Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1783
Policy Title	Proton Beam Therapy for Children, Teenagers and Young Adults in the treatment of malignant and non-malignant tumours Proposal **for routine commission** (ref A3.1)

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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.	The policy covers a number of rare cancers and prevalence varies by condition and age group (paediatric, teenage & young adult (TYA)). *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	This policy replaces and updates the current policies for PBT for children (paediatrics) and TYA for the Overseas Programme. In 2018/19 119 paediatric patients and 59 TYA patients were approved for referral for the Proton Overseas Programme. The new policy will expand the eligibility criteria for PBT in this age group as it encompasses additional indications that it was not possible to treat overseas for clinical reasons. The availability of an NHS PBT service will also mean patients who could not access PBT overseas for non-clinical reasons (e.g. travel restrictions) will now be able to access PBT. There will be two NHS PBT Centres. The first became operational from December 2018 and the second will be operational in 2021. The capacity plan for the full NHS PBT service is for 330 paediatric patients per annum and 220 TYA. Each NHS PBT centre will go through a capacity ramp-up and it is anticipated that full capacity will be reached in 2021-22 *Source: NHS PBT Capacity Plan. Proton Overseas Programme database*

A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Other** Paediatrics and TYA.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	This policy covers people aged between 0 – 24 years (up to 25th birthday).
A1.5 How is the population currently distributed geographically?	**Unknown** *Source: Policy Proposition section 6* Emerging analysis suggests some geographical variance in referral and uptake across England. This suggests that in some regions referral and uptake rates are lower than would expected, however, this data requires further validation. Note: This policy will be adopted by the Devolved Administrations (DAs) of Wales, Scotland and Northern Ireland. Projected patient numbers for the DAs have been included in demand and capacity calculations.
A2 Future Patient Population & Demography	
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?	Increasing *Source: Policy Proposition section 6*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**Yes**

<table>
<tr><td></td><td>The UK has the second highest growth rate in Western Europe. With growth in population, it is estimated that growth in paediatric and TYA cancers will be 6.45% for 2018 – 2028. This will have a disproportionate impact (increasing) on demand for PBT.

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?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td>
<table>
<tr><td></td><td>Paediatric</td><td>TYA</td></tr>
<tr><td>YR2 +/-</td><td>+ 57</td><td>+ 11</td></tr>
<tr><td>YR3 +/-</td><td>+ 154</td><td>+ 84</td></tr>
<tr><td>YR4 +/-</td><td>+ 181</td><td>+ 141</td></tr>
<tr><td>YR5 +/-</td><td>+ 181</td><td>+ 141</td></tr>
<tr><td>YR10 +/-</td><td>Stead state</td><td>Steady state</td></tr>
</table>
2018/19 approved referral data used as the baseline.

Source: NHS PBT Service Transition & Ramp-up Plan

<u>Yes</u>
Estimated increase in demand as commencement and development of NHS PBT Service makes proton therapy to more patients previously unable to travel overseas for treatment.
Emerging analysis (which needs to be fully validated) suggests some geographical variance in referral and uptake across England. This suggests that in some regions referral and uptake rates are lower than would expected.</td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Revise existing policy (expand or restrict an existing treatment threshold / Add an additional line of treatment / stage of treatment</u>** The policy will replace the existing policies for PBT for paediatrics and TYA: - Proton Beam Radiotherapy (High Energy) for Paediatric Cancer Treatment – NHS Overseas Programme - Proton Beam Radiotherapy (High Energy) for Teenage and Young Adult Cancer Treatment – NHS Overseas Programme The new policy will expand the number of indications eligible for PBT in the paediatric and TYA age groups.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	119 paediatric patients and 59 TYA patients. *Source: Proton Overseas Programme – 2018/19 approved referral for the Proton Overseas Programme.*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	550 (planned capacity) Planned capacity for NHS PBT Service at full-ramp (21/22): - Paediatrics – 330 per annum. - TYA – 220 per annum. *Source: NHS PBT Service Transition & Ramp-up Plan*

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
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	There are currently 2 clinical commissioning policies for PBT: • Proton Beam Radiotherapy (High Energy) for Paediatric Cancer Treatment • Proton Beam Radiotherapy (High Energy) for Teenage and Young Adult Cancer Treatment An application for referral for PBT is made to the National PBT Clinical Panel via the PBT online referral portal. This is a virtual panel consisting of clinical experts from across the country. The panel reviews each 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 treatment centre. Since 2008, 929 paediatric and 219 TYA patients were 'approved for referral'. Approximately 90% of paediatric and 83% of TYA applications are approved for referral. *Source: NHS PBT Service Specification; Standard Operating Procedure - Process for applying for Proton Beam Therapy and subsequent treatment centre allocation for eligible patients; Proton Overseas Programme database.*

A4.2. What are the current treatment access and stopping criteria?	Current access to treatment is via approval for referral through the National PBT Clinical Panel in line with the criteria set out in existing NHS England Clinical Commissioning Policies (see A4.1 above).
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 criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	a) Paediatric & TYA 100% b) Paediatric 10%, TYA 17% c) Paediatric & TYA estimated 95% d) Paediatric & TYA estimated 100% e) Paediatric & TYA estimated 100% It is important to note that this a complex service covering the radiotherapy element of treatment in group of relatively rare cancers. Estimates are taken from the Proton Overseas Programme. This, in itself, is problematic as having to access treatment overseas will impact on estimates, especially take-up. Compliance with and completion of treatment rates are high. *Source: Proton Overseas Programme*
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*	**<u>No</u>** The policy replaces the existing PBT policies for paediatric and TYA for the Proton Overseas Programme which were published in 2015. There is an established care and patient pathway for these patients.

• *Actual or estimated eligibility and uptake*	
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 criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable.
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 criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Applications (assessment) for PBT are expected to increase in line with population growth, expansions of eligible indications and inclusion of patients previously unable to travel overseas for clinical or social reasons. The number of applications not eligible for treatment is expected to remain similar to those experienced through the Proton Overseas Programme. Uptake, compliance and completion of treatment rates are expected to remain high. With the introduction of the NHS PBT service these rates will be monitored and recorded. a) Paediatric & TYA 100% b) Paediatric 10%, TYA 17% c) Paediatric & TYA estimated 95% d) Paediatric & TYA estimated 100% e) Paediatric & TYA estimated 100% *Source: Proton Overseas Programme*

<table>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Time limited</u>

Treatment will be delivered on an outpatient basis, 5 days per week over a 6-8 week period.

Source: PBT Service Specification</td></tr>
<tr><td colspan="2">A7 Treatment Setting</td></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Select all that apply:
<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☒</td></tr><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><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>
Treatment will be delivered on an outpatient basis, 5 days per week over a 6-8 week period. Many patients require other treatment such as chemotherapy concurrent to PBT. For some this will include an acute</td></tr>
</table>

<table>
<tr><td></td><td>inpatient stay. In addition, acute inpatient stays may be required as a result of complications arising from treatment.</td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td>
<table>
<tr><th>NHS England and Improvement Region</th><th>Number of Providers</th></tr>
<tr><td>North East and Yorkshire</td><td>0</td></tr>
<tr><td>North West</td><td>1</td></tr>
<tr><td>Midlands</td><td>0</td></tr>
<tr><td>East of England</td><td>0</td></tr>
<tr><td>London</td><td>0</td></tr>
<tr><td>South East</td><td>0</td></tr>
<tr><td>South West</td><td>0</td></tr>
</table>
</td></tr>
<tr><td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td><td><u>Yes</u>

There will be two NHS PBT Centres. The first at The Christie NHS Foundation Trust, Manchester became operational from December 2018 and the second at University College London Hospitals NHS Foundation Trust is under development and will be operational in 2021.

Source: PBT Development Agreement. NHS Service Contract – PBT The Christie</td></tr>
<tr><td colspan="2">A8 Coding</td></tr>
</table>

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:
RTDS
Further data collection – referrals, outcomes will be collected by the NHS PBT service.

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

OPCS v4.8	☐
ICD10	☒
Treatment function code	☐
Main Speciality code	☐
HRG	☐
SNOMED	☐

	Clinical coding / terming methodology used by clinical profession ☒ ICD03/ICC3 – NCRAS Diagnosis coding
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** NCBPS01B Proton Beam Therapy
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.	**Yes - other** Specific analytical information, monitoring and reporting is required for the following: - Open-book accounting (finance and activity) - Activity - Quality Indicators - Outcomes - Clinical

	- Patient reported outcomes
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.	Not applicable.
A9.3 **Business intelligence** Is there potential for duplicate reporting?	**No**
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** Monthly contract meetings are being/will be held with each NHS PBT provider Trust.
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** Detailed Quality Indicators have been developed for this service. These will be included in section 6 of the standard NHS Contract agreed for the service.
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?	**No**
Section B - Service Impact	

B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Patients whose conditions are eligible for PBT under current clinical commissioning policy and are able to travel are treated overseas in centres in the USA and Germany. Patients whose conditions are not eligible or patients who are unable to travel are treated with conventional radiotherapy within the NHS. *Source: Proton Overseas Programme*
B1.2 Will the proposition change the way the commissioned service is organised?	**Yes** The majority of curative paediatric radiotherapy (excluding total body irradiation, palliative radiotherapy and whole brain radiotherapy for leukaemia) will be undertaken at the NHS PBT centres, thus impacting significantly on the current NHS paediatric radiotherapy service. Since its introduction in 2008, the Proton Overseas Programme has already had a very significant impact on the activity of paediatric radiotherapy in existing paediatric RT centres. There will be a 'transitional phase' as the NHS PBT service 'ramps up'. This is estimated to be until around 2021/22 when the NHS PBT Service will be at full clinical and technical capacity.
B1.3 Will the proposition require a new approach to the organisation of care?	**Other** The stakeholder comments raised on the impact of PBT on paediatric radiotherapy and cancer services are important and noted by NHS England.

<table>
<tr><td></td><td>Over the last 18months NHS England, through a subgroup of the Radiotherapy CRG, has been working with experts in the field to understand and quantify the potential impact of PBT on paediatric radiotherapy services. This work is ongoing and is led by the National Cancer Programme of Care. All relevant stakeholders will be kept informed as the work progresses.</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:
<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table>
Referrals are made via Specialist Cancer Centres</td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>

Referral sources/networks are already established through the Proton Overseas Programme.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>Increase</u>

The new policy will allow for the expansion of clinical indications eligible for PBT.</td></tr>
</table>

	Source: Equalities Impact Assessment
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** See B2.3 above. An expected benefit of PBT is that patient outcomes, particularly the reduction in late side effects, increasing local control and cure rates will improve significantly. *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** NHS PBT Service Specification was published in 2018 and relevant contracts signed.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**Yes - go to B3.3** The NHS PBT Service will go through a period of clinical and capacity ramp-up. Until full ramp-up is complete, estimated 2021/22, some patients may still be referred overseas for treatment. Contracts are in place with overseas providers to cover this period.
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**
B3.4 Is a change in provider physical infrastructure required?	**Yes**

	There will be two NHS PBT Centres. The first at The Christie NHS Foundation Trust, Manchester became operational from December 2018 and the second at University College London Hospitals NHS Foundation Trust is under development and will be operational in 2021.
B3.5 Is a change in provider staffing required?	**Yes** Each NHS PBT Centre has or will need to recruit specialist clinical and support staff. Each centre has a workforce development plan which has been agreed with the PBT Programme Board.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**Yes** As per the published NHS PBT Service Specification 'undertaking PBT within a major cancer centre, linked to an academic oncology and medical physics framework is essential'. 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, e.g. chemotherapy for paediatric patients attending The Christie PBT centre will be provided at the Royal Manchester Children's Hospital.
B3.7 Are there changes in the support services that need to be in place?	**Yes** 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.

<table>
<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>

The Christie and UCLH will be the NHS PBT service provider Trusts.</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>Please complete table:
<table>
<tr><th>Region</th><th>Current no. of providers</th><th>Future
State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North East and Yorkshire</td><td>0</td><td>0</td><td>Not applicable.</td></tr>
<tr><td>North West</td><td>1</td><td>1</td><td><u>C</u></td></tr>
<tr><td>Midlands</td><td>0</td><td>0</td><td>Not applicable.</td></tr>
<tr><td>East of England</td><td>0</td><td>0</td><td>Not applicable.</td></tr>
<tr><td>London</td><td>0</td><td>1</td><td><u>C</u></td></tr>
<tr><td>South East</td><td>0</td><td>0</td><td>Not applicable.</td></tr>
<tr><td>South West</td><td>0</td><td>0</td><td>Not applicable.</td></tr>
<tr><td>Total</td><td>1</td><td>2</td><td>Not applicable.</td></tr>
</table>

There will be two NHS PBT Centres. The first at The Christie NHS Foundation Trust, Manchester became operational from December 2018 and the second at University College London Hospitals NHS Foundation</td>
</tr>
</table>

<table>
<tr><td></td><td>Trust is under development and will be operational in 2021. Both were selected through a competitive process.</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table><tr><td>Publication and notification of new policy</td><td>☐</td></tr><tr><td>Market intervention required</td><td>☐</td></tr><tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr><tr><td>Any qualified provider</td><td>☐</td></tr><tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr><tr><td>Procurement</td><td>☐</td></tr><tr><td>Other</td><td>☒</td></tr></table>
A competitive procurement process was held in 2010 which designated the two Trusts as providers of the NHS PBT service.
The Development Agreement for the NHS PBT service was signed by DH, NHS England and both Trusts in July 2015. The Development Agreement commits NHS England to contract with both Trusts for a minimum of 20 years. A 10 year NHS Standard Contract has been signed with The Christie and it is anticipated a similar contract will be signed with UCLH in 2020/21.</td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
</table>

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** The service falls to the direct commissioning responsibility of NHS England.

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	☐

	<table><tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr></table>
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.	Not applicable.
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 %)	Not applicable.
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	Not applicable.

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.	The two PBT services are covered by a development agreement, which stipulates that costs will be reimbursed on an actual basis via an open-book arrangement until 2024/25. The agreement covers all PBT activity including this policy proposition. At the end of the open-book period, a longer-term payment model will be agreed.
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**Yes** A referral pathway and portal that 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? Are there any changes expected in year 6-10 which would impact the model?	The indicative cost per patient is c£43.7k. This is based on the financial modelling undertaken for the PBT Service Specification (NHS England URN: 1737) and is the anticipated cost once the service has fully ramped up (expected to be 2021/22). None.
C3 Overall Cost Impact of this Policy to NHS England	

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost neutral** The patients covered by this policy are already included in the total number of patients set out in the PBT Service Specification (1737) and therefore do not represent an increase in overall patient numbers or costs.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable.
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: **No impact on CCGs** Budget impact for providers: **Cost neutral** An Open Book method of reimbursement is being operated until five years after the opening of the service at UCLH to ensure there is no budgetary impact to Trusts during the ramp up stage of the service development.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral**

	The costs relating to this policy are all covered with the PBT Service Specification financial modelling (1737).
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** Costs of treatment are solely within the NHS.
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.	Not applicable.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	The financial risks associated with the new PBT service were covered within the PBT Service Specification (1737) and original Full Business Case. The main risk is that the ramp up of capacity takes longer than planned as NHS England will need to cover the fixed costs associated with the new service whilst continuing to send patients overseas. Current indications are that ramp-up is progressing to plan.

C6.2 How can these risks be mitigated?	A transition and ramp-up plan is in place with the NHS PBT providers to ensure the switch from overseas provision to NHS provision.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	The patient cohort covered by this policy are covered in the overall financial modelling of the new PBT service, as set out in the Service Specification (1737). The models tested included a fully ramped up baseline of 1,300 and 1,500 patients.
C6.4 What scenario has been approved and why?	1,300 patients per annum has been agreed as the most likely scenario and provides for a value for money, affordable, and sustainable service. This was agreed between NHS England and both Trusts and is as set out in the signed Development Agreement.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**<u>There is no published evidence of cost-effectiveness</u>** The current service provision involves sending patients either to the USA or to Europe. The average cost per patient exceeds £130k. At full clinical and technical capacity of 1,300 patients (including adults), it is expected that the cost of treatment in the NHS service will be c£43.7k. The true impact will not be quantified until both Trusts are at full operational and technical capacity.
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐

<table>
<tr><td></td><td>
<table>
<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>

Comparison with costs per patient currently being paid through the Proton Overseas Programme and tested against the procurement for interim PBT service provision in 2017.
</td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u>

Any non-recurring costs will be captured in the open book accounting period.</td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Not applicable.</td></tr>
</table>