Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1742
Policy Title	Allogeneic Haematopoietic Stem Cell Transplant for Primary Immunodeficiencies (all ages) Proposal **for routine commission** (ref A3.1)

Integrated Impact Assessment – Index		
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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- 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.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Over 320 different genetic forms of Primary Immune Deficiencies (PID) are described, all of which are rare. The estimated prevalence of PID in the UK is around 4500 patients. Most patients with severe combined immune deficiency (SCID) present shortly after birth and require immediate intervention, but other forms of immune deficiency may present in later childhood or adulthood. *Source: Policy section 6.*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	Currently the number of eligible patients for Allo-HSCT is between 70-80 transplants per year (all ages). Eligibility is determined by disease, availability of appropriate donor and medical fitness for transplant. *Source: British Society of Bone and Marrow Transplant (BSBMT) registry.* Between 2013 and 2016, 60-68 people per year received Allo-HSCT for PID in the UK. These transplants were mainly in children, and a small number in adults funded via IFR based on the assessment of individual cases. The recently published interim urgent policy statement (Jan 2018) for Allo-HSCT for adult PID patients has resulted in 10 transplants per year in adults.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** Allo-HSCT for PID is already commissioned for paediatrics (18 years and under) by NHS England, this policy extends this to adults.

<table>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>0-65 years (patients need to be judged medically fit for Allo-HSCT).
We expect the majority of adult patients will be aged 19-50 years, with rare older exceptions.
Source: UK PIN Registry and BSBMT Registry.
Please specify
It is expected that the vast majority of Allo-HSCT for PID will continue to be performed for paediatric patients (approx. 85% of total Allo-HSCT).
Adult PID patients will constitute up to 15% of total Allo-HSCT performed under this policy.</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Unevenly</u>
If unevenly, estimate regional distribution by %:<table><tr><td>North</td><td>40%</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>60%</td></tr><tr><td>South</td><td>enter %</td></tr></table>Source: Policy Section 6
Please specify
Patients 18 years and under:
Currently > 90% of Allo-HSCT for PID is carried out in two centres in the Newcastle and London. It is likely the activity would remain similar with all ages policy.

The proposed policy recommends that Allo-HSCT for PID is performed in centres with appropriate expertise after approval by the National MDT (Policy Section 10).</td></tr>
<tr><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2">A2 Future Patient Population & Demography</th></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Constant</u>

If other, Click here to enter text.
Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Please specify
Click here to enter text.
Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?</td><td>
<table>
<tr><td>YR2 +/-</td><td>13</td></tr>
<tr><td>YR3 +/-</td><td>13</td></tr>
<tr><td>YR4 +/-</td><td>13</td></tr>
<tr><td>YR5 +/-</td><td>13</td></tr>
<tr><td>YR10 +/-</td><td>14</td></tr>
</table>
Source: Service specification proposition section 3.1
This net increase includes the 10 adult patients covered by the current urgent policy statement. Net change in Allo-HSCT above 2018-19 activity over the next 2-5 and 10 years is likely to be small, 3-5 per year.

Net growth is expected to be broadly stable, any increases will be due to:
I. increased awareness of role of Allo HSCT for selected adult PID patients,
II. small increase in identification of eligible patients as a result of genome sequencing initiatives and/or newborn screening for SCID.</td></tr>
</table>

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	The average number of babies/children transplanted per year is not expected to change significantly. **Yes** Due to very small numbers involved ONS growth of adult population is negligible.
A3 Activity	
A3.1 What is the purpose of new policy?	**Confirm routine commissioning position of an additional new treatment** Please specify • Replace the urgent policy statement currently in place for adults with PID with a full commissioning policy. • Develop a documented commissioning policy for the existing routinely commissioned Allo-HSCT service for PID in children. • Define the subgroups of patients with PID for whom Allo-HSCT will be commissioned routinely. • Reduce variation in access to Allo-HSCT for PID patients by producing an all ages policy.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	Between 2013 and 2016, 60-68 people per year in UK. *Source:* BSBMT database. Please specify Since the approval of the Urgent Policy Statement, an additional 10 adult patients have been transplanted since February 2018
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	70-80 Allo HSCT per year (all ages). *Source:* BSBMT Registry and National Adult PID BMT MDT.

	Please specify Estimates based on current activity from BSBMT database and under urgent policy statement.
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable as no other curative options currently available in routine clinical practice. *Source: required* Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Paediatric Patients The current standard treatment for severe combined immune deficiencies (SCID) in children (18 years and under) is Allo-HSCT. Allo-HSCT is a curative treatment for SCID, and without it no patients would survive to adolescence. For other types of PID in children the decision to treat with Allo-HSCT is made on an individual basis. NHS England has routinely commissioned Allo-HSCT in children in accordance with the 2011 BSBMT paediatric indications table, since 1993 it has been commissioned routinely as part of the Highly Specialised Service (HSS) for Severe Combined Immunodeficiency and Related Disorders (children). Adult Patients The standard alternative treatments to Allo-HSCT include: immunoglobulin (IVIg) replacement therapy for patients with B cell deficits; systemic immunosuppressive therapy for patients with auto-inflammatory/immune dysregulation complications; chemotherapy for patients with PID-associated malignancies and broad spectrum

	antimicrobials (including anti-virals and anti-fungals) for all patients with susceptibility to infections. Since February 2018 an Urgent Policy Statement allowed Allo-HSCT for selected adult patients with PID. *Source: Policy*
A4.2. What are the current treatment access and stopping criteria?	Alternative conservative treatment is not curative and is lifelong. Stopping criteria not relevant for Allo-HSCT. *Source: Policy*
A4.3 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 e) Complete treatment?	If not known, please specify Click here to enter text. Adult Conservative PID Management a) 100% b) 0% c) 100% d) 90% e) 90% *Source: estimate based on clinical experience* Adult Allo-HSCT (Urgent Policy Statement) – currently 11 per year a) 100% b) 0% c) 100% d) 100% e) 100% *Source: National Adult PID BMT MDT* Paediatric Allo-HSCT (Highly Specialist Commissioning) – currently 60-68 per year a) 100%

	b) 0% c) 100% d) 100% e) 100% *Source: estimate based on clinical experience*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **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*
A5.2 What percentage of the total eligible population is estimated 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 e) Complete treatment?	Not applicable a) b) c) d) e) *Source:*
A6 New Patient Pathway	

A6.1 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 e) Complete treatment?	If not known, please specify Click here to enter text. a) 100% b) 20% c) 80% d) 80% e) 80% *Source: Policy*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Allogeneic Haematopoietic stem cell transplantation (HSCT – also known as BMT): 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 immune system functions. The patient pathway is described in detail in the BMT service specifications for adults (B04/S/a) and children (B04/S/b) respectively. For time limited treatments, specify frequency and/or duration. Click here to enter text. *Source: Policy*
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	*Select all that apply:* Emergency/Urgent care attendance ☐ Acute Trust: inpatient ☒ Acute Trust: day patient ☐ Acute Trust: outpatient ☐

	<table><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table> Please specify: Click here to enter text.
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>8</td></tr><tr><td>MIDLANDS & EAST</td><td>6</td></tr><tr><td>LONDON</td><td>7</td></tr><tr><td>SOUTH</td><td>4</td></tr></table> NHSE will commission from specialised Allo-HSCT centres, which must have the appropriate level of expertise, experience and infrastructure to deliver allo-HSCT in this patient population which must consist of Adult and Paediatric PID services. It may be considered more appropriate clinically for the procedure to be undertaken by an alternative HSCT centre, where this is advised by the National PID HSCT MDT. Where this is decided networking arrangements between providers must be in place, with the appropriate level of governance for shared care agreements.

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: Click here to enter text. *Source: required*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☐ Patient level contract monitoring ☒ Patient level drugs dataset ☒ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☒ Mental Health Services DataSet (MHSDS) ☐ National Return** ☐ Clinical Database** ☐ Other** ☐ **If National Return, Clinical database or other selected, please specify: Click here to enter text.
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:*

	<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☒</td></tr><tr><td>Treatment function code</td><td>☒</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☒</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table>
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**Not applicable**
A8.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** NCBPS02Z BLOOD AND MARROW TRANSPLANTATION SERVICES
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**None** Please specify Click here to enter text.

<table>
<tr>
<td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td>
<td>Select all that apply:
<table>
<tr><td>Drugs or Device MDS</td><td>☐</td></tr>
<tr><td>Blueteq</td><td>☐</td></tr>
<tr><td>Other prior approval</td><td>☒</td></tr>
</table>
Please specify: Decisions on patient treatment will be undertaken by the existing regional paediatric or national adult PID HSCT MDTs, with commissioner oversight of the governance arrangements.</td>
</tr>
<tr>
<td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td>
<td><u>No</u>
If yes, please specify mitigation:
Click here to enter text.</td>
</tr>
<tr>
<td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td>
<td><u>Yes</u>
If yes, please specify contract monitoring requirement:
Monitored as per local arrangements for BMT contract monitoring</td>
</tr>
<tr>
<td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td>
<td><u>Yes</u>
If yes, specify how routine performance monitoring data will be used for dashboard reporting.
Submission to BSBMT database
If no, will one be developed?
Click here to enter text.</td>
</tr>
<tr>
<td>A9.6 NICE reporting
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?</td>
<td><u>No</u>
If yes, specify how performance monitoring data will be used for this purpose.
Click here to enter text.</td>
</tr>
</table>

<table>
<tr><th colspan="2">Section B - Service Impact</th></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Tertiary Allogeneic Stem Cell Transplant Centres
Source: required</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u>
Please specify:
Click here to enter text.
Source: required</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
GP ☐
Secondary care ☐
Tertiary care ☒
Other ☐
Please specify:
Click here to enter text.</td></tr>
</table>

B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: Click here to enter text.
B2.3 Is the new policy likely to improve equity 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*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** Please specify: Click here to enter text. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Click here to enter text.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.

<table>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>No change</u>
Please complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future
State expected range</td><td>Provisional or confirmed</td></tr>
<tr><td>North</td><td>8</td><td>8</td><td>C</td></tr>
</table></td></tr>
</table>

Midlands & East	6	6	C
London	7	7	C
South	4	4	C
Total	25	25	C

Please specify:

NHSE will commission from specialised Allo-HSCT centres, which must have the appropriate level of expertise, experience and infrastructure to deliver allo-HSCT in this patient population which must consist of Adult and Paediatric PID services. It may be considered more appropriate clinically for the procedure to be undertaken by an alternative HSCT centre, where this is advised by the Combined All Ages National PID HSCT MDT. Where this is decided networking arrangements between providers must be in place, with the appropriate level of governance for shared care agreements.

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

Publication and notification of new policy	☒
Market intervention required	☐
Competitive selection process to secure increase or decrease provider configuration	☐
Price-based selection process to maximise cost effectiveness	☐
Any qualified provider	☐
National Commercial Agreements e.g. drugs, devices	☐
Procurement	☐
Other	☒

	Please specify: Click here to enter text.
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No** 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 ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐

		Paid entirely by Local Tariffs	☒
		Partially paid by National Tariffs	☐
		Partially paid by Local Tariffs	☐
		Part/fully paid under a Block arrangement	☐
		Part/fully paid under Pass-Through arrangements	☒
		Part/fully paid under Other arrangements	☐
C1.2 **Drug Costs** 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. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Drug costs included in local tariffs.		
C1.3 **Device Costs** 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.	Not applicable.		
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Click here to enter text.		

C1.5 **Activity Costs covered by Local Tariff** 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) The average cost of providing an adult BMT recognising the ratios of provision is £TBC.
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**Yes** Please specify: Decisions on patient treatment will be undertaken by the existing regional paediatric or national adult PID HSCT MDTs, with commissioner oversight of the governance arrangements.
C2 Average Cost per Patient	
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	YR1 £TBC

<table>
<tr>
<td>Are there any changes expected in year 6-10 which would impact the model?</td>
<td>
<table>
<tr><td>YR2</td><td>£TBC</td></tr>
<tr><td>YR3</td><td>£TBC</td></tr>
<tr><td>YR4</td><td>£TBC</td></tr>
<tr><td>YR5</td><td>£TBC</td></tr>
</table>
If yes, please specify:
Yes development of national tariff for Allo-HSCT
</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.</td>
<td>
<u>TBC</u>
Please specify:
<table>
<tr><td>YR1</td><td>£TBC</td></tr>
<tr><td>YR2</td><td>£TBC</td></tr>
<tr><td>YR3</td><td>£TBC</td></tr>
<tr><td>YR4</td><td>£TBC</td></tr>
<tr><td>YR5</td><td>£TBC</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>Not applicable</td>
</tr>
</table>

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?	Not applicable
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost neutral** Budget impact for providers: **Cost neutral** Please specify: Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**TBC** Please specify:
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not Applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** 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 What are the material financial risks to implementing this policy?	There is a risk that the number of people diagnosed with PID for allo-HSCT, and therefore eligible for allo-HSCT, will increase in future years due increased awareness of role of Allo HSCT for selected adult PID patients and a small increase in identification of eligible patients as a result of genome sequencing initiatives and/or newborn screening for SCID.
C6.2 How can these risks be mitigated?	The increase in numbers is likely to be low in the short-term. Also there are likely to be more new treatments such as gene therapy coming to market in the medium term to long term whose introduction is likely to further affect the number of people treated with Allo-HSCT.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	The scenarios tested were: 1. Continuing with current conservative management pathway for adults with PID and Allo-HSCT for paediatric patients with PID, or 2. Implement Allo-HSCT for a group of adults that meet commissioning criteria and continuing with Allo-HSCT for paediatrics as currently commissioned.
C6.4 What scenario has been approved and why?	Continuing with current commissioning for Allo-HSCT in paediatric patients and providing Allo-HSCT in adult patients that meet commissioning criteria. This option is more expensive in years 1-3, however overall it becomes a cost saving to NHS England due to

<table>
<tr><td></td><td>reduced on-going treatment costs of serious PID in a small number of adults.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☒</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr>
</table>Please specify:
Click here to enter text.</td></tr>
</table>

C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	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 not for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing routine commissioning