

Integrated Impact Assessment Report for Service Specifications

Service Specification Reference Number	1668		
Service Specification Title	Thrombotic thrombocytopenic purpura Proposal <u>for routine commission</u> (source A3.1)		
Lead Commissioner	Joan Ward	Clinical Lead	Prof Marie Scully
Finance Lead	Keith Moulds	Analytical Lead	Craig Charlton

Integrated Impact Assessment – Index

Section A – Activity	Section B - Service	Section C – Finance
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this service specification to NHS England
A4 Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this service specification to the NHS as a whole
A5 Service Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this service specification
A7 Monitoring		C7 Value for Money
		C8 Cost Profile

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 service specification 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

<p>A1.1 Prevalence of the disease/condition.</p>	<p>TTP is a very rare, complex condition which can present as an acute life threatening disorder that requires prompt diagnosis, early referral and effective immediate management in a centre with comprehensive provision and a multi-discipline approach. Specialist aftercare is also required. There is also a cohort of patients who have a congenital form of the disease who require on going apheresis. The Specialist led co-ordinated care is key to improving outcomes for this patient group. The prevalence is 330 patients in England, with an acute incidence of 150 patients in England</p> <p><i>Source: Service Specification Proposition section 3.1</i></p>
<p>A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.</p>	<p>It is estimated that the prevalence of this disease in England is 330 people with approximately 150 acute admissions a year , the whole cohort are eligible for follow up care</p> <p><i>Source: TTP Patient Registry</i></p> <p>Please specify</p> <p>Click here to enter text.</p>
<p>A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.</p>	<p><u>All ages</u></p> <p>Please specify</p> <p>Click here to enter text.</p>
<p>A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria</p>	<p>Not applicable</p> <p><i>Source: required</i></p> <p>Please specify</p> <p>Click here to enter text.</p>

A1.5 How is the population currently distributed geographically?

unknown

If unevenly, estimate regional distribution by %:

North	enter %
Midlands & East	enter %
London	enter %
South	enter %

Source: Service specification proposition section 6

Please specify

[Click here to enter text.](#)

A2 Future Patient Population & Demography

A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?

Constant

If other, [Click here to enter text.](#)

Source: Service specification proposition section 3.1

A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?

No

Please specify

[Click here to enter text.](#)

Source: Service specification proposition section 6/other

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?

YR2 +/-	2
YR3 +/-	3
YR4 +/-	4

<p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p>	<table border="1"> <tr> <td>YR5 +/-</td> <td>5</td> </tr> <tr> <td>YR10 +/-</td> <td>10</td> </tr> </table>	YR5 +/-	5	YR10 +/-	10	<p><i>Source: Service specification proposition section 3.1</i></p> <p><u>Yes</u> Click here to enter text.</p>
YR5 +/-	5					
YR10 +/-	10					
<p>A3 Activity</p>						
<p>A3.1 What is the purpose of new service specification?</p>	<p><u>Provide service specification for a new service approved to be commissioned by NHS England for the first time in accordance with PSSAG / other recommendation</u></p> <p>*PSSAG (Prescribed Specialised Services Advisory Group) Please specify Click here to enter text.</p>					
<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>c150 <i>Source:</i> Please specify TTP Registry</p>					
<p>A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?</p>	<p>c150 <i>Source:</i> TTP Patient Registry Please specify Click here to enter text.</p>					

A4 Patient Pathway	
<p>A4.1 Patient pathway Describe the current patient pathway and service.</p>	<p>There is no formal commissioned pathway for this disease. TTP presents very acutely and patients normally present in Accident and Emergency departments. They may be referred to a centre with some expertise in this disease or they may be treated in the presenting hospital, with our without expert advice. Patients become acutely ill very quickly and may require admission to critical care; they will always require acute admission to haematology. The first line treatment is apheresis, usually two sessions a day but can be three dependent on the patient. Patients will usually be inpatient for two weeks. Patients can be treated with monoclonal antibodies and this drug is continued post discharge and may be used to help prevent a relapse. This is a lifelong condition with a high risk of relapse. There is also a cohort of patients with suspected TTP whom do not have the disease. Due to the severe morbidity of the disease these patients are treated as though they have TTP for the first 24 hours approximately of the pathway. Once the diagnosis is confirmed as being another disorder, the patients leave the TTP pathway. The paediatric activity already sits within the NHS England portfolio and no changes are proposed to this pathway so it is therefore not considered in this document.</p> <p><i>Source: required</i></p>
<p>A4.2. What are the current service access and stopping criteria?</p>	<p>Patients present in an acute context, the condition is lifelong and patients will require lifelong monitoring</p> <p><i>Source: required</i></p>
<p>A4.3 What percentage of the total eligible population are:</p> <ul style="list-style-type: none"> a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria 	<p>If not known, please specify Click here to enter text.</p> <ul style="list-style-type: none"> a) It is not known how many patients die without being diagnosed but approximately 150 patients present for treatment acutely each year b) 100% c) 0% <p><i>Source TTP Registry and BSH guidelines</i></p>

A4.4 What percentage of the total eligible population is expected to:

- a) Be referred to the proposed service
- b) Be eligible for care according to the proposed criteria for the service
- c) Take up care according to the proposed criteria for the service
- d) Continue care according to the proposed criteria for the service?

If not known, please specify [Click here to enter text.](#)

- a) All patients who present acutely, approximately 50% of the prevalent population
- b) 100%
- c) All patients with a confirmed diagnosis would be expected to take up the care
- d) 100%

Source:BSH Guideline

A4.5 Specify the nature and duration of the proposed new service or intervention.

Life long

[Click here to enter text.](#)
Source: required

A5 Service Setting

A5.1 How is this service delivered to the patient?

Select all that apply:

Emergency/Urgent care attendance	<input checked="" type="checkbox"/>
Acute Trust: inpatient	<input checked="" type="checkbox"/>
Acute Trust: day patient	<input checked="" type="checkbox"/>
Acute Trust: outpatient	<input checked="" type="checkbox"/>
Mental Health provider: inpatient	<input type="checkbox"/>
Mental Health provider: outpatient	<input type="checkbox"/>

	<table border="1"> <tr> <td data-bbox="972 97 1536 156">Community setting</td> <td data-bbox="1536 97 1615 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="972 156 1536 215">Homecare</td> <td data-bbox="1536 156 1615 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="972 215 1536 276">Other</td> <td data-bbox="1536 215 1615 276"><input type="checkbox"/></td> </tr> </table>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input type="checkbox"/>			
Community setting	<input type="checkbox"/>									
Homecare	<input type="checkbox"/>									
Other	<input type="checkbox"/>									
<p>A5.2 What is the current number of contracted providers for the eligible population by region?</p>	<table border="1"> <tr> <td data-bbox="972 427 1391 486">NORTH</td> <td data-bbox="1391 427 1615 486">1</td> </tr> <tr> <td data-bbox="972 486 1391 545">MIDLANDS & EAST</td> <td data-bbox="1391 486 1615 545">0</td> </tr> <tr> <td data-bbox="972 545 1391 604">LONDON</td> <td data-bbox="1391 545 1615 604">1</td> </tr> <tr> <td data-bbox="972 604 1391 644">SOUTH</td> <td data-bbox="1391 604 1615 644">0</td> </tr> </table>	NORTH	1	MIDLANDS & EAST	0	LONDON	1	SOUTH	0	<p>Please specify: Click here to enter text.</p> <p>There are two providers who have services which are formally recognised by local commissioners as providing specialised services to patients with TTP. Royal Liverpool and Broadgreen FT is one of these providers, the service is wholly funded by CCGs. UCLH provide the largest service in England, the service receives funding from NHS England as part of a legacy agreement and also receives funding from CCGs .</p> <p>There are approximately 20 providers who contribute to the TTP registry who would regard themselves as providing a service but it is not officially commissioned as such by CCGs or NHS England</p>
NORTH	1									
MIDLANDS & EAST	0									
LONDON	1									
SOUTH	0									
<p>A5.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p><u>yes</u> Please specify:</p> <ul style="list-style-type: none"> . Designated providers will have to guarantee capacity in relation to critical care and acute haematology <ul style="list-style-type: none"> • 24/7 access to therapeutic apheresis; where this is not directly provided but subcontracted, the clinical responsibility and decision making 									

	<p>remains with the regional specialist TTP team.</p> <ul style="list-style-type: none"> • Level 3 Critical Care Facilities • Interventional Radiology/ IV Access Team access 24/7 for urgent line insertion for patients not entering critical care • Specialist Haematology Ward • Dedicated TTP Consultant Team with 24/7 on call availability • A named paediatric haematologist for congenital TTP delivered through the clinical partnership with the paediatric specialist centre • Intensive care specialists with experienced in the management of this condition. • Support patient groups as part of the service development • Clinical Nurse Specialist, • Trust Approved Patient Pathways, SOPs and Protocols will be based on the Clinical guideline that accompanies this service specification. • Ability to carry out the appropriate diagnostics, including access to ADAMTS13 testing 7 days a week. • Access to neurological, cardiac and other relevant services e.g. rheumatology, HIV, specialist obstetrics • Access to a dedicated clinical psychologist. • Participate in national clinical forum and enter data onto the national registry <p><i>Source: Service Specification</i></p>
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A6 Coding

<p>A6.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="987 1273 1749 1334"> <tr> <td data-bbox="987 1273 1653 1334">Aggregate Contract Monitoring *</td> <td data-bbox="1653 1273 1749 1334" style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> </table>	Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>
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	<table border="1"> <tr><td>Patient level contract monitoring</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Patient level drugs dataset</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Patient level devices dataset</td><td><input type="checkbox"/></td></tr> <tr><td>Devices supply chain reconciliation dataset</td><td><input type="checkbox"/></td></tr> <tr><td>Secondary Usage Service (SUS+)</td><td><input type="checkbox"/></td></tr> <tr><td>Mental Health Services DataSet (MHSDS)</td><td><input type="checkbox"/></td></tr> <tr><td>National Return**</td><td><input type="checkbox"/></td></tr> <tr><td>Clinical Database**</td><td><input type="checkbox"/></td></tr> <tr><td>Other**</td><td><input type="checkbox"/></td></tr> </table>	Patient level contract monitoring	<input checked="" type="checkbox"/>	Patient level drugs dataset	<input checked="" type="checkbox"/>	Patient level devices dataset	<input type="checkbox"/>	Devices supply chain reconciliation dataset	<input type="checkbox"/>	Secondary Usage Service (SUS+)	<input type="checkbox"/>	Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>	National Return**	<input type="checkbox"/>	Clinical Database**	<input type="checkbox"/>	Other**	<input type="checkbox"/>	
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Clinical Database**	<input type="checkbox"/>																			
Other**	<input type="checkbox"/>																			
<p>A6.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr><td>OPCS v4.8</td><td><input type="checkbox"/></td></tr> <tr><td>ICD10</td><td><input type="checkbox"/></td></tr> <tr><td>Service function code</td><td><input type="checkbox"/></td></tr> <tr><td>Main Speciality code</td><td><input type="checkbox"/></td></tr> <tr><td>HRG</td><td><input type="checkbox"/></td></tr> <tr><td>SNOMED</td><td><input type="checkbox"/></td></tr> <tr><td>Clinical coding / terming methodology used by clinical profession</td><td><input checked="" type="checkbox"/></td></tr> </table>	OPCS v4.8	<input type="checkbox"/>	ICD10	<input type="checkbox"/>	Service function code	<input type="checkbox"/>	Main Speciality code	<input type="checkbox"/>	HRG	<input type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>					
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<p>A6.3 Identification Rules for Drugs:</p>	<p><u>Not already specified in current NHS England Drugs List document</u></p>																			

<p>How are any drug costs captured?</p>	<p>If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply: The drugs used to treat TTP are on the NHS England Drugs list but listed for this indication. The drugs that are excluded from tariff are monoclonal antibodies, velcade. Octaplas is in tariff but in the volumes used for treating patients with TTP it is regarded as excluded for this service.</p> <p>Click here to enter text.</p> <p>If drug(s) NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:</p> <p>SMT agreed that NHS England would assume the commissioning responsibility for this service, including the drugs used currently and that policies for their use would be developed with two years.</p> <p>Click here to enter text.</p>
<p>A6.4 Identification Rules for Devices: How are device costs captured?</p>	<p><u>Not applicable</u></p> <p>If device(s) covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance) for all that apply:</p> <p>Click here to enter text.</p> <p>If device(s) not excluded from Tariff nor covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.</p> <p>Click here to enter text.</p>
<p>A6.5 Identification Rules for Activity: How are activity costs captured?</p>	<p><u>Not captured by an existing specialised service line</u></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>Click here to enter text.</p> <p>If activity costs are already captured please specify whether this service needs a separate code. <u>Yes</u></p> <p>If the activity is captured but the service line needs amendment please specify</p>

	<p>whether the proposed amendments have been documented and agreed with the Identification Rules team.</p> <p>Raised with the IR team</p> <p>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <u>No has been raised with the IR team</u></p>
A7 Monitoring	
<p>A7.1 Contracts</p> <p>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p> <p>Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.</p>	<p><u>Yes - population of clinical databases</u></p> <p>Please specify</p> <p>Providers will be required to report to the TTP registry</p>
<p>A7.2 Business intelligence</p> <p>Is there potential for duplicate reporting?</p>	No
<p>A7.3 Contract monitoring</p> <p>Is this part of routine contract monitoring?</p>	<p><u>Yes</u></p> <p>If no, please specify contract monitoring requirement: This is the contractual expectation when the service is commissioned.</p> <p>Click here to enter text.</p>
<p>A7.4 Dashboard reporting</p> <p>Specify whether a dashboard exists for the proposed service?</p>	<p><u>No</u></p> <p>If yes, specify how routine performance monitoring data will be used for dashboard reporting.</p>

	<p>Click here to enter text.</p> <p>If no, will one be developed</p> <p>Yes</p>
<p>A7.5 NICE reporting</p> <p>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new service specification?</p>	<p>No</p> <p>If yes, specify how performance monitoring data will be used for this purpose.</p> <p>Click here to enter text.</p>
<p>Section B - Service Impact</p>	
<p>B1 Service Organisation</p>	
<p>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</p>	<p>There is no formal commissioned pathway for this disease. TTP presents very acutely and patients normally present in Accident and Emergency departments. They may be referred to a centre with some expertise in this disease or they may be treated in the presenting hospital, with our without expert advice. Patient become acutely ill very quickly and may require admission to critical care; they will always require acute admission to haematology. The first line treatment is apheresis, usually two sessions a day but can be three dependent on the patient. Patients will usually be inpatient for two weeks. Patients can be treated with monoclonal antibodies and this drug is continued post discharge. This is a lifelong condition with a high risk of relapse. Follow up is not stanadardised.</p> <p><i>Source: required</i></p>
<p>B1.2 Will the specification change the way the commissioned service is organised?</p>	<p>Yes</p> <p>Please specify:</p> <p>The service will be reorganised into about eight regional footprints .TTP specialist centres will sit within a defined geographical site/Trusts covered by the service. This information will be readily accessible by referring Trusts and the ambulance</p>

	<p>service covering the defined area. Regional Services must be accessible within a window transfer time of 2 hours to avoid delays in treatment Air transport is also an option for patients in very exceptional circumstances. Paediatric patients present in very small numbers and the expertise to care for this cohort is limited. Regional centres will develop a clinical partnership with expert paediatric haematologists.</p> <p><i>Source: required</i></p>								
<p>B1.3 Will the specification require a new approach to the organisation of care?</p>	<p><u>Implement a new model of care</u></p> <p>Services will be delivered from approximately 8 regional centres that may develop shared care with other hospitals, dependent on the clinical scenario and the patient's preference. Acute care will be centralised in the regional centres.</p>								
<p>B2 Geography & Access</p>									
<p>B2.1 Where do current referrals come from?</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="987 815 1496 1050"> <tr> <td>GP</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Tertiary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table> <p>Please specify: Click here to enter text.</p>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input type="checkbox"/>								
<p>B2.2 What impact will the new service specification have on the sources of referral?</p>	<p><u>No impact</u></p> <p>Please specify: Click here to enter text.</p>								

<p>B2.3 Is the new service specification likely to improve equity of access?</p>	<p><u>Increase</u> Please specify: Patients will be able to access expert centres in a managed pathway of care from a network of regional centres. <i>Source: Equalities Impact Assessment</i></p>
<p>B2.4 Is the new service specification likely to improve equality of access and/or outcomes?</p>	<p><u>Increase</u> Please specify: As patients will be able to access expert centres in a managed pathway of care from a network of regional centres it is expected that the mortality and morbidity rate will be greatly improved. Currently the mortality rate is 50% in non-specialist centres; this will reduce by 30% following the implementation of the service specification. <i>Source: Equalities Impact Assessment</i></p>
<p>B3 Implementation</p>	
<p>B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?</p>	<p><u>Procurement action</u> Please specify: There will need to be a provider selection process in a lotted approach across the country</p>
<p>B3.2 Time to implementation: Is a lead-in time required prior to implementation?</p>	<p><u>Yes - go to B3.3</u> If yes, specify the likely time to implementation: 3-6 months for most potential providers 3-6 months</p>
<p>B3.3 Time to implementation:</p>	<p><u>Yes</u></p>

<p>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p>If yes, outline the plan: It is likely that some areas in the country would be in a position to mobilise more quickly than others so when the provider selection is completed an implementation plan can be developed in more detail.</p>
<p>B3.4 Is a change in provider physical infrastructure required?</p>	<p>No Please specify: Click here to enter text.</p>
<p>B3.5 Is a change in provider staffing required?</p>	<p>Yes Please specify: Dedicated TTP Consultant Team with 24/7 on call availability A named paediatric haematologist for congenital TTP delivered through the clinical partnership with the paediatric specialist centre Clinical Nurse Specialist, Access to a clinical psychologist</p>
<p>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p>	<p>Yes Please specify: Access to apheresis 24/7 within 90 minutes, neurological, cardiac and other relevant services e.g. rheumatology, HIV, specialist obstetrics</p>
<p>B3.7 Are there changes in the support services that need to be in place?</p>	<p>No Please specify: Click here to enter text.</p>
<p>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p>	<p>Yes Please specify: Whilst the majority of the acute care will be delivered by the regional centre, there</p>

	<p>will be some areas of the country for whom the physical distance will be greater. Specialist regional centres will make appropriate arrangements for either initial plasma exchange treatment or for expedited transfer to the regional centre</p>																								
<p>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</p>	<p>Choose an item. Please complete the table:</p> <table border="1" data-bbox="987 352 1912 799"> <thead> <tr> <th>Region</th> <th>Current no. of providers</th> <th>Future State expected range</th> <th>Provisional or confirmed</th> </tr> </thead> <tbody> <tr> <td>North</td> <td>5</td> <td>3</td> <td>select</td> </tr> <tr> <td>Midlands & East</td> <td>6</td> <td>3</td> <td>select</td> </tr> <tr> <td>London</td> <td>4</td> <td>1</td> <td>select</td> </tr> <tr> <td>South</td> <td>5</td> <td>1</td> <td>select</td> </tr> <tr> <td>Total</td> <td></td> <td></td> <td>select</td> </tr> </tbody> </table> <p>Please specify: The current pool of providers offer a differential level of expertise based on the number of patients presenting. This is a very rare disease. The more centres that are commissioned the more the expertise to provide the care to the appropriate standard are diluted. Some regions have more developed services than others, one centre in London treats a third of patients in the country diagnosed with an acute phase of the disease annually. The distance to treatment centres has been modelled using isochrones which supports the modelling and will be repeated during the procurement process.</p>	Region	Current no. of providers	Future State expected range	Provisional or confirmed	North	5	3	select	Midlands & East	6	3	select	London	4	1	select	South	5	1	select	Total			select
Region	Current no. of providers	Future State expected range	Provisional or confirmed																						
North	5	3	select																						
Midlands & East	6	3	select																						
London	4	1	select																						
South	5	1	select																						
Total			select																						
<p>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</p>	<p>Select all that apply:</p> <table border="1" data-bbox="987 1254 1899 1342"> <tr> <td>Publication and notification of new service specification</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Publication and notification of new service specification	<input checked="" type="checkbox"/>																						
Publication and notification of new service specification	<input checked="" type="checkbox"/>																								

	Market intervention required	<input checked="" type="checkbox"/>
	Competitive selection process to secure increase or decrease provider configuration	<input checked="" type="checkbox"/>
	Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>
	Any qualified provider	<input type="checkbox"/>
	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>
	Procurement	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
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:

This is a rare disease and the provider catchment areas will extend over more than one STP/integrated care system

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	<input checked="" type="checkbox"/>
		Excluded from tariff - other	<input type="checkbox"/>
	Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
		Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>
		Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>
		Via Zero Cost Model	<input type="checkbox"/>
		Activity	Paid entirely by National Tariffs
	Paid entirely by Local Tariffs		<input type="checkbox"/>
	Partially paid by National Tariffs		<input checked="" type="checkbox"/>
	Partially paid by Local Tariffs		<input checked="" type="checkbox"/>
	Part/fully paid under a Block arrangement		<input checked="" type="checkbox"/>
	Part/fully paid under Pass-Through arrangements		<input checked="" type="checkbox"/>
	Part/fully paid under Other arrangements		<input type="checkbox"/>
<p>C1.2 Drug Costs</p> <p>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.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>Patients will require the following drugs and dosing</p> <ol style="list-style-type: none"> 1. Rituximab (mabthera) list price of £1,886 per dose inc VAT and patients will require up to 20 doses per annum an average cost of £7,543 per patient; this takes into account those patients who require additional doses on an outpatient basis to avoid relapse and readmission 2. Octoplas – patients will require excess Octoplas as having apheresis multiple times per day at a cost of £66.30 inclusive of VAT, patients will require up to 22 additional octoplas doses per treatment 		
<p>C1.3 Device Costs</p>	<p>N/A</p>		

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.

C1.4 Activity Costs covered by National Tariff
 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.

Non elective

		Spells	Tariff
SA14Z	Plasma Exchanges, 2 to 9	31	£10,980
SA13 A	Single Plasma Exchange, Leucophoresis or Red Cell Exchange, 19 years and over	18	£582
HD23J	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 0-2	16	£846
HD23 H	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 3-4	15	£1,600
SA15Z	Plasma Exchanges, 10 to 19	10	£10,980
	Other	60	

Day cases

		Spells	Tariff
SA13 A	Single Plasma Exchange, Leucophoresis or Red Cell Exchange, 19 years and over	365	£437
HD23J	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 0-2	218	£349
SA13 B	Single Plasma Exchange, Leucophoresis or Red Cell Exchange, 18 years and under	52	£579

	HD23 H	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 3-4	33	£392
	PH34 D	Paediatric, Musculoskeletal or Connective Tissue Disorders, with CC Score 0	27	£615
	HD23 G	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 5-6	24	£448
	HD23 F	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 7-8	16	£729
	YR43 A	Attention to Central Venous Catheter, 19 years and over	13	£227
	SB97Z	Same Day Chemotherapy Admission or Attendance	11	£0
	HD23 E	Inflammatory, Spine, Joint or Connective Tissue Disorders, with CC Score 9-11	10	£1,303
		Other	23	

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

[Click here to enter text.](#)

proposed or established and if newly proposed how is has been derived, validated and tested.

C1.6 Other Activity Costs not covered by National or Local Tariff
 Include descriptions and estimates of all key costs.

Proposed Block payment for infrastructure staff

Post	WTE	Grade	Gross Cost for 1.00	Additional costs
Consultants	0.7	YC72	£125,000	£87,500
Clinical Nurse Specialists	1.0	8a	£58,000	£58,000
Psychologist	0.5	7	£52,000	£26,000
	2.2			£171,500
Total For 8 Sites	17.6			£1,372,000

Notes and assumptions
1-each site requires 2 PA's per consultant per site for outreach and 5 PA's for clinical time
2-Salaries do not include London HCAS
3-Grades are assumed as bandings as shown
4-Cost include all on costs

C1.7 Are there any prior approval mechanisms required either during

No
 Please specify: [Click here to enter text.](#)

implementation or permanently?

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	£40.8k
YR2	£40.8k
YR3	£40.8k
YR4	£40.7k
YR5	£40.6k

If yes, please specify:
None

Are there any changes expected in year 6-10 which would impact the model?

C3 Overall Cost Impact of this Service specification to NHS England

<p>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</p>	<p><u>Cost pressure</u> Please specify: Cost pressure of £2.2m which is due to the switch of activity at the designated centres from CCG to NHSE and also the additional costs of staffing at the new centres.</p>
<p>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</p>	<p>N/A</p>
<p>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?</p>	<p>The current activity will vary geographically from year to year so the proposed methodology would be a top slice based on current allocations.</p>

C4 Overall cost impact of this service specification to the NHS as a whole

<p>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</p>	<p>Budget impact for CCGs: <u>For CCG's there will be a saving based on the activity transferring to NHSE . Their saving will not be the same as the additional costs as there will be additional spells pre transfer of patients to the designated centres.</u> Budget impact for providers: <u>Cost neutral</u> Please specify: Click here to enter text.</p>
<p>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</p>	<p><u>Cost pressure</u> Please specify:</p>
<p>C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured</p>	<p>N/A</p>
<p>C4.4 Are there likely to be any costs or</p>	<p><u>No</u> Please specify:</p>

savings for non-NHS commissioners and/or public sector funders?	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.	Clinical Panel Advisory Group (CPAG) prioritisation which may be offset by transfers from CCG if these can be negotiated
C6 Financial Risks Associated with Implementing this Service specification	
C6.1 What are the material financial risks to implementing this service	No Material Financial risks

specification?	
C6.2 How can these risks be mitigated?	N/A
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Prudent approach adopted recognising the maximum number of patients potentially impacted
C6.4 What scenario has been approved and why?	Maximum Patient volume of 150
C7 Value for Money	
C7.1 What published evidence is available that the service is	<u>There is no published evidence of cost-effectiveness</u> Please specify: Click here to enter text.

<p>cost effective as evidenced in the evidence review?</p>																
<p>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="344 347 1391 959"> <tr> <td data-bbox="344 347 1317 475">Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td> <td data-bbox="1317 347 1391 475"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="344 475 1317 564">Available pricing data suggests the service is lower cost compared to current/comparator treatment</td> <td data-bbox="1317 475 1391 564"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="344 564 1317 654">Available clinical practice data suggests the new service specification has the potential to improve value for money</td> <td data-bbox="1317 564 1391 654"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="344 654 1317 715">Other data has been identified</td> <td data-bbox="1317 654 1391 715"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="344 715 1317 775">No data has been identified</td> <td data-bbox="1317 715 1391 775"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="344 775 1317 865">The data supports a high level of certainty about the impact on value</td> <td data-bbox="1317 775 1391 865"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="344 865 1317 959">The data does not support a high level of certainty about the impact on value</td> <td data-bbox="1317 865 1391 959"><input type="checkbox"/></td> </tr> </table> <p>Please specify: Click here to enter text.</p>	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	<input type="checkbox"/>	Available pricing data suggests the service is lower cost compared to current/comparator treatment	<input type="checkbox"/>	Available clinical practice data suggests the new service specification has the potential to improve value for money	<input type="checkbox"/>	Other data has been identified	<input type="checkbox"/>	No data has been identified	<input checked="" type="checkbox"/>	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>	
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Other data has been identified	<input type="checkbox"/>															
No data has been identified	<input checked="" type="checkbox"/>															
The data supports a high level of certainty about the impact on value	<input type="checkbox"/>															
The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>															
<p>C8 Non-Recurrent Costs</p>																
<p>C8.1 Are there non-recurrent revenue costs</p>	<p>No If yes, please specify and indicate whether these would be incurred or passed through to NHS England: Click here to enter text.</p>															

<p>associated with this service specification?</p>	<p>If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact. Choose an item.</p>
<p>C8.2 Are there any non-recurrent provider capital costs associated with the service specification?</p>	<p>No If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs). Click here to enter text.</p>