Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1830
Policy Title	Allogeneic Haematopoietic Stem Cell Transplantation for adults with sickle cell disease
Proposal	**for routine commission**

Integrated Impact Assessment – Index		
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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes with each theme setting out a number of questions. • All figures should be provided up to 5 years only. • The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year. • All questions are answered by selecting a drop-down option or including free text.

- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact	
A1 Activity	
A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment. Include OPCS codes where applicable.	30-40 patients currently eligible *Source:* Policy (clinical consensus) Of the approximate 12-14,000 patients with SCD in the UK, approximately 7-8000 are adults. 10-15% have severe disease with recurrent pain events, recurrent acute complication or severe chronic complications (e.g. stroke). Estimates would indicate that between 128-138 patients may be both eligible and willing to proceed to HSCT at present, including a back-log of patients who are awaiting this treatment. Of these only around 30% would have a fully matched sibling donor (i.e. 30-40 patients). In view of the back log of eligible patients currently awaiting HSCT we would expect this number to be reduced in subsequent years.
A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial)	
A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Current therapies include hydroxycarbamide and blood transfusion. Hydroxycarbamide is the only licensed medication. It should be offered to all adults with repeated acute pain crises, episodes of acute chest syndrome, or severe anaemia. A small population of patients do not respond to hydroxycarbamide and are difficult to transfuse: for these patients we have no alternative treatments. These patients face a life of intermittent severe pain, frequent hospital admissions and an elevated risk of early death in their 20's to 40's. It is no surprise therefore that health related quality of life in adults with sickle cell disease is significantly worse than the general population, with scores that are in

	keeping with those seen in patients on long term haemodialysis (McClish et al 2005 Health Quality Life Outcomes). *Source:* Policy
A2.2 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment	If not known, please specify Click here to enter text or 'Not applicable'.. a) 100% b) 10-15% c) 10-15% d) 10% *Source: Policy*
A3 Comparator (next best alternative treatment) Patient Pathway **(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)**	
A3.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** If yes, Click here to enter text. *Source: required*
A3.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment	Total estimated eligible or 'Not applicable'. a) enter % b) enter %

b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment	c) enter % d) enter % *Source:* *required*
A4 New Patient Pathway	
A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, e.g patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle. Include OPCS codes where applicable.	**One off** Allogeneic Haematopoietic stem cell transplantation (HSCT) (also known as BMT) is a procedure which replaces the patient's own blood stem cells and immune system with those from a healthy donor, enabling the establishment of normal blood and immune system functions. The rationale for proposing allogeneic stem cell transplantation for adults is to provide a curative option for those people with severe disease in whom other treatments have failed or have not been tolerated. This pathway will only be commissioned for HLA matched sibling HSCT as this is associated with the best survival figures and the lowest rates of adverse outcomes. The outcomes following this type of HSCT are better than outcomes with standard care for those with severe SCD. Only about 20% of patients will have a HLA matched sibling donor and will be able to have this type of HSCT *Source:* *Policy*
A5 Treatment Setting	
A5.1 How is this treatment delivered to the patient?	**Acute inpatient hospital setting**

A5.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>5</td></tr><tr><td>MIDLANDS & EAST</td><td>4</td></tr><tr><td>LONDON</td><td>6</td></tr><tr><td>SOUTH</td><td>3</td></tr></table>
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	No
A6 Coding	
A6.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* <table><tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr><tr><td>Patient level contract monitoring</td><td>☒</td></tr><tr><td>Patient level drugs dataset</td><td>☒</td></tr><tr><td>Patient level devices dataset</td><td>☐</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☒</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr><tr><td>Clinical Database**</td><td>☐</td></tr></table>

	Other** ☐ **If National Return, Clinical database or other selected, please specify: Click here to enter text.
A6.2 Specify how the activity related to the new patient pathway will be identified.	ICD10 ☒ Treatment function code ☒ HRG ☒ Data will also be on survival and long term outcomes also provided via British Society of Bone Marrow Transplant Database
A6.3 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A6.4 **Identification Rules for Activity:** How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** NCBPS02Z BLOOD AND MARROW TRANSPLANTATION SERVICES
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Tertiary Allogeneic Stem Cell Transplant Centres *Source: required*
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify:

	Click here to enter text. *Source: required*
B2 Geography & Access	
B2.1 How is the service currently accessed (e.g., self referral, referral from GP, secondary care, other)	Please specify: secondary care referral Click here to enter text.
B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: Will be referred from current Haemoglobinopathy specialist centres
B2.3 Is the new policy likely to improve equity[1] of access?	**Increase** Please specify: The new policy specifically addresses equity of access to Allo-HSCT based medical indication and not age. *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B2.4 Is the new policy likely to improve equality[1] of access and/or outcomes?	**Increase** Improve equality as offers a curative option for those people with severe disease in whom other treatments have failed or have not been tolerated. Click here to enter text. *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*

[1] https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf

B3 Commissioning Responsibility

B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibility), future CCG lead, devolved commissioning arrangements, STPs)	**No change - NHSE** Please specify: Click here to enter text.

Section C - Finance Impact

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff – other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding HCTED programme) – pass through	☐
	Excluded from tariff (excluding HCTED) – other	☐
	Via HCTED model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☒
	Partially paid by National Tariffs	☐

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>C1.2 Drug Costs (to be completed by LC)
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Drug costs included in local tariffs</td></tr>
<tr><td>C1.3 Device Costs(to be completed by LC)
Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information.
NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Click here to enter text.</td></tr>
<tr><td>C1.4 Activity Costs covered by National Tariffs (to be completed by Finance)
List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatients appointment etc.</td><td>Click here to enter text.</td></tr>
</table>

C1.5 **Activity Costs covered by Local Tariff** *(to be completed by Finance)* List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	The service is covered by the following national currency codes which are locally priced: SA38A Peripheral Blood Stem Cell Transplant, Allogeneic (Sibling), 19 years and over SA38B Peripheral Blood Stem Cell Transplant, Allogeneic (Sibling), 18 years and under SA39A Peripheral Blood Stem Cell Transplant, Allogeneic (Volunteer Unrelated Donor), 19 years and over SA39B Peripheral Blood Stem Cell Transplant, Allogeneic (Volunteer Unrelated Donor), 18 years and under SA40Z Peripheral Blood Stem Cell Transplant, Allogeneic (Donor Type Not Specified)
C1.6 **Other Activity Costs not covered by National or Local Tariff** *(to be completed by Finance)* Include descriptions and estimates of all key costs.	Click here to enter text.
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	**Yes** Please specify: Decisions on patient treatment will be undertaken by the existing National Haemoglobinopathy Panel with clinical transplantation input, with commissioner oversight of the governance arrangements.
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	Include the cost per patient over 5 years e.g. 1 average patient starting on day 1 of year 1 continuing for 5 years (for ongoing treatment) or in any 1 financial year (for one-off treatments). Costs are **prior** to commercially confidential or volume based discounts. Provide clear description of how the calculation was reached or provide the calculation.

<table>
<tr><td></td><td></td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.</td><td>Choose an item.<table><tr><td>Year 1</td><td>£k</td></tr><tr><td>Year 2</td><td>£k</td></tr><tr><td>Year 3</td><td>£k</td></tr><tr><td>Year 4</td><td>£k</td></tr><tr><td>Year 5</td><td>£k</td></tr></table></td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Click here to enter text.</td></tr>
<tr><td>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</td><td>Click here to enter text.</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
Choose an item.</td></tr>
</table>

	<table><tr><td>Year 1</td><td>£k</td></tr><tr><td>Year 2</td><td>£k</td></tr><tr><td>Year 3</td><td>£k</td></tr><tr><td>Year 4</td><td>£k</td></tr><tr><td>Year 5</td><td>£k</td></tr></table> Budget impact for providers: Choose an item. <table><tr><td>Year 1</td><td>£k</td></tr><tr><td>Year 2</td><td>£k</td></tr><tr><td>Year 3</td><td>£k</td></tr><tr><td>Year 4</td><td>£k</td></tr><tr><td>Year 5</td><td>£k</td></tr></table>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	Choose an item. <table><tr><td>Year 1</td><td>£k</td></tr><tr><td>Year 2</td><td>£k</td></tr><tr><td>Year 3</td><td>£k</td></tr><tr><td>Year 4</td><td>£k</td></tr><tr><td>Year 5</td><td>£k</td></tr></table>

C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	Choose an item. Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG prioritisation reserve
C6 Financial Risks Associated with Implementing this Policy	
C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	Click here to enter text.
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	Click here to enter text.
C7 Cost Profile	
C7.1 Factors which impact on costs	Choose an item. If yes, specify type and range: Click here to enter text.

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

<table>
<tr><td></td><td></td><td>Source</td><td>Please specify any further detail</td></tr>
<tr><td>Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.</td><td>[Enter number]</td><td></td><td></td></tr>
<tr><td>Age group for which the treatment is proposed according to the proposed criteria</td><td>Adults only</td><td>Policy</td><td>Paediatrics already commissioned</td></tr>
<tr><td>Age distribution of the patient population eligible according to the proposed criteria</td><td>Not applicable</td><td></td><td></td></tr>
<tr><td>How is the population currently geographically distributed</td><td>Evenly/unevenly
<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table></td><td>Policy proposition (section 6)</td><td></td></tr>
<tr><td>What are the growth assumptions for the disease / condition?</td><td></td><td>Policy proposition (section 6)</td><td></td></tr>
</table>

Is there evidence of current inequalities in access to service or outcomes?			
Is there evidence that implementing the service specification will improve current inequities of access or outcomes?			