

Integrated Impact Assessment Report for Service Specifications

Service Specification Reference Number	1737		
Service Specification Title	Proton Beam Therapy PBT (All ages) Proposal <u>for routine commission</u> (source A3.1)		
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Finance Lead	Keith Moulds	Analytical Lead	Click here to enter text.

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Section A - Activity Impact

A1 Current Patient Population & Demography / Growth

<p>A1.1 Prevalence of the disease/condition.</p>	<p>The service specification covers a number of rare cancers and prevalence varies by age group (paediatric, teenage & young adult (TYA), adult) <i>Source: Clinical Commissioning Policies for PBT (Paediatric, TYA, Adult)</i></p>
<p>A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.</p>	<p>At full capacity up to 1500 patients per year will be eligible for Proton Beam Therapy (PBT) <i>Source: Service Specification</i> Please specify</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> Please specify The service specification should be read in conjunction with the clinical commissioning policies for PBT which can be found at https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b01/</p>
<p>A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria</p>	<p>All Ages <i>Source: Service specification Proposal section 3.1. Clinical Commissioning Policies for Paediatric, TYA & Adult</i> Please specify All Ages</p>
<p>A1.5 How is the population currently distributed geographically?</p>	<p><u>Evenly</u> If unevenly, estimate regional distribution by %:</p>

	<table border="1"> <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>	North	enter %	Midlands & East	enter %	London	enter %	South	enter %	<p><i>Source: Service specification proposition section 6</i></p> <p>Please specify</p> <p>The NHS PBT service will be a national service, provided from two centres in Manchester (from Aug 2018) and London (from 2020). Although numbers within current commissioning policies are very low, there are patients that will access the service from Scotland and Northern Ireland and possibly Wales (especially North Wales pathway).</p>
North	enter %									
Midlands & East	enter %									
London	enter %									
South	enter %									
<p>A2 Future Patient Population & Demography</p>										
<p>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?</p>	<p><u>Increasing</u></p> <p>If other, <i>Source: Service specification proposition section 3.2</i></p>									
<p>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</p>	<p><u>Yes</u></p> <p>Please specify</p> <p>UK population has grown from 61.4m in 2008/09 to 65.5m in 2017 & the UK has the second highest birth rate in western Europe. With a very high proportion of paediatric and TYA cancers indicated for PBT, a relative growth rate of population has been assumed to be 10% for these cases up to 2018 and 6.4% for 2018-2028, as this will have a disproportionate impact on proton demand.</p> <p>A growth rate of overall 7% has been assumed for adult cancers to 2018 and 6.4% 2018 - 2028.</p>									

	<i>Source: ONS.</i>											
<p>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?</p> <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>YR2 +/-</td> <td>578</td> </tr> <tr> <td>YR3 +/-</td> <td>852</td> </tr> <tr> <td>YR4 +/-</td> <td>1316</td> </tr> <tr> <td>YR5 +/-</td> <td>1500</td> </tr> <tr> <td>YR10 +/-</td> <td>1500</td> </tr> </table>	YR2 +/-	578	YR3 +/-	852	YR4 +/-	1316	YR5 +/-	1500	YR10 +/-	1500	<p><i>Source: PBT Transition Plan</i></p> <p>No</p> <p>The clinical indications eligible for PBT will be expanded as available capacity increases up to 1500 patients per week. It is anticipated that the majority of the additional clinical indications will be for adult patients.</p>
YR2 +/-	578											
YR3 +/-	852											
YR4 +/-	1316											
YR5 +/-	1500											
YR10 +/-	1500											
A3 Activity												
<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)</p> <p>Please specify</p> <p>Two PBT centres are under construction, at The Christie, Manchester and University College London Hospitals (UCLH). These are complex multi-million pound builds underwritten by DH (capital) and NHS England (revenue). The Christie centre will open in summer 2018 and treat its first patient in August 2018. UCLH will open in late summer 2020.</p>											

<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>Approximately 200 patients per annum <i>Source: PBT Overseas Programme</i> Please specify Under the Proton Overseas Programme approximately 200 patients are eligible and able to access PBT in the USA or Switzerland. It is anticipated that changes in clinical commissioning policy will add up to 50 cases per annum prior to the NHS service opening in August 2018</p>
<p>A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?</p>	<p>1500 patients at full capacity <i>Source: PBT Service Specification</i> Please specify Maximum capacity for the NHS PBT service will be 1500 patients per annum. Clinical indications eligible for PBT will be expanded as capacity is available</p>
<p>A4 Patient Pathway</p>	
<p>A4.1 Patient pathway Describe the current patient pathway and service.</p>	<p>There are currently 4 clinical commissioning policies for PBT:</p> <ul style="list-style-type: none"> • Proton Beam Radiotherapy (High Energy) for Paediatric Cancer Treatment • Proton Beam Radiotherapy (High Energy) for Teenage and Young Adult Cancer Treatment • Proton Beam Radiotherapy (High Energy) for Skull Base Tumour Treatment (Adult) • Proton Beam Therapy for Cancer of the Prostate <p>An application for referral for PBT is made to the National PBT Clinical Panel, chaired by Dr Adrian Crellin. This is a virtual panel consisting of clinical experts from across the country. The panel reviews each</p>

	<p>application and assess this against the criteria contained in the clinical commissioning policies. If approved, the panel makes a commissioning recommendation that a referral can be made and this is communicated to the referring clinician. The referring clinician will then make a direct referral to an approved overseas treatment centre.</p> <p>Approximately 200 - 230 patients are 'approved for referral' per annum. It is estimated this figure could reach as high as 250.</p> <p><i>Source: PBT Overseas Programme</i></p>
<p>A4.2. What are the current service access and stopping criteria?</p>	<p>These are included in the clinical commissioning policies listed in A4.1</p> <p><i>Source: PBT Clinical Commissioning Policies</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: This is a complex service as it covers the radiotherapy element of treatment in a group of relatively rare cancers. The challenges of treatment abroad will limit access in itself and should not to be underestimated, so the figures below represent what is referred into the Overseas Programme and numbers approved for PBT. For paediatric cancer there are limits to current referral, mainly concerning timing and safety, but the relative referral rate is very high but exact quantification is difficult to judge without an analysis of RTDS and/or CCLG activity profiles by centre. For certain paediatric diagnoses very high levels of referral are already within the Proton Overseas Programme pathways (Low Grade Glioma/Ependymoma/Rhabdomyosarcoma/Peripheral Primitive Neuroectodermal Tumours (PPNET) The pathways of referral away from local radiotherapy departments in these areas are well established. For the very different tumour range in adult policies, whilst the pathways exist now, in skull base, spinal and head and neck cancers there are barriers due to surgical quality aspects or complications in alignment of UK vs EU and USA clinical policies and supportive care before and after treatment that mean uptake for PBT is still variable and approvals against policy relatively low.</p> <ul style="list-style-type: none"> a) Numbers referred Average per annum

	<p>a)1 -Paediatric 133 a)2 TYA 34 a)3 Adult 58 b)1 Paediatric 92% b)2 TYA 91% b)3 Unknown as no denominator numbers</p> <p><i>Source: NHS England Proton Overseas Programme database years 2014-2016</i></p>
<p>A4.4 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> 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? 	<p>If not known, please specify Changes to the Paediatric and TYA Policies that include Medulloblastoma and several other rare cancers will increase potential access to PBT. In addition, having a service delivered in the UK will allow an unmet need for many patients (often immediate post-op or at risk due to chemotherapy and too ill to safely travel abroad) to be addressed.</p> <p>The impact of radiotherapy with PBT for adult skull base spinal and other sarcomas as well as less common head and neck cancers close to the skull base will increase access. This aligns with the concepts within the wider current NHS England Radiotherapy Modernisation framework.</p> <p>For all other future adult indications the numbers are likely to be very small relative numbers of patients spread across the whole range of cancer types for which radiotherapy is used and limited to small subsets of more common cancers and also patients in clinical trials. Given that the overall PBT capacity available within the two NHS PBT centres represents only 0.5-1% of all radiotherapy in the UK and therefore very limited, the impact on the existing adult RT services will be minimal.</p> <p>The assessment given below against current commissioning policies can only be in orders of magnitude as disease and site-specific data is not available for what is Not currently referred (see explanations above).</p>

	<p>a1 – Paediatric cancer RT uptake HIGH (excluding TBI/whole brain RT and palliative RT)</p> <p>a) a2 – TYA cancers RT uptake MEDIUM/HIGH</p> <p>a) a3 – Adult Skull Base Sarcomas uptake HIGH</p> <p>a) a4 - Adult Spinal /Paraspinal Sarcomas uptake HIGH</p> <p>Adult Paranasal and Head and Neck spectrum Skull Base Cancers uptake MEDIUM/HIGH</p> <p>b) Uptake estimates as above in a</p> <p>c) Inverse of above</p> <p>Source: Experience from Proton Overseas Programme and Site Specialist National Clinical Reference Panel discussions and NHS England RT Modernisation framework.</p>		
<p>A4.5 Specify the nature and duration of the proposed new service or intervention.</p>	<p>One off</p> <p>For time limited services, specify frequency and/or duration.</p> <p>Treatment will be delivered on an outpatient basis, 5 days per week over a 6-8 week period.</p> <p>Source: PBT Service Specification 3.2</p>		
<p>A5 Service Setting</p>			
<p>A5.1 How is this service delivered to the patient?</p>	<p>Select all that apply:</p> <table border="1" data-bbox="1086 1281 1713 1342"> <tr> <td data-bbox="1086 1281 1637 1342">Emergency/Urgent care attendance</td> <td data-bbox="1637 1281 1713 1342"><input type="checkbox"/></td> </tr> </table>	Emergency/Urgent care attendance	<input type="checkbox"/>
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	<table border="1"> <tr> <td>Acute Trust: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: day patient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: outpatient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Homecare</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table>	Acute Trust: inpatient	<input type="checkbox"/>	Acute Trust: day patient	<input type="checkbox"/>	Acute Trust: outpatient	<input checked="" type="checkbox"/>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input type="checkbox"/>	
Acute Trust: inpatient	<input type="checkbox"/>																	
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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>	<p>Please specify: Treatment will be delivered on an outpatient basis, 5 days per week over a 6-8 week period.</p> <table border="1"> <tr> <td>NORTH</td> <td>1</td> </tr> <tr> <td>MIDLANDS & EAST</td> <td>number</td> </tr> <tr> <td>LONDON</td> <td>1</td> </tr> <tr> <td>SOUTH</td> <td>number</td> </tr> </table>	NORTH	1	MIDLANDS & EAST	number	LONDON	1	SOUTH	number									
NORTH	1																	
MIDLANDS & EAST	number																	
LONDON	1																	
SOUTH	number																	
<p>A5.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p>yes Please specify: Two PBT centres are under construction, at The Christie, Manchester and University College London Hospitals (UCLH). These are complex multi-million pound builds underwritten by DH (capital) and NHS England (revenue). The Christie centre will open in summer 2018 and treat its first patient in August 2018. UCLH will open in late summer 2020. <i>Source: PBT Development Agreement</i></p>																	

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:

Aggregate Contract Monitoring *	<input type="checkbox"/>
Patient level contract monitoring	<input type="checkbox"/>
Patient level drugs dataset	<input 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 checked="" type="checkbox"/>

**If National Return, Clinical database or other selected, please specify:
RTDS

A6.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

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"/>

	<table border="1"> <tr> <td data-bbox="1081 97 1753 156">SNOMED</td> <td data-bbox="1753 97 1850 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1081 156 1753 248">Clinical coding / terming methodology used by clinical profession</td> <td data-bbox="1753 156 1850 248"><input checked="" type="checkbox"/></td> </tr> </table>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>
SNOMED	<input type="checkbox"/>				
Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>				
<p>A6.3 Identification Rules for Drugs: How are any drug costs captured?</p>	<p><u>Not applicable</u> If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply:</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>A6.4 Identification Rules for Devices: How are device costs captured?</p>	<p><u>Not applicable</u> 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>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>A6.5 Identification Rules for Activity: How are activity costs captured?</p>	<p><u>Already captured by an existing specialised service line (NCBPS code) within the PSS Tool but needs amendment</u></p> <p>If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.</p>				

	No. Radiotherapy HRG will need to be amended to include PBT
A7 Monitoring	
<p>A7.1 Contracts Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. 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 - other</u> Please specify Specific analytical information, monitoring and reporting is required for the following:</p> <ul style="list-style-type: none"> - Open-book accounting (finance and activity) - Activity - Quality Indicators - Outcomes <ul style="list-style-type: none"> - Clinical - Patient reported outcomes
<p>A7.2 Business intelligence Is there potential for duplicate reporting?</p>	<p><u>No</u> If yes, please specify mitigation:</p>
<p>A7.3 Contract monitoring Is this part of routine contract monitoring?</p>	<p><u>Yes</u> If no, please specify contract monitoring requirement:</p>
<p>A7.4 Dashboard reporting Specify whether a dashboard exists for the proposed service?</p>	<p><u>No</u> If yes, specify how routine performance monitoring data will be used for dashboard reporting.</p>

	<p>If no, will one be developed?</p> <p>Detailed Quality Indicators have been developed for this service. These will be included in section 6 of the standard NHS Contract to be put in place for the service</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>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>Patients whose conditions are eligible for PBT under current clinical commissioning policy and are able to be treated overseas in centres in the USA and Switzerland.</p> <p>Patients whose conditions are not eligible or unable to travel are treated with conventional radiotherapy.</p> <p><i>Source: PBT Overseas Programme</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 majority of curative paediatric radiotherapy, excluding TBI, will be undertaken at the NHS PBT centres, thus impacting significantly on the NHS paediatric radiotherapy service. The proton overseas programme has already had a very significant impact on the activity of paediatric radiotherapy in existing paediatric RT centres. The NHS based PBT service will allow access to patients currently unable to travel abroad due to safety, logistic (including being denied entry into the USA) or timing</p>

	<p>issues. It is anticipated there will be further impact on the throughput and activity levels at current NHS providers of paediatric radiotherapy, particularly as the treatment of Craniospinal radiation for Medulloblastoma transfers to the NHS PBT service.</p> <p><i>Source: Cancer Programme of Care Board</i></p>								
<p>B1.3 Will the specification require a new approach to the organisation of care?</p>	<p>Other</p> <p>Please specify:</p> <p>The Radiotherapy CRG is reviewing the impact the new PBT service will have on paediatric radiotherapy</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="1086 751 1599 986"> <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:</p> <p>Referrals are made via Specialist Cancer Centres</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>No impact</p> <p>Please specify:</p> <p>Referral sources/networks are already established through the Proton Overseas Programme</p>								

<p>B2.3 Is the new service specification likely to improve equity of access?</p>	<p><u>Increase</u> Please specify: The new NHS PBT service will allow for the expansion of clinical indications eligible for PBT. It will also allow those patients currently eligible, but unable to access PBT for clinical (too unwell) or social reasons (e.g. not allowed entry to the USA) to access treatment <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 2.3 above. An expected benefit of PBT is that patient outcomes, particularly the reduction in late side effects, increasing local control and cure rates <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>Contract action</u> Please specify: This a new service for the NHS and will require an NHS contract with finance, activity, quality indicators etc included. Work on this is in progress and on schedule.</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: The service at The Christie will open (take first referrals in summer 2018 and first patient treatment will be on 31st August 2018. UCLH will open in September 2020</p>

<p>B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p><u>Yes</u> If yes, outline the plan:</p> <p>A full transition plan outlining the transition of activity from the Proton Overseas Programme and 'ramp-up' of the NHS PBT service at The Christie has been developed and will be refined over the intervening period.</p>
<p>B3.4 Is a change in provider physical infrastructure required?</p>	<p><u>Yes</u> Please specify:</p> <p>Two PBT centres are under construction, at The Christie, Manchester and University College London Hospitals (UCLH). These are complex multi-million pound builds underwritten by DH (capital) and NHS England (revenue). The Christie centre will open in summer 2018 and treat its first patient in August 2018. UCLH will open in late summer 2020.</p>
<p>B3.5 Is a change in provider staffing required?</p>	<p><u>Yes</u> Please specify:</p> <p>Each PBT centre has workforce development and recruitment plans in place. These have been agreed with the PBT Programme Team.</p>
<p>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p>	<p><u>Yes</u> Please specify:</p> <p>As per the service specification 'undertaking PBT within a major cancer centre, linked to an academic oncology and medical physics framework is essential'.</p> <p>Dependency and adjacencies are outlined in the service specification. Specifically many patients will be receiving concurrent treatment for their condition such as chemotherapy which will need to be provided at or close to the PBT centre.</p>

B3.7 Are there changes in the support services that need to be in place?

Yes

Please specify:

Due to the nature of the treatment (typically outpatient 5 days per week over a 6-8 week period) and locations of the centres, the majority of patients will need to be away from home for long periods and therefore comprehensive accommodation and support services will need to be in place.

B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)

No

Please specify:

The Christie and UCLH will be PBT provider Trusts

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

Increase

Please complete the table:

Region	Current no. of providers	Future State expected range	Provisional or confirmed
North	0	1	<u>C</u>
Midlands & East	0	0	<u>C</u>
London	0	1	<u>C</u>
South	0	0	<u>C</u>
Total	0	2	<u>C</u>

Please specify:

This is a new service to the NHS. Both provider trusts were selected through a competitive process

B3.10 Specify how revised provision will be secured by NHS

Select all that apply:

England as the responsible commissioner.	Publication and notification of new service specification	<input type="checkbox"/>
	Market intervention required	<input type="checkbox"/>
	Competitive selection process to secure increase or decrease provider configuration	<input 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 type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
Please specify: A competitive procurement process was held in 2010 which designated the two Trusts as providers of the NHS PBT service		

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)	<p>No</p> <p>Please specify: The service will fall within the direct commissioning responsibility of NHS England</p>
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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	<input type="checkbox"/>
	Excluded from tariff – pass through	<input 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	<input type="checkbox"/>
	Paid entirely by Local Tariffs	<input type="checkbox"/>
	Partially paid by National Tariffs	<input type="checkbox"/>
	Partially paid by Local Tariffs	<input type="checkbox"/>
	Part/fully paid under a Block arrangement	<input type="checkbox"/>
	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>
	Part/fully paid under Other arrangements (see C1.6)	<input checked="" type="checkbox"/>

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.

Not applicable

<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>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.</p>	<p>Not applicable</p>
<p>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 %)</p>	<p>Not applicable</p>
<p>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.</p>	<p>Not applicable</p>
<p>C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.</p>	<p>The development agreement with the two provider Trusts state that in the first five years payments after service commences payments will be made on actual costs validated by NHSE as covered by the open book accounting period. Technical and clinical capacity will be 'ramped-up' over a period of 18months – two years at each service. Costs identified in the open-book accounting period will be used to calculate the tariff for future years at which point it will be decided if there should be a national or local tariff.</p>
<p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>	<p><u>Yes</u> Please specify: A referral pathway and portal is under development that</p>

	will ensure referrals are made within clinical commissioning policy and directed to a multi-disciplinary team (MDT) within each Trust.	
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	enter number.
	YR2	enter number.
	YR3	enter number.
	YR4	enter number.
	YR5	34,700
Are there any changes expected in year 6-10 which would impact the model?	<p>If yes, please specify: It is not possible to identify a revenue cost per patient until at least full technical and clinical capacity has been achieved, expected to be year 5. The year 5 figure is current budget / maximum capacity as a placeholder</p>	
C3 Overall Cost Impact of this Service specification to NHS England		
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	<p><u>Cost neutral</u> Please specify: This is noted as neutral as NHSE currently has a budget of £52m for Proton beam therapy and that is the quantum used for the UK service at the Christie and UCLH and any residual overseas treatments. In the initial years the expectation is that as the services in the UK come on line the requirements for overseas facilities reduce.</p>	
C3.2 If the budget impact on NHS England cannot be identified set	N/A	

out the reasons why this cannot be measured.	
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?	N/A
C4 Overall cost impact of this service specification to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	<p>Budget impact for CCGs: <u>No impact on CCGs</u></p> <p>Budget impact for providers: <u>Cost neutral</u></p> <p>Please specify: In the first five years the service will be paid for based on validated costs</p>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u>Cost neutral</u></p> <p>Please specify: The base assumption is that the new service will cost the same as the existing budget for PBT</p>
4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	N/A
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<p><u>No</u></p> <p>Please specify: Costs of treatment are solely within the NHS</p>

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.

N/A

C6 Financial Risks Associated with Implementing this Service specification

C6.1 What are the material financial risks to implementing this service specification?

The main risk is the providers not getting up to capacity quick enough and that NHS England will have to cover fixed costs while continuing to send patients overseas.
It will also be necessary to identify non-PBT costs incurred such as chemotherapy that are not connected to the introduction of PBT but which must be given concurrent to PBT and will need to move as patient flows change.
The other risk is other costs that emerge that were not included in the original business case or Development Agreement, an example of which is accommodation.

C6.2 How can these risks be mitigated?

To manage the referrals issue the project team are working up transition plans with the providers to ensure the switch from overseas provision to UK.
For the non PBT costs the invoices for current PBT activity are being analysed.
Emerging costs are reviewed with the Trusts to mitigate on a case by case basis within the £52m quantum

C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost

Costs and budgets have been based on the Full Business Cases submitted by both Trusts and agreed in the Development Agreement,

scenarios?	signed by Department of Health, NHS England & the two Trusts															
C6.4 What scenario has been approved and why?	Not applicable															
C7 Value for Money																
C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?	<p><u>There is no published evidence of cost-effectiveness</u></p> <p>Please specify:</p> <p>The current service provision involves sending patients either to the USA. or to Europe. The average cost per patient exceeds £100k. At full clinical and technical capacity, it is expected that treatment in the UK will show reduced costs / case. The true impact will not be quantified until the services are up and running at both sites.</p>															
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1086 798 2132 1377"> <tr> <td data-bbox="1086 798 2056 927">Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td> <td data-bbox="2056 798 2132 927" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 927 2056 1018">Available pricing data suggests the service is lower cost compared to current/comparator treatment</td> <td data-bbox="2056 927 2132 1018" style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1018 2056 1109">Available clinical practice data suggests the new service specification has the potential to improve value for money</td> <td data-bbox="2056 1018 2132 1109" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1109 2056 1166">Other data has been identified</td> <td data-bbox="2056 1109 2132 1166" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1166 2056 1224">No data has been identified</td> <td data-bbox="2056 1166 2132 1224" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1224 2056 1315">The data supports a high level of certainty about the impact on value</td> <td data-bbox="2056 1224 2132 1315" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1315 2056 1377">The data does not support a high level of certainty about the</td> <td data-bbox="2056 1315 2132 1377" style="text-align: center;"><input type="checkbox"/></td> </tr> </table>		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 checked="" 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 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	<input type="checkbox"/>
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The data does not support a high level of certainty about the	<input type="checkbox"/>															

	<div data-bbox="1086 97 2056 145" style="border: 1px solid black; padding: 2px;"> impact on value </div> <div data-bbox="2056 97 2136 145" style="border: 1px solid black; width: 36px; height: 30px; margin-left: 5px;"></div> <p data-bbox="1086 156 2136 272">Please specify: Comparison with costs per patient currently being paid through the Proton Overseas Programme</p>
C8 Non-Recurrent Costs	
<p data-bbox="91 469 999 539">C8.1 Are there non-recurrent revenue costs associated with this service specification?</p>	<p data-bbox="1086 469 2074 746"><u>Yes</u> If yes, please specify and indicate whether these would be incurred or passed through to NHS England: Any non recurring costs will be captured in the open book accounting period If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.</p> <p data-bbox="1086 759 1144 794"><u>Yes</u></p>
<p data-bbox="91 852 1037 922">C8.2 Are there any non-recurrent provider capital costs associated with the service specification?</p>	<p data-bbox="1086 852 2047 970"><u>No</u> If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs).</p>