

- Reinforce the patients' understanding of the nature, effects and potential side effects of the drug as part of the shared care programme and contact the specialist for clarification where appropriate.
- Monitor patient's overall health and well-being.
- Report any adverse events to the consultant, where appropriate.
- Report any adverse events to the CSM, where appropriate.
- Help with clinical monitoring as appropriate
- Prescribe the drug as part of the shared care programme.

c. Clinical commissioning group

- To provide feedback to trusts via Trust Medicines Committee.
- To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
- To support trusts in resolving issues that may arise as a result of shared care.

d. Patient or parent/carer:

- Report any adverse effects to their GP and/or specialist
- Ensure they have a clear understanding of their treatment.
- Report any changes in disease symptoms to GP and/or specialist.
- Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.
- Take/ administer the medication as prescribed.
- Undertake any monitoring as requested by the GP and/or specialist.

10. Contact Information

Barts Health NHS Trust	
The Royal London Hospital Consultant Staff (Adults and Paediatrics) Dr Banu Kaya / Dr Paul Telfer / Dr Andrea Simmons / Dr Filipa Barroso / Dr Sarah Bennett Clinical Nurse Specialists	0203 246 0352 (Paediatric secretary) 0203 246 0338 (Adult secretary)

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Newham University Hospital Consultant Staff (Adults) Dr Olivia Kreze / Dr Filipa Barroso / Dr Sarah Bennett Consultant Staff (Adults and Paediatrics) Dr Anjum Babadur Clinical Nurse Specialists H. Rahman (Paediatrics)	0207 363 9413 (Department secretary)
Whipps Cross University Hospital Consultant Staff Dr Upal Hossain (Adult) Dr Bashir Farzana (Paediatrics)	Adult service direct line: 0208 535 6687(Department secretary) Switchboard 0208 539 5522 - ext 5196
Waltham Forest Community Haemoglobinopathy and Whipps Cross University Hospital Adult service (NELFT) Dr Teju Ademole (GPwSI for the service) Dr Upal Hossain Clinical Nurse Specialists Connie Harewood, Marcia Hird and Corine Larocque-Joseph	0208 430 7639 (Haemoglobinopathy service run by NELFT)
Newham Sickle Cell and Thalassaemia Centre (ELFT) Service manager/lead nurse: Sekayi Tangayi	02088210800 elt-tr.sickleandthal@nhs.net
Medicine Management Teams: Tower Hamlets CCG Waltham Forest CCG Newham CCG	 Telephone: 020 36882556 THCCG.medicinesoptimisation@nhs.net Telephone: 0203 688 2654 WFCCG.MedicinesOptimisation@nhs.net Telephone: 0203 688 2654 NEWCCG.medcinesmanagement@nhs.net

11. References

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12. Document Management

Document ratification and history	
Produced by:	Clinical Haematology Team, Barts Health NHS Trust
Approved by:	Barts Health Drugs and Therapeutics Committee (DTC) Waltham Forest and East London Medicines Optimisation and Commissioning Committee (WELMOCC)
Date approved:	Barts Health NHS Trust DTC: 1st Sept 2021 WELMOCC: 22nd Sept 2023
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Appendix 1.

Shared Care Guideline: Prescribing Agreement

Section A: To be completed by the hospital consultant initiating the treatment

GP Practice Details:	**Patient Details:**
Name:	Name:
Tel No:	DOB:
Email (nhs.net):	NHS Number (10 digits):

Consultant Details:
Consultant Name:
Secretary Contact Details:
Tel No:
Email (nhs.net):

Diagnosis:	**Drug Name (to be prescribed by GP):** **Dose:** **Frequency:**

I will review the patient in clinic in weeks / months (*Delete as appropriate*).

Dear

Your patient started treatment with the above drug for the above diagnosis on (insert date) and in my view; his/her condition is now stable.

The patient has given consent to treatment under a shared care prescribing agreement and has agreed to comply with instructions and follow up requirements.

I am requesting your agreement to sharing the care of this patient from (insert date) in accordance with the attached Shared Care Prescribing Guideline.

This patient was reviewed on (insert date). These are the results relevant for the drug and/or condition, as outlined in the shared care document:

Test	Baseline	Date

Please continue to monitor the patient as outlined in the shared care guidelines. Refer to the attached guidelines for monitoring criteria.

Other relevant information:

Consultant Signature:	Date:

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above [If returned via e-mail, use NHS.net email account ONLY]

Please sign and return your agreement to shared care within 14 days of receiving this request.

☐ Yes, I accept sharing care as per shared care prescribing guideline.

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☐ No, I am not willing to undertake shared care for this patient for the following reason: (Please give reason)		
GP Name:	GP Signature:	Date:

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