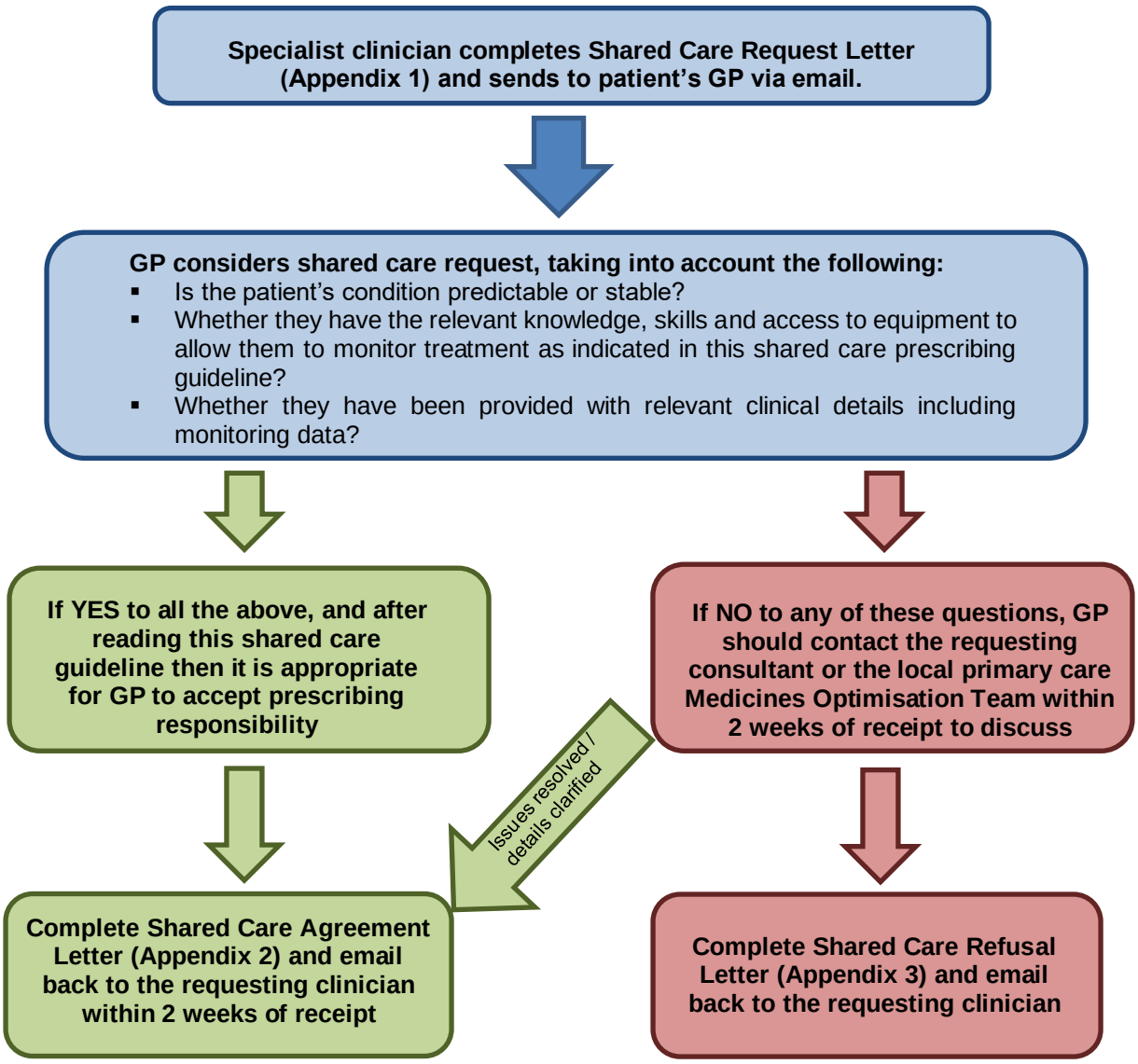
SHARED CARE PRESCRIBING GUIDELINE
Disease modifying drug: Hydroxycarbamide for the treatment of Sickle cell disease in PAEDIATRICS aged 9 months – 17 years

SHARED CARE PROCESS FLOWCHART



NOTES

There may be implications for the patient where invitation to share care is declined. For example, the patient may need to be changed to an alternative treatment regimen. It would not normally be expected that shared care prescribing would be declined on the basis of cost.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **It is important that patients are consulted about treatment and are in agreement with it**.

Prescribing should follow requirements in the South East London Interface Prescribing Policy.
The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient's best interests are always paramount.

If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

1. AREAS OF RESPONSIBILITY

Consultant / Specialist team responsibilities

- Ensuring patient fits criteria for use of this drug (e.g. no contraindications, cautions, fits local agreement for use of the drug)
- Baseline monitoring tests (to be listed)
- To initiate, stabilize and supply treatment over the first 3 months
- To inform patients of practical issues related to the use of hydroxycarbamide, such as administration, storage and maximum dose – see "Clinical Information" section on pages 4-5
- At the time of initiating, notify GP in writing that hydroxycarbamide has been prescribed for the treatment of sickle cell disease. The GP should be invited to share care once the patient is stable. Information provided to the GP should include:
    - A copy of the shared care guidelines
    - That a prescription for the first 3 months supply has been given
    - Information on when the patient will next be reviewed and by whom
    - A request that the GP continue prescribing after 3 months
- Any monitoring that will remain under the consultant's responsibility, including informing GP about any new evidence or data
- To review patient every 3 months as a minimum. To additionally review patient at the request of GP should any problems arise (side-effects / lack of efficacy) within 4 – 6 weeks.
- To communicate promptly, within 2 weeks, with the GP if treatment is changed.
- To report any suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk
- To elicit and record consent on the National Haemoglobinopathy Registry for treatment with hydroxycarbamide annually.

General Practitioner responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is agreed to complete the letter in Appendix 3 and return this to the requesting consultant
- If shared care is not agreed to, complete the letter in Appendix 2, and discuss with the requesting consultant or local primary care Medicines Optimisation Team
- To provide ongoing prescriptions for hydroxycarbamide after 3 months
- To adjust the dose as advised by the specialist
- To agree monitoring requirements with specialist – see pages 6-7 of this document for GP monitoring requirements
- To report and seek advice regarding any concerns, for example: side-effects, co-morbidities, pregnancy, or lack of efficacy to the specialist team
- To advise the specialist if non-adherence is suspected
- To refer back to specialist if the patient's condition deteriorates
- To stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- To report any suspected adverse effects to the MHRA via the Yellow Card scheme: http://www.yellowcard.gov.uk

Patient's / Carer's responsibilities

- To contact the specialist or GP if he or she does not have a clear understanding of any aspect of the treatment.
- To inform prescribing specialist, GP and other healthcare professionals of any other medication being taken, including over the counter products, alternative therapies or recreational drugs.
- To inform community pharmacists that they are using hydroxycarbamide before purchasing medication over-the-counter
- To attend all hospital and GP appointments
- To take medicines as agreed and take steps to ensure that no doses are missed and not to share medicines with others
- To read the patient information leaflet included with the medication.
- To report any adverse effects or warning symptoms to GP or hospital specialist
- To report to GP and maternity services team if pregnant or breastfeeding.
- To inform GP and hospital of any changes in addresses or telephone contact numbers.

Additional Information
Please note there is a national shared care protocol: Hydroxycarbamide for myeloproliferative disorders and sickle cell disease within adult services. This guidance covers PAEDIATRICS with SICKLE CELL disease only and there are therefore some differences between this and the national protocol. This guidance is based on the licensing of hydroxycarbamide in paediatrics with sickle cell disease, along with the clinical knowledge and expertise of specialist clinicians and reflects nationally recognised practice of treating this condition.

2. CLINICAL INFORMATION

NOTE: The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPC) for hydroxycarbamide prior to prescribing for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via www.medicines.org.uk)

Background	Sickle cell disease is a term that encompasses a group of inherited haemoglobin disorders of different genotypes, such as homozygous sickle cell anaemia HbSS, heterozygous HbSC, and HbS/Beta thalassaemia (Sβ0), and other compound heterozygous genotypes. Hydroxycarbamide is the preferred first line licenced drug in the UK for the treatment of sickle cell disease. It has been shown to be decrease episodes of pain and acute chest syndrome (ACS) and reduce the need for transfusion, as well as being efficacious in disease modification and improving survival. Contra-indications to initiating a child on hydroxycarbamide are limited and listed in the Summary of Product Characteristics (see "references" to access online). They include: • Hypersensitivity to the active substance of to any of the excipients in the formulation prescribed • Severe hepatic impairment – for detail see "adverse effects and management" pg 6 • Severe renal impairment - for detail see "adverse effects and management" pg 6 • Toxic ranges of myelosuppression - for detail see "adverse effects and management" pg 6
Indications Note if indication is unlicensed or not	**Recommendations from the British Society of Haematology:** • In infants with SS/Sβ^0 aged 9–42 months, offer hydroxycarbamide regardless of clinical severity to reduce sickle cell complications (pain, dactylitis, ACS) and anaemia • In children aged >42 months with SS/Sβ^0, offer treatment with hydroxycarbamide in view of the impact on reduction of mortality • In children with SS/Sβ^0 who have 3 or more sickle cell-associated moderate to severe pain crisis in a 12-month period, treat with hydroxycarbamide • In children with SS/Sβ^0 who have sickle cell pain that interferes with daily activities and quality of life, treat with hydroxycarbamide • In children with SS/Sβ^0 and a history of severe and/or recurrent ACS treat with hydroxycarbamide • Children who have started regular blood transfusions for abnormal Transcranial Doppler (TCD) can be switched to hydroxycarbamide therapy (with or without venesection) if they have received at least 1 year of regular transfusions and have no magnetic resonance angiography-defined severe vasculopathy • In children who are treated for primary stroke prevention who are changing from regular blood transfusions to hydroxycarbamide therapy, transfusion should be continued until they have reached maximum tolerated dose of hydroxycarbamide

	• Children with TCD velocities in the range 170–200 cm/s (conditional risk category) should be treated with hydroxycarbamide therapy to help prevent progression from conditional to abnormal TCD velocity • In children with a previous history of acute ischaemic stroke or infarcts, hydroxycarbamide should be recommended as second line therapy for secondary stroke prevention when transfusions are contraindicated or unavailable • In patients with sickle nephropathy with persisting proteinuria despite angiotensin-converting-enzyme inhibitor/angiotensin receptor blocker therapy, consider the addition of hydroxycarbamide therapy • In children and adults with chronic hypoxia, recommend treatment with hydroxycarbamide • In children and adults with SS/Sβ^0 and symptomatic chronic anaemia that interferes with daily activities or quality of life, recommend treatment with hydroxycarbamide • Hydroxycarbamide therapy should be considered in adults and children with sickle cell disease with genotypes other than SS and Sβ^0 thalassaemia who have recurrent acute pain, acute chest syndrome or episodes of hospitalisation • Hydroxycarbamide therapy should be considered in adults and children with SCD with genotypes other than SS and Sβ^0 thalassaemia for other indications on a case-by-case basis
Place in Therapy Indicate what drugs should have been tried before this drug is considered	Hydroxycarbamide should be discussed with parents/carers of all children with HbSS/Sβ0 thalassemia in the first year of life and be revisited during clinical reviews as appropriate. Hydroxycarbamide can be initiated from 9 months of age in practice; licence is from 2 years of age
Locally agreed off-label use Including supporting information	Off label use from 9 months of age is recommended by the SEL specialist paediatric haematology teams. N.B. licensing is from 2 years of age. Off label use of hydroxycarbamide from 9 months of age is supported by the The British Society of Haematology and The Sickle Cell Society (Guidelines for the use of hydroxycarbamide in children and adults with sickle cell disease and Sickle Cell Disease in Childhood: Standards and Recommendations for Clinical Care » Sickle Cell Society) whose recommendations are based on the results of the BABY HUG trial A multicenter randomised controlled trial of hydroxyurea (hydroxycarbamide) in very young children with sickle cell anaemia - PMC (nih.gov). The national standard for clinical care of children with sickle cell disease is that hydroxvcarbamide should be discussed with all parents of sickle cell disease children and that initiating treatment from 9 months of age can significantly recue the frequency of pain and other vaso-occlusive complications.
Initiation and ongoing dose regime **Note:** • Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimized 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	**Initial stabilisation:** **20 mg / kg/ day*** *it is acknowledged that the licensed starting dose is 10-15mg/kg/day. However local (and national) practice is to start at the higher dose of 20mg/kg/day, based on results of the BABY HUG trial, and consequent recommendations made by the British Society of Haematology. The therapeutic dose range of hydroxycarbamide is 15-35 mg/kg daily. Most children start at a dose of 20 mg/kg daily, rounded to the nearest 100mg. For most patients, the dose is increased by 5mg/kg every 8-12 weeks, until there is evidence of clinical benefit, which is the **lowest effective dose**. **Maintenance dose (following initial stabilisation):**

<table>
<tr><td>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.</td><td colspan="2">Doses can be increased in increments of 2 – 5 mg/kg, with at least 8 -12 weeks between dose changes.
The maximum dose is 35 mg/kg/day

For some indications e.g. Cerebrovascular disease associated with sickle-cell disease, the maximum tolerated dose (MTD) is aimed for i.e. dose at which myelosuppression occurs.

The dose aimed for will be instructed by the specialist team and will be communicated clearly to the GP.

<u>Conditions requiring dose adjustment</u>

Dose increase:
Weight increase (children weighed at least every 6 months by the specialist team), suboptimal response (Hb, MCV, HbF%)

Dose reduction/ temporary discontinuation:
Cytopenia (neutropenia, thrombocytopenia, reticulocytopenia), decreased renal function and any side effect should be discussed and a dose adjustment may be considered

<u>Duration of treatment</u>
Once initiated it is agreed that the treatment should be for no less than 6 months as it can take a considerable amount of time before clinical benefit is seen by the patient/their carer and time must be allowed for this.

When hydroxycarbamide is associated with clinical improvement, it is typically continued long-term. The specialist team may review the patient to discuss initiating alternative disease modifiers alone or alongside hydroxycarbamide if treatment with hydroxycarbamide is suboptimal.</td></tr>
<tr><td rowspan="4">Pharmaceutical aspects

Refer to the SEL Paediatric Formulary for further detail</td><td>Route of administration</td><td>Enteral</td></tr>
<tr><td>Formulation</td><td>Oral solution Xromi® 100mg/1mL (500mg/5mL)
Tablet Siklos® 100mg, 1000mg
Capsule 500 mg</td></tr>
<tr><td>Administration details</td><td>The prescribed dose should be taken once a day.
It may be taken with or after meals at any time of the day but patients should standardise the method of administration and time of day.

Doses should be taken at the same time each day, however it can be taken within 12 hours.
If a dose is missed, and it is more than 12 hours after the time it is normally taken, do not take it and do not double the next dose.

Siklos® 100mg tablets may be halved
Siklos® 1000mg tablets may be quartered
For patients who are not able to swallow the tablets, these can be disintegrated immediately before use in a small quantity of water in a teaspoon. Adding a drop of syrup or mixing with food can mask a possible bitter taste</td></tr>
<tr><td>Other important information</td><td>Xromi ®oral solution must be kept in the refrigerator. It has a shelf life of 2 years, or 12 weeks after opening.

The formulation a child is prescribed is dependent on patient preference and in discussion with the specialist team. The specialist team will recommend the formulation that the GP should prescribe and will notify them of any changes in this.</td></tr>
<tr><td>Baseline investigations, initial monitoring and</td><td colspan="2"><u>Baseline investigations:</u></td></tr>
</table>

<table>
<tr><td>ongoing monitoring to be undertaken by specialist</td><td colspan="2">FBC, U&Es (including eGFR), sickle cell +thalassaemia screen (including reticulocyte count and HbF%), LFTs

<u>Initial monitoring:</u>

FBC, U&Es (including eGFR), sickle cell +thalassaemia screen (including reticulocyte count and HbF%), LFTs

<u>Ongoing monitoring:</u>

FBC, U&Es (including eGFR), sickle cell +thalassaemia screen (including reticulocyte count and HbF%), LFTs</td></tr>
<tr><td rowspan="2">Ongoing monitoring requirements to be undertaken by primary care*

*N.B. it may be agreed that the specialist haematology team continue to organise ongoing monitoring e.g. if the child is local to the hospital. This arrangement must be confirmed between the specialist and primary care teams.</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>FBC, U&Es (including eGFR), sickle cell +thalassaemia screen (including reticulocyte count and HbF%), LFTs</td><td>Every 2 – 3 months*

*the exact frequency will be specified by the specialist. Note the frequency may change in the event of an adverse effect resulting in a dose change/stop – see below for further detail</td></tr>
<tr><td rowspan="5">Adverse effects and management

Any serious adverse reactions should be reported to the MHRA via the Yellow Care scheme www.mhra.gov.uk/yellowcard

In all cases of a suspected adverse effect, please contact the patient's sickle cell team for advice and support</td><td>Result</td><td>Action for GP</td></tr>
<tr><td>Neutrophils > 1.0, reticulocytes >80 or > 1%, platelets > 80</td><td>Continue current dose.</td></tr>
<tr><td>Neutrophils < 1.0, reticulocytes < 80 (unless Hb > 90g/L) or < 1%, platelets < 80

N.B. If reticulocytes < 80 AND Hb > 90 g/L–continue on the same dose.</td><td>Stop treatment and recheck FBC weekly until
• Neutrophils >1.0 x 10^9/L
• Platelets >80 x 10^9/L
• Hb >45gL and
• Reticulocytes >80 x 10^9/L (unless Hb>90g/L)

Then restart at lower dose. Consider the formulation the child is prescribed; reduce by
2.5-5 mg/kg/day OR
500 mg/day (1 capsule) OR
100 mg/day (1 tablet)

Monitor FBC after 2 weeks and follow as above for dose modifications.

This is the Maximum Tolerated Dose (MTD)</td></tr>
<tr><td>Renal function
Serum creatinine greater than 2x upper limit of normal (ULN) or serial rise over a number of visits</td><td>Discuss with specialist team</td></tr>
<tr><td>Liver function tests
ALT or AST greater than 3x ULN

Leg ulcers or cutaneous vasculitic ulcerations</td><td>Discuss with specialist team

Discuss with specialist team</td></tr>
<tr><td>Advice to patients and carers</td><td colspan="2">The patient should be advised to report any of the following signs or symptoms to their GP/ or attend A&E without delay:</td></tr>
</table>

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.	Fever > 38C, sore throat, bruising, bleeding, lethargy, jaundice, dark urine, alopecia, skin rash, hyperpigmentation of nails, GI disturbances (including nausea, vomiting or diarrhoea) and/or pain not responding to simple analgesia. Patients should be advised 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.
Criteria for stopping treatment e.g. poor response, adverse effects requiring cessation	Neutrophils < 1.0, reticulocytes < 80 or < 1%, platelets < 80 (unless Hb > 90g/L). Stop treatment and recheck FBC weekly until • Neutrophils >1.0 x 10^9/L • Platelets >80 x 10^9/L • Hb >45g/L and • Reticulocytes >80 x 10^9/L (unless Hb>90g/L) Then restart at lower dose –consider the formulation the child is prescribed; reduce by 2.5-5 mg/kg/day OR 500 mg/day (1 capsule) OR 100 mg/day (1 tablet) Monitor FBC after 2 weeks and follow as above for dose modifications. Patients or their carers may wish to withdraw treatment due to lack of clinical improvement, personal views or circumstances, or unwanted side-effects.
Follow up arrangements e.g. frequency of specialist clinic attendance	Face to face every 6 months Telephone consultation – CNS led hydroxycarbamide clinic every 3 months
Pregnancy, paternal exposure 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 GP and the specialist.	<u>Women of childbearing potential/Contraception in males and females</u> Women of childbearing age receiving hydroxycarbamide should be advised to avoid becoming pregnant, and to inform the treating physician immediately should this occur. An effective method of contraception is strongly recommended in women of childbearing potential. Male and female patients on hydroxycarbamide wishing to conceive should stop treatment 3 to 6 months before pregnancy if possible. The evaluation of the risk-benefit ratio should be made on an individual basis taking into consideration the respective risk of hydroxycarbamide therapy against the switch to a blood transfusion programme **<u>Pregnancy</u>** Studies in animals have shown reproductive toxicity (see section 5.3). Patients on hydroxycarbamide should be made aware of the risks to the foetus. There is limited amount of data from the use of hydroxycarbamide in pregnant women. Hydroxycarbamide can cause foetal harm when administered to a pregnant woman. Therefore it must not be administered to patients who are pregnant. Patients on hydroxycarbamide wishing to conceive should stop treatment 3 to 6 months before pregnancy if possible. The patient should be instructed to immediately contact a doctor in case of suspected pregnancy. **<u>Breastfeeding</u>** Hydroxycarbamide is excreted in human breast milk. Because of the potential for serious adverse reactions in breast-feeding infants, breast-feeding must be discontinued while taking hydroxycarbamide
Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Prescribers should be aware that hydroxycarbamide causes macrocytosis, which may mask the incidental development of folic acid and vitamin B12 deficiency. The specialist

	team should be consulted if there are any concerns or any clinical symptoms suggestive of this. Children with sickle-cell disease receiving treatment with hydroxycarbamide should follow the UK schedule of routine immunisations, as well as receiving additional vaccinations due to their risk of infection. Details can be found in the 'Green Book' **Chapter 7: Immunisation of individuals with underlying medical conditions.**
Evidence base for treatment and key references Include hyperlinks to original sources and access dates	• A multicenter randomised controlled trial of hydroxyurea (hydroxycarbamide) in very young children with sickle cell aneamia. The BABY HUG trial. Accessed online 10/7/23. A multicenter randomised controlled trial of hydroxyurea (hydroxycarbamide) in very young children with sickle cell anaemia - PMC (nih.gov) • Guidelines for the use of Hydroxycarbamide in children and adults with sickle cell disease: A British Society for Haematology Guideline. Qureshi et al: British Journal of Haematology 2018 181, 460-475. Accessed online 5/7/23. https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.15235?sid=nlm%3Apubmed • South East London Paediatric Formulary • Charache S, Terrin ML, Moore RD et al. Effect of hydroxycarbamide on the frequency of painful crises in sickle cell anaemia. Multicentre Study of Hydroxyurea. N Engl J Med 1995: 332: 1317-1322 • Sickle Cell Disease in Childhood: Standards & Guidelines for Clinical Care. 3rd Edition November 2019. Accessed online 5/7/23. https://www.sicklecellsociety.org/paediatricstandards/ • Medicines Information for Children: Hydroxycarbamide for sickle cell disease. Accessed online 23/11/22. https://www.medicinesforchildren.org.uk/medicines/hydroxycarbamide-for-sickle-cell-disease/ • Summary of Product Characteristics Hydrea 500mg Hard Capsules. Neon Healthcare Ltd. Last updated 16/08/22. Accessed online 23/11/22. https://www.medicines.org.uk/emc/product/13886/smpc • Summary of Product Characteristics Siklos® (Hydroxycarbamide) 100mg and 1000mg film coated tablets. Masters Pharmaceuticals Ltd. Last updated 13/06/22. Accessed online 23/11/22. https://www.medicines.org.uk/emc/product/10351/smpc • Summary of Product Characteristics Xromi®(Hydroxycarbamide) 100mg/mL oral solution. Nova Laboratories Ltd. Last updated 27/06/22. Accessed online 23/11/22. https://www.medicines.org.uk/emc/product/10549/smpc • BNF for Children. Accessed online 05/06/2023. https://bnfc.nice.org.uk/drugs/hydroxycarbamide/ • NHS England National Shared Care Protocol: Hydroxycarbamide for myeloproliferative disorders and sickle cell disease for patients within adult services. Accessed online 05/06/2023, https://www.england.nhs.uk/publication/shared-care-protocols/#heading-8
To be read in conjunction with the following documents	Medicines for Children patient information leaflet: Hydroxycarbamide for Sickle Cell Disease. Hydroxycarbamide for sickle cell disease – Medicines For Children
Local arrangements for referral Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.	**Guys and St Thomas' NHSFT Paediatric haematology team:** HaemoglobinopathyCNS@gstt.nhs.uk In hours bleep: 2733/ 1621 Out of hours contact: Bleep 0294 (haematology SPR) **Kings College Hospital NHSFT Paediatric haematology team:** kch-tr.paedhaematologycns@nhs.net Out of hours contact: Bleep 544 (haematology SPR) Lewisham and Greenwich NHSFT Paediatric haematology team: lg.paedsicklecellservice@nhs.net Out of hours contact: Bleep 6486 (SPR for the paediatric acute assessment ward)

3. COMMUNICATION AND SUPPORT

Guy's and St. Thomas' Hospital switchboard: 0207 188 7188	
Consultant/specialist team Dr. Samah Babiker – consultant Dr. Nicholas Fordham – consultant **Paediatric Haemoglobinopathy Clinical Nurse Specialists**	Tel: 02071887188 EXT: 56244 Email: Samah.babiker@gstt.nhs.uk Email: Nicholas.Frodham@gstt.nhs,uk Alternative contact: HaemoglobinopathyCNS@gstt.nhs.uk **In hours bleep: 2733/ 1621.** Out of hours contact: Bleep 0294 (haematology SPR)
Medication – Prescribing advice, interactions, availability of medicines GSTT Pharmacy Medicines Helpline	Tel: 0207 188 3003 Email: letstalkmedicines@gstt.nhs.uk
King's College and Princess Royal Hospitals switchboard: 0203 299 9000	
Consultant/specialist team Dr John Brewin – Consultant Dr Subarna Chakravorty – Consultant Dr Sue Height – Consultant Professor David Rees – Consultant **Paediatric Haemoglobinopathy Clinical Nurse Specialists**	Tel: 02032991916 Email: Annette.lamont@nhs.net Alternative contact: kch-tr.paedhaematologycns@nhs.net Out of hours contact: Bleep 544
Medication – Prescribing advice, interactions, availability of medicines Ekua Mills-Robertson Women's and Children Pharmacy Team	Tel: 0203 299 9000 Ext: 39654 Email: ekua.mills-robertson@nhs.net Tel: 0203 299 9000 Ext: 35723 Email: kch-tr.WomenandChildrenPharmacyTeam@nhs.net
Lewisham and Greenwich Hospitals switchboard 020 8333 3000	
Consultant/specialist team Dr.Sarah Wilkinson – consultant (Lewisham Hospital site) Dr. Mustafa Sabir – consultant (Queen Elizabeth Hospital) Hetty Adamah – paediatric sickle cell CNS	Tel: 0203 191 6401 Email: s.wilkinson6@nhs.net Tel: 020 8836 5090 Email secretary Parin Kassam. Parin.kassam@nhs.net Tel: 07741233556 Email: henrietta.adamah@nhs.net Generic email: lg.paedsicklecellservice@nhs.net
Medication – Prescribing advice, interactions, availability of medicines LGT Medicines Information	Tel: 020 8836 4900 Email: LG.QE-Medinfo@nhs.net

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed South East London shared care prescribing guideline for *[insert medicine name]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient/parent/carer	*Yes / No*
The roles of the Specialist/specialist team/ Primary Care Prescriber / Patient/parent/carer and pharmacist have been explained and agreed	*Yes / No*
The patient/parent/carer has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient/parent/carer has received	*Yes / No*
I have provided the patient/parent/carer with sufficient medication to last until	
I have arranged a follow up with this patient in the following timeframe e.g. within 3 months / 6 months (please specify)	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

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, the local NHS in South East London have classified *[insert medicine name]* as a Shared Care medicine, 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 (Regional Medicines Optimisation Committees) 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. NB: Capacity issues to be discussed with local primary care Medicines Optimisation Team prior to returning this form)**	

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: