SCHEDULE 2 – THE SERVICES

A. Service Specifications

<table>
<thead>
<tr>
<th>Service Specification No:</th>
<th>170125S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service</td>
<td>Specialist Haemoglobinopathy Services (all ages)</td>
</tr>
<tr>
<td></td>
<td>• Haemoglobinopathy Coordinating Care Centres</td>
</tr>
<tr>
<td>Commissioner Lead</td>
<td>For local completion</td>
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<tr>
<td>Provider Lead</td>
<td>For local completion</td>
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</table>

1. Scope

1.1 Prescribed Specialised Service

This service specification covers Haemoglobinopathy Coordinating Centres (HCC) to support the provision of specialist and non-specialist haemoglobinopathy services to adults and children and to provide expert opinion and management for complex patients.

1.2 Aim of Service

The overall aim of the service is to reduce levels of morbidity and mortality and improve the experience of all haemoglobinopathy patients by reducing inequities and improving timely access to high quality expert care.

The HCC provides a coordinated leadership function, supporting Specialist Haemoglobinopathy Teams (SHTs) in the delivery of clinical care. Overall, the model of care is about the effectiveness of the SHT and HCC in delivering equity irrespective of where patients live through:

- Governance to improve:
  - access to services
  - access to expertise
- Leadership to improve:
  - patient experience
  - outcomes

HCCs are responsible for coordinating, supporting and promoting a system-wide networked approach to the delivery of haemoglobinopathy services. HCCs will free up SHTs’ time and clinical resources by providing support for the administrative aspects of networked care within its geographical area.

This structure will support and strengthen the network concept; improve sharing of best practice and address systems learning; and reduce unwarranted variation. The HCC will provide additional coordination, training and clinical leadership support for existing networking arrangements.
In order to be a HCC a trust must have, and comply with, a contract to provide SHT services with NHS England. Whilst the HCC’s role is primarily that of a network coordinator, HCCs must demonstrate that they have the clinical expertise to lead the development of their networks and HCCs must be equipped to provide specialist advice. Therefore, HCCs are required to discharge this role in addition to their role as a provider of direct patient care through their role as an SHT.

The purpose of the specification is to outline the responsibilities of HCCs and the relationships that need to be in place with SHTs, the wider health economy and patients.

1.3 Service Description

The role of the HCC is to support and develop its defined network in order to improve access to care and the standards of care. It will do this through various means.

The diagram below describes the network and relationship between the teams. Depending on location and prevalence, a HCC could be responsible for providing network support for one, two or several SHTs.

2.3 Roles and Responsibilities

HCCs will receive funding to coordinate a support team with multidisciplinary specialists. This will be clinically led and professionally managed. An annual programme of work (such as pathway development, supporting training, audit, etc.) will be agreed with commissioners. This will describe the support that will be provided to the SHT network and all hospitals in that geographical area so they can deliver care to their local affected population in accordance with agreed standards, protocols and pathways.
The HCC together with local network arrangements will be responsible for:

- Supporting local providers to register all consented patients on the National Haemoglobinopathy Register and demonstrating that resources invested are delivering effective network arrangements
- Organising a minimum of two meetings a year for all healthcare staff involved in the delivery of care for haemoglobinopathy patients in the defined network; this may be shared through partnership with other networks, if feasible.
- Ensuring local and national protocols and pathways are in place
- Identification of Trans Cranial Doppler (TCD) screening lead who has the responsibility for ensuring the network has adequate numbers of appropriately trained practitioners
- Ensuring nationally agreed quality assurance requirements are met for local providers including TCD, MRI imaging and quality review programmes
- Ensuring NICE guidelines are followed for automated red call transfusions
- Working in partnership with NHSBT to ensure adequate supplies of blood with special requirements available in timely manner to meet patient needs

HCCs will hold a minimum of two business meetings a year. These meetings will include representatives from all SHTs and Local Haemoglobinopathy Teams (LHT) in the agreed network area. These meetings will be used to oversee the agreed programme of work, such as protocol reviews, education and audit.

HCCs will support local workforce planning and will be able to escalate this to a national level, including the national haemoglobinopathies Clinical Reference Group.

Each HCC will work with network and local providers to enable all those involved in the commissioning and delivery of care to haemoglobinopathy patients to put in place models of care supported by pathways, protocols and agreements to:

- Focus on meeting the needs of the local population within its geographical area and service provision, including the training and development of the workforce involved in delivering haemoglobinopathy care
- Interface with other appropriate network arrangements for associated care (e.g. maternity, stroke, hepatitis C, etc.)
- Promote effective work to improve acute care needs of patients by working with local Emergency Departments / local commissioners
- Develop and promote pathways for chronic pain management based on best-practice which avoids unnecessary admissions and improves quality of life for patients
- Work with SHTs to ensure that all eligible patients have access to the appropriate screening for the prevention, identification, monitoring and treatment of complications
- Work with SHTs to promote best practice to ensure access to all transfusion modalities for indicated patients
- Support networks to have effective arrangements for all patients to have an annual review of their care and treatment plan and their condition by appropriately trained staff
- Monitor the NHR, subject to consent, and work with SHTs to ensure
compliance with recording requirements

- Develop pathways for clear and direct access to network specialist advice for complex cases, including out of hours
- Develop pathways for clear and direct access to the NHP for rare or very complex cases or for the consideration of novel therapies
- Ensure that patients and public are involved in clinical service improvement and development across the network
- Work with SHTs and the wider health system to promote self-care and an holistic approach to care
- Support the use of technologies that are able to improve patient care

HCCs will assist with the development of the local pathways that SHTs may have developed, especially where there is best practice to be shared or where pathways cross SHT boundaries. If the pathways are not working effectively, the HCC will work with SHTs and other local teams to address the issues. Changes to the pathway must be quality assured and subject to audit.

The HCC will offer additional clinical specialist support and specialist advice for the management of very complex patients as part of the regional MDTs for non-urgent cases or through the provision of telephone or email advice for outpatient / inpatient care. Complex patients may occasionally (and by exception) have to attend the HCC for review and discussion of disease modifying or experimental therapy or to attend supra-specialist clinics (e.g. pulmonary hypertension, neurology). Exceptionally, it might be necessary to transfer patients for care. HCCs will have the responsibility for ensuring access to supra-specialist/multidisciplinary clinics is equitable across its geographical area.

Elective issues that require escalation to the HCC will normally be via the HCC MDT. The HCC will also need to ensure that there is a mechanism in place for providing advice on emergencies that occur outside of normal working hours. Implementation will be agreed between HCCs and commissioners.

In recognition of the major impact of non-medical determinants of health outcomes in these disorders, the HCC will support networks to demonstrate close working with local commissioners and providers to capitalise on the expertise available outside of the SHT (including secondary, primary, community and voluntary sectors and existing specialist nurses) when designing the care pathways and including discharge planning. Any shortfalls will be reported to the responsible commissioner.

The HCC will lead on research and development, audit (as it relates to demonstrating national consistency / equity of access / outcomes) and educational activities within its network and ensure such activities are linked. It will also co-ordinate and publicise research trials within its geographical area.

The HCC will oversee and support the production of a training and development plan for all healthcare staff involved in the delivery of care for haemoglobinopathy patients in its network. The responsibility for resourcing appropriate training for healthcare staff remains with their employing organisations. Concerns about staff training across a network should be escalated through the network and to the HCC for exploration and resolution with Royal Colleges / GMC / NMC / HEE / commissioners.
HCCs will ensure that, with the right oversight, training, protocols and audit, is high quality care, can be delivered locally by haematologists; paediatricians; pharmacists; primary care; community services; and third sector organisations but that very complex patients can access the expert clinical teams they need. In areas of low prevalence this may mean that HCCs will need to work together.

HCCs will also support access to transfusion expertise where needed and input from red cell immunology expertise within NHSBT for patients with complex transfusion needs.

The HCC will support SHTs to ensure training and protocols for acute care of Sickle Cell disease and thalassaemia are available for all Emergency Departments and haemoglobinopathy hospital care providers in the geographical area. This will ensure that every hospital knows who it should contact for specialist advice and that each network is aware of the local hospitals for which it has responsibility with regard to the haemoglobinopathy referral pathway. Through these links and with the support of commissioners, the HCC will have links with other care providers in the pathway.

The HCC will have responsibility for overseeing the Trans Cranial Doppler (TCD) screening. The HCC will:

- Identify a TCD lead (this could be a vascular scientist or a clinician) who will have the responsibility for ensuring they have adequate numbers of appropriately trained practitioners within their geographical area. The HCC TCD lead will have the responsibility to ensure that the practitioners undergo appropriate quality assurance once this process has been established.
- Hold a list of trained practitioners and review this list on an annual basis
- Provide an annual review, detailing the number of TCDs performed and the number of abnormal TCDs.

The HCC will have responsibility for overseeing access to automated red cell exchange transfusion for sickle cell patients needing long term transfusion therapy for all patients in the geographical region via one or more of the SHTs or LHT depending on where local expertise resides.

This should include a strategy for emergency exchange transfusion in sick patients presenting at centres where Apheresis is not available with clearly defined referral pathways covering in and out of working hours procedures and processes.

1.4 Multi-Disciplinary Teams

Where SHTs feel they need clinical support for patients with complex needs, they may refer to the HCC and/ or the National Haemoglobinopathy Panel (see section 1.5). HCCs will develop protocols for referral.

The HCC will coordinate clinical regional MDT meetings to cover all the SHTs in its area where more complex cases which cannot be fully supported through the SHT or LHT MDT are discussed. Each HCC will agree with its SHTs/LHTs the criteria for such cases to be referred to the HCC and this may vary slightly in each HCC,
depending on the available expertise in the SHT.

The HCC will be responsible for the governance of the MDT. This includes developing and agreeing terms of reference, minute taking and, where appropriate, onward referrals to the National Haemoglobinopathy Panel.

A regional Morbidity and Mortality meeting will be held as part of the regional MDT framework to ensure that learning is shared across all the SHTs in the geographical region of adverse clinical outcomes.

Clinical and laboratory transfusion expertise should be available within MDTs for patients with complex transfusion needs.

HCC MDTs will be expected to utilise videoconferencing and other technologies to improve efficiency. HCCs need to decide what approaches work best for them, providers and their patients. Frequency of meetings will depend on the number and mix of referred cases, but will be expected to be at least monthly. Arrangements will ensure the appropriate expertise and time is available for both sickle cell and thalassaemia/IA patients and this may necessitate separate meetings for these conditions depending on prevalence. For thalassaemia/IA it is likely that HCCs will need to work collaboratively to ensure that the access to expert advice and clinical oversight matches the prevalence and available specialist expertise.

It will adopt best clinical practice, including the recording of advice, discussions and meetings and ratification of advice given by email.

The clinical responsibility of a patient remains with the treating clinician. The HCC will establish shared care agreements with SHTs and LHTs which will describe how the provision of specialist expert support, advice and oversight will be made available to local treating clinicians.

1.5 National Haemoglobinopathy Panel

All HCCs will be required to collaborate in a National Haemoglobinopathy Panel (NHP) for SCD, thalassaemia and rare inherited anaemias. One HCC will be reimbursed to oversee and coordinate it. The contract for coordination of the National Haemoglobinopathy Panel will be reviewed every 3 years.

The NHP will work alongside the Specialised Haemoglobinopathies Clinical Reference Group (CRG), the HCCs, the SHTs and other key bodies in haemoglobinopathies care in order to:

- Drive the delivery of a nationally consistent approach to care envisaged by the CRG and approved by commissioners
- Coordinate the actions taken at SHT and HCC levels to deliver access to specialist oversight and to reduce unwarranted variation
- Provide SHTs and HCCs access to national expert clinical opinion with regard to the treatment of complex patients
- Support the introduction of commissioned innovative therapies by acting as a national panel to consider individual patients most able to benefit and to enable
patients have access to these therapies, irrespective of where they live.

Referrals will be accepted directly or via the SHT or HCC MDT arrangements, depending on what is most appropriate for the patient and the local network. The frequency of meetings will depend on the clinical needs of complex patients. The NHP is expected to use available technologies to improve the efficiency of meetings.

The NHP will also review national mortality/morbidity data to inform the CRG of any changes required in national policy. The NHP will also maintain a list of currently open trials.

The national role will also include collaboration to support and develop work on haemoglobinopathy workforce, working with the Royal Colleges / GMC / NMC / Health Education England etc. to influence training and workforce development.

The NHP will oversee TCD quality assurance (QA) and will agree on requirements for QA once this process has been agreed upon. TCD training may be offered by the NHP or HCC.

The NHP will have representations from:
- Clinicians - medical and nursing representatives from HCC
- Psychology
- Pharmacy
- Co-opted members
- Admin staff
- Patient representation for non-clinical components of leadership discussions, but not as part of MDTs considering patient care.

The clinical responsibility of a patient remains with the treating clinician. The NHP will establish shared care agreements with the HCCs which will describe how the provision of specialist expert support, advice and oversight will be made available to local treating clinicians.

The national Haemoglobinopathies Clinical Reference Group will be available to provide support and advice as required.

1.6 National Haemoglobinopathy Registry

This model will be supported by the National Haemoglobinopathy Registry. This will act as a national repository for:
- Patient information including details of local haemoglobinopathy services and contacts
- Guidelines and protocols
- Educational materials
- Data

Whilst these materials may already be shared on network websites, inclusion on a national website will support patients who may access services across the country.

Each individual HCC and SHTs will have primary responsibility for entering data on their own patients into the Registry and for data quality. HCCs will be responsible for
auditing and benchmarking data quality in their network.

1.7 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

Not applicable for this service specification which is for a coordinating service only.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

Haemoglobinopathies and some rare inherited anaemias are lifelong conditions and patients will access both ongoing routine, as well as specialist, care throughout their lifetime. Patients’ care will be delivered as close to home as possible. Whilst rare and sometimes complex, the ongoing and routine monitoring and treatment of patients with haemoglobinopathy can be managed with the use of protocols, pathways and access to oversight. All care should be linked to and supported by a Haemoglobinopathy Coordinating Centre (HCC).

The configuration of care provision will be based on networks linked to local prevalence, expertise and availability of service providers; this may include acute hospitals, community care, primary care and the voluntary sector. Although much of the care pathway is not specialised, the role of the HCC and SHTs leading networks is specialised and supports the integration of the pathway for the benefit of patients.

HCCs will collaborate with its network of providers, commissioners and other HCCs to develop protocols and pathways to include but not limited to the following:

- Patient information, support, training and self-management
- Patient involvement in service development and improvement across the network jointly with other provider trusts within the network
- Service information and links to NHS Choices
- Contact information, referrals and arrangements for 24/7 access to specialist clinicians by patients and healthcare professionals
- Care plans and alert cards etc.
- Life course (new-born screening; family centred care; transition; pregnancy; reproductive health; end of life)
- Prevention and screening (including TCD screening and screening for chronic complications)
- Education and training
- Routine outpatient monitoring and annual review
- Planned day case and inpatient care
- Emergency care
- Treatment and interventions
- Management of acute complications
- Management of chronic complications
- Co-ordination of supra-specialist services to ensure all eligible patients have access
- Regular audits and benchmarking of clinical and operational service delivery to inform service improvement across the network
• Research and development
• Plan and lead on the service improvement initiatives across the geographical region with its SHTs and local/regional commissioners
• Collaborate with other HCCs across the country for regular benchmarking, guidance development and audits.
• Collaborate with other HCCs across the country as necessary for specialist clinical advice in areas of low prevalence.

Wherever possible, national templates will be produced. The HCC will ensure that an MDT for the consideration of very complex patients is in place and linked to the NHP.

2.2 Referral

New patients enter the service either as babies (notified through the NHS neonatal Sickle Cell and Thalassaemia Screening Programme) or as new migrants to England notified via GPs, community services, emergency departments and other clinical specialities. Patients may also move geographical area.

In all cases, the care provider should be notified in accordance with the specification for care and should in turn notify the HCC.

2.3 Interdependence with other Services

For the specific role of HCC, the interdependencies with other services are
• Specialist haemoglobinopathy teams, local haemoglobinopathy teams and local care services
• Sickle Cell and Thalassaemia Screening Programme
• Access to teleconferencing and videoconferencing facilities

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This specification applies to: all children and adults with Sickle Cell Disease and Thalassaemia and other inherited anaemias requiring transfusion and/ or chelation therapy such as Blackfan Diamond anaemia, pyruvate kinase deficiency and congenital sideroblastic anaemia amongst others.

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?, Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

Note: for the purposes of commissioning health services, this excludes patients who, whilst resident in England, are registered with a GP Practice in Wales, but includes patients resident in Wales who are registered with a GP Practice in England.

3.2 Understanding Local Population Needs
In England there are about 1,500 patients with thalassaemia and 15,000 with SCD and circa 1,000 with rare inherited anaemias. A large number are under 19 years of age. Around 250 babies are born in England each year with SCD compared with 20-30 babies with thalassaemia.

Nearly all SCD affected children born in England, and the majority with thalassaemia, will be identified by the NHS Sickle Cell and Thalassaemia antenatal and neonatal Screening programme. Other new patients may present through migration or late diagnosis. The patient population is unevenly distributed through the country, making equity of access a priority.

Patients with rarer inherited anaemias are scattered throughout England and are often diagnosed late and managed by local haematologists and paediatricians. The numbers of patients in this population are unknown but expected to be relatively small.

Life expectancy for both conditions is progressively improving and is now likely to be in excess of 50 years. Maximising quality of life is an important factor in the organisation of care and in treatment decisions.

Services will need to develop to meet the needs of their local populations. This may mean using outreach and technology to share expertise.

The increasing life expectancy of individuals with these conditions means that the overall prevalence will increase and services will need to develop to meet the needs of older patients with the additional comorbidities encountered with age.

Over time, the advent of new treatments such as gene therapy has the potential to change the prevalence of haemoglobinopathy disorders.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement

This specification has been developed on the basis of clinical consensus, taking into account other examples of networks and multi-disciplinary teams.

The standards, guidelines and quality requirements referred to include:
- Royal College of Nursing – Caring for people with sickle cell disease and thalassaemia syndromes – a framework for nursing staff (2011).
• Specialised Services National Definitions Set (SSNDS) 3rd edition – specialised haemoglobinopathy services (all ages) – Definition No. 38 (2009).
• NHS Sickle Cell and Thalassaemia Screening Programme.
• Sickle cell disease: managing acute painful episodes in hospital, NICE (2012).
• The National Confidential Enquiry into Patient Outcome and Death
• Understanding the Contribution of sickle cell and thalassaemia specialist nurses: a summary report (2012), NHS Sickle Cell and Thalassaemia Screening Programme.
• Transition: Getting it Right for Young People, improving the transition of young people with long term conditions (2006), Department of Health. Gateway reference 5914.
• Spectra Optia for automatic red blood cell exchange in patients with sickle cell disease, NICE Medical technologies guidance [MTG28], March 2016

NHS Outcomes Framework Domains

<table>
<thead>
<tr>
<th>Domain 1</th>
<th>Preventing people from dying prematurely</th>
<th>X</th>
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<tbody>
<tr>
<td>Domain 2</td>
<td>Enhancing quality of life for people with long-term conditions</td>
<td>X</td>
</tr>
<tr>
<td>Domain 3</td>
<td>Helping people to recover from episodes of ill-health or following injury</td>
<td>X</td>
</tr>
<tr>
<td>Domain 4</td>
<td>Ensuring people have a positive experience of care</td>
<td>X</td>
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<tr>
<td>Domain 5</td>
<td>Treating and caring for people in safe environment and protecting them from avoidable harm</td>
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## 4.2 Indicators Include:

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<thead>
<tr>
<th>Number</th>
<th>Indicator</th>
<th>Data Source</th>
<th>Outcome Framework Domain</th>
<th>CQC Key question</th>
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<tr>
<td></td>
<td><strong>Clinical Outcomes</strong></td>
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<tr>
<td>101</td>
<td>Number of cases referred to the HCC for specialist clinical opinion and discussion</td>
<td>HCC via SSQD</td>
<td>1, 2, 3, 4, 5</td>
<td>Effective</td>
</tr>
<tr>
<td>102</td>
<td>The proportion of patients that are referred for clinical advice and guidance to the national panel.</td>
<td>HCC via SSQD</td>
<td>1, 2, 3, 4, 5</td>
<td>Effective</td>
</tr>
<tr>
<td>103</td>
<td>Average length of stay for patients following emergency admission across HCC referring organisations..</td>
<td>HCC via SSQD</td>
<td>3, 4</td>
<td>Effective, caring</td>
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<tr>
<td>104</td>
<td>Proportion of serious events entered on to NHR system by SHTs and reviewed at the HCC morbidity /mortality meetings</td>
<td>HCC via SSQD</td>
<td>2, 4</td>
<td>Safe, well-led</td>
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<td>105</td>
<td>Proportion of patients entered on to the NHR database across the HCC</td>
<td>HCC via SSQD</td>
<td>2, 4</td>
<td>Safe, effective</td>
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<td></td>
<td><strong>Patient Experience</strong></td>
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<td></td>
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<tr>
<td>201</td>
<td>The HCC arranges a consistent approach to the formulation of the patient experience exercise which is undertaken at least annually by SHTs.</td>
<td>Self declaration</td>
<td>4</td>
<td>safe, effective, caring, caring, responsive</td>
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<tr>
<td>202</td>
<td>The HCC will monitor a consistent approach to the patient information available in the SHTs.</td>
<td>Self declaration</td>
<td>4</td>
<td>safe, effective, caring, caring, responsive</td>
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<tr>
<td></td>
<td><strong>Structure and Process</strong></td>
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<tr>
<td>301</td>
<td>There is a policy and process in place for establishing an MDT to discuss complex cases.</td>
<td>Self declaration</td>
<td>1, 2, 3</td>
<td>well-led, effective</td>
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<tr>
<td>302</td>
<td>The HCC meets with their SHTs and Local Hospital Trusts at least twice a year to discuss issues relating to strategy and governance.</td>
<td>Self declaration</td>
<td>2, 4</td>
<td>well-led, safe, effective, responsive</td>
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<td>303</td>
<td>The HCC has a training and education strategy.</td>
<td>Self declaration</td>
<td>2, 4</td>
<td>well-led, safe, effective, responsive</td>
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<tr>
<td>304</td>
<td>There is a named lead for trans-cranial doppler (TCD) screening</td>
<td>Self declaration</td>
<td>2, 4</td>
<td>Safe, effective</td>
</tr>
<tr>
<td>305</td>
<td>The HCC attends National Haemoglobinopathy panel meetings.</td>
<td>Self declaration</td>
<td>2, 4, 5</td>
<td>Well-led</td>
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<tr>
<td>306</td>
<td>There are agreed clinical guidelines in place as detailed within the service specification.</td>
<td>Self declaration</td>
<td>1, 2, 3, 4</td>
<td>Safe, effective, caring, responsive</td>
</tr>
</tbody>
</table>
307 The HCC will formulate and agree clinical pathways and protocols across the geographical area as detailed within the service specification. | Self declaration | 1, 2, 3, 5 | Safe, effective, caring, responsive

308 The HCC consider patients for clinical trials and other well designed studies | Self declaration | 1, 3 | Safe, effective, caring, responsive

Detailed definitions of indicators, setting out how they will be measured, are included in schedule 6.

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C.

4.4 Applicable CQUIN goals are set out in Schedule 4D.

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards
None.

5.2 Other Applicable National Standards to be met by Commissioned Providers
https://www.nice.org.uk/guidance/gs58
https://www.nice.org.uk/guidance/mtg28

5.3 Other Applicable Local Standards
Not applicable

6. Designated Providers (if applicable)
To be completed following provider selection exercise

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

HCC: Haemoglobinopathy Coordinating Centre
SHT: Specialist Haemoglobinopathy Team
LHT: Local Haemoglobinopathy Team
NHP: National Haemoglobinopathy Panel
HEE: Health Education England
SCD: Sickle Cell Disease
MDT: Multi-Disciplinary Team
CRG: Clinical Reference Group
TCD: Trans-Cranial Doppler
MRI: Magnetic Resonance Imaging
RIA: Rare Inherited Anaemia