

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	170012/S
Service	Proton Beam Therapy Service (Adults and Children)
Commissioner Lead	Highly Specialised Commissioning, NHS England
Provider Lead	N/A
Period	1st April 2017 – 31st March 2020
Date of Review	October 2019.

1. Population Needs

1.1 National/local context and evidence base

1.1.1. Proton Beam Therapy (PBT) provides radiation by delivering a beam of proton particles, rather than by external beam radiotherapy (EBRT) using X-Rays. PBT facilitates the safe use of controlled doses of ionising radiation to treat people who have cancer with the aim of delivering as high a dose of radiation as possible to the cancer, whilst sparing the surrounding normal tissues. A phenomenon known as the Bragg Peak means that almost no radiation dose is deposited in the normal tissue beyond the tumour. This is in contrast to X-rays where there is dose extension beyond the tumour, reducing as the beam diverges and attenuates

1.1.2 PBT can be used alone or as part of a multi-modality treatment regime with surgery and /or chemotherapy. PBT is complex and requires an understanding of the principles of medical physics, radiobiology, radiation safety, dosimetry, radiation treatment planning, simulation and interaction of radiation with other treatment modalities.

1.1.3 PBT is a treatment that is given with curative intent. Its use can reduce some acute toxicity and more significantly can reduce the long term permanent side effects of treatment and improve the chances of maintaining quality of life. PBT can also be used as part of a dose escalation strategy to increase tumour control, by sparing critical structures. It is typically delivered to patients every weekday, over a number of weeks, depending on the tumour site. Most patients are treated on an outpatient basis.

1.1.4 PBT is a highly complex technology that is still undergoing rapid technical advances. Rigorous quality standards are thus essential. The core group of patients for whom benefit has a strong evidence base are also complicated and require integration with the infrastructure of a major cancer centre, including highly specialist surgery and cancer services. There is a need to

accompany PBT with robust outcomes assessment. For all these reasons undertaking PBT within a major cancer centre, linked to an academic oncology and medical physics framework is ideal.

1.2 Proton Overseas Programme

1.2.1. Proton beam therapy has been offered to all clinically appropriate patients in England since 2008 through the NHS Proton Beam Programme. NHS England will continue to do so in line with agreed clinical policies for the duration specified.

1.3 NHS Proton Beam Therapy Service

1.3.1 In 2009, planning began on the development of an NHS Proton Beam Therapy service. Two PBT centres have been commissioned by the Department of Health and NHS England at The Christie NHS Foundation Trust in Manchester and University College London Hospitals NHS Foundation Trust in London.

1.3.2 It is anticipated that when the NHS service starts it will still be necessary for some patients requiring PBT to continue to be sent for treatment abroad. This is to allow the NHS service to increase its clinical expertise and capacity in a safe and controlled manner.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	X
Domain 2	Enhancing quality of life for people with long-term conditions	X
Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X

2.2 Local defined outcomes

The Programme aims to deliver:

- improved cancer survival and cure rates
- delivery of accurately targeted therapeutic doses of radiation to tumours
- ability to minimise and reduce the short and long-term side effects of treatment
- maintenance of good patient (and family) experience of treatment
- maintenance of safe integration with other aspects of treatment and interventions within the

clinical pathway of care

- development of clear clinical outcome information to support further clinical and service development
- development of the UK based service, infrastructure, clinical protocols and pathways of care.

2.3 Provider Outcomes

The provider must:

- have a structured clinical outcomes collection and analysis programme
- collect relevant diagnosis specific data on clinical outcome measures
 - overall survival
 - progression free survival
 - tumour local control
 - acute and late toxicity
- collect patient satisfaction and patient experience data and demonstrate how this has been acted upon.
- describe links to clinical trials, national registries and academic studies.

3. Scope

3.1 Aims and objectives of service

Aims

3.1.1 The aim of the service is to provide high energy proton beam therapy services for adult, teenage and young adult (age 16 – 24 years), and paediatric patients (age < 16 years), overseas to improve cancer outcomes, reduce morbidity arising from treatment, and support the patient and family throughout their cancer journey and beyond.

Objectives

3.1.2 The objective of the Proton Overseas Programme service is that:

- all eligible patients that can safely travel overseas without compromise to other aspects of care and outcomes, are able and willing to do so receive PBT at the recognised high quality treatment providers overseas commissioned by NHS England.

3.2 Service description/care pathway

3.2.1 In addition to the standards required within the Contract, specific quality standards and measures will be expected. The provider must:

Facilities and equipment

Essential

- meet technical standards in accordance with the equipment specification and equipment supplier's service delivery model
- ensure modern equipment is used including image guidance (MRI, CT scanner), treatment planning system tools and Oncology Information Systems
- be fully integrated with a conventional radiotherapy programme and department
- have a minimum of two rooms and two full gantries (or equivalent)
- have full patient immobilisation systems available
- have contingency plans and contracts in place for patient treatment to continue in the event of technical interruptions and/or breakdown.

Desirable

- be able to deliver passive and active (spot scanning) Intensity Modulated Proton Therapy (IMPT) Proton modalities
- have the PBT centre situated within a Hospital campus
- have in-patient and out-patient care on the same campus/site available.

Staffing

Essential

- ensure all staff delivering PBT are adequately trained and have the appropriate skills and competencies to do so
- ensure adequate site specialist oncology staff with links to integrated Multi-Disciplinary Teams (MDTs)
- meet the national standards for training and practice of the relevant professional bodies (equivalent to for example Royal College of Radiologists (RCR), Society and College of Radiographers (SCoR) and Institute of Physics and Engineering in Medicine (IPEM))
- demonstrate processes for the management of risk to staff
- support the development of the UK PBT service by, for example, making provision by agreement for training placements for UK PBT clinicians and technicians.

Clinical standards and pathways

Essential

- provide assurance that radiotherapy is delivered according to national and international standards where appropriate and applicable
- provide assurance that their services match standards for Radiotherapy, that are consistent with the Cancer Reform Strategy Commitment to develop World Class services and the NHS England Vision for Radiotherapy Services (2014)

- be accredited by national and/or state regulatory board
- participate in national quality assurance programme
- have treatment capacity and administrative processes to be able to accept patients within a timescale to allow pathways that meet clinically relevant start-to-radiotherapy target times (will vary according to tumour)
- ensure the safe treatment of patients in accordance with agreed protocols
- demonstrate processes for the management of risk to patients
- have dedicated programmes for children, teenagers & young adults and adults e.g. base of skull
- deliver care in settings appropriate to age
- take a lead in engagement with appropriate multi-disciplinary diagnostic and treatment teams
- provide full interdisciplinary care (Paediatric Oncology, Anaesthesia, Endocrine, Head & Neck Surgery, Neurosurgery)
- provide supportive therapy including chemotherapy, emergency management and tumour multi-disciplinary teams
- make provision for psychosocial multi-disciplinary teams
- use effective communication pathways between the referring treatment centre multi-disciplinary team and the overseas provider multi-disciplinary team
- provide treatment summaries back to the referring centres on completion of treatment within two weeks of completion of treatment
- enter patients prospectively into local or national registry and outcome evaluation programmes
- collaborate with UK data collection on treatment details, clinical outcomes and transfer of full RTDICOM data, for NHS England Overseas programme to be able to store and analyse
- provide treatment to patients in accordance with the nationally agreed (NCRI, CCL, CSG and NHRC) clinical trial protocols within the UKCRN Study Portfolio and guidelines (CCLG) where these exist
- have a record of presenting practice and outcomes in national and international conferences, specialist meetings and in peer reviewed publications.

Desirable

- have formal links or form part of an Academic/University centre.

Patients

Essential

- ensure protection of children and other vulnerable people in line with national standards (equivalent to "Safeguarding Vulnerable People in the Reformed NHS: Accountability and

Assurance Framework <https://www.england.nhs.uk/wp-content/uploads/2013/03/safeguarding-vulnerable-people.pdf>)

- have case/patient management/concierge service to facilitate patient pathways and referrals including arranging accommodation and providing day to day support to families and carers of PBT patients whilst receiving treatment
- provide patients with information appropriate to their needs and treatment pathway.

Paediatric Specific

Essential

- have a throughput of over 70 paediatric cases per annum
- anaesthesia services used has minimum throughput of over 30 sedated paediatric cases per annum (across all specialties).
- ensure out-patient specialist paediatric anaesthesia is available for all patients if required, including deep i.v. sedation (standard) or full narcosis with intubation, induction and recovery rooms
- ensure Play therapy access is available for all patients
- be formally connected to high-volume Paediatric Oncology department ideally on the same campus and within the same organisational framework
- participate in multicentre, multidisciplinary clinical trials e.g. SIOP links
- ensure that the paediatric service has formal specialist academic leadership and links
- ensure specialised Paediatric Oncologists supervising appropriate children at least weekly and ideally within the PBT centre.

3.3 Population covered

- For further information see clinical commissioning policies for:
 - Proton Beam Radiotherapy Paediatric Cancer Treatment
 - Proton Beam Radiotherapy for Teenagers and Young Adult Cancer Treatment
 - Proton Beam Radiotherapy for Adult Cancer Treatment

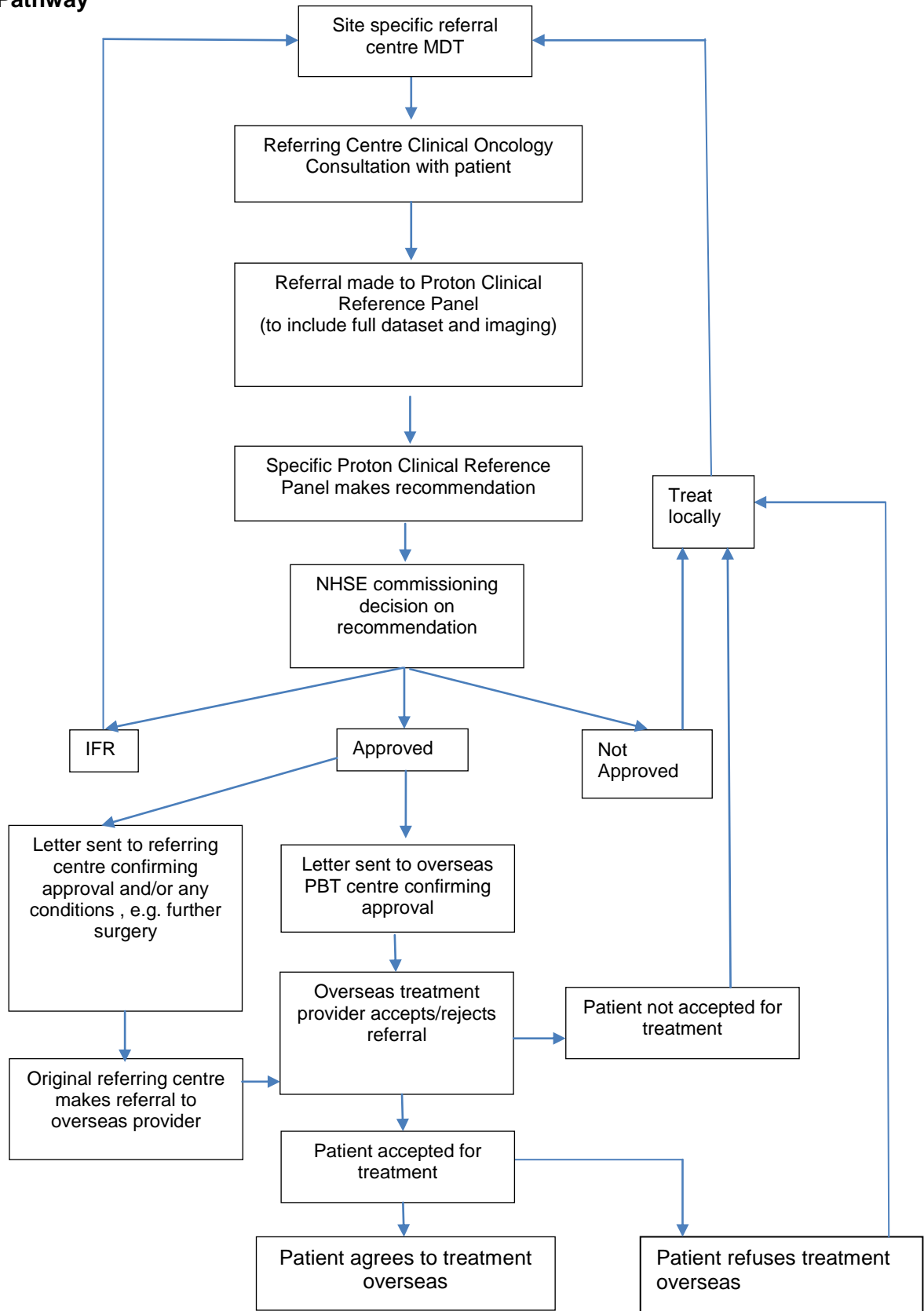
<http://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b01/>

3.4 Any acceptance and exclusion criteria and thresholds

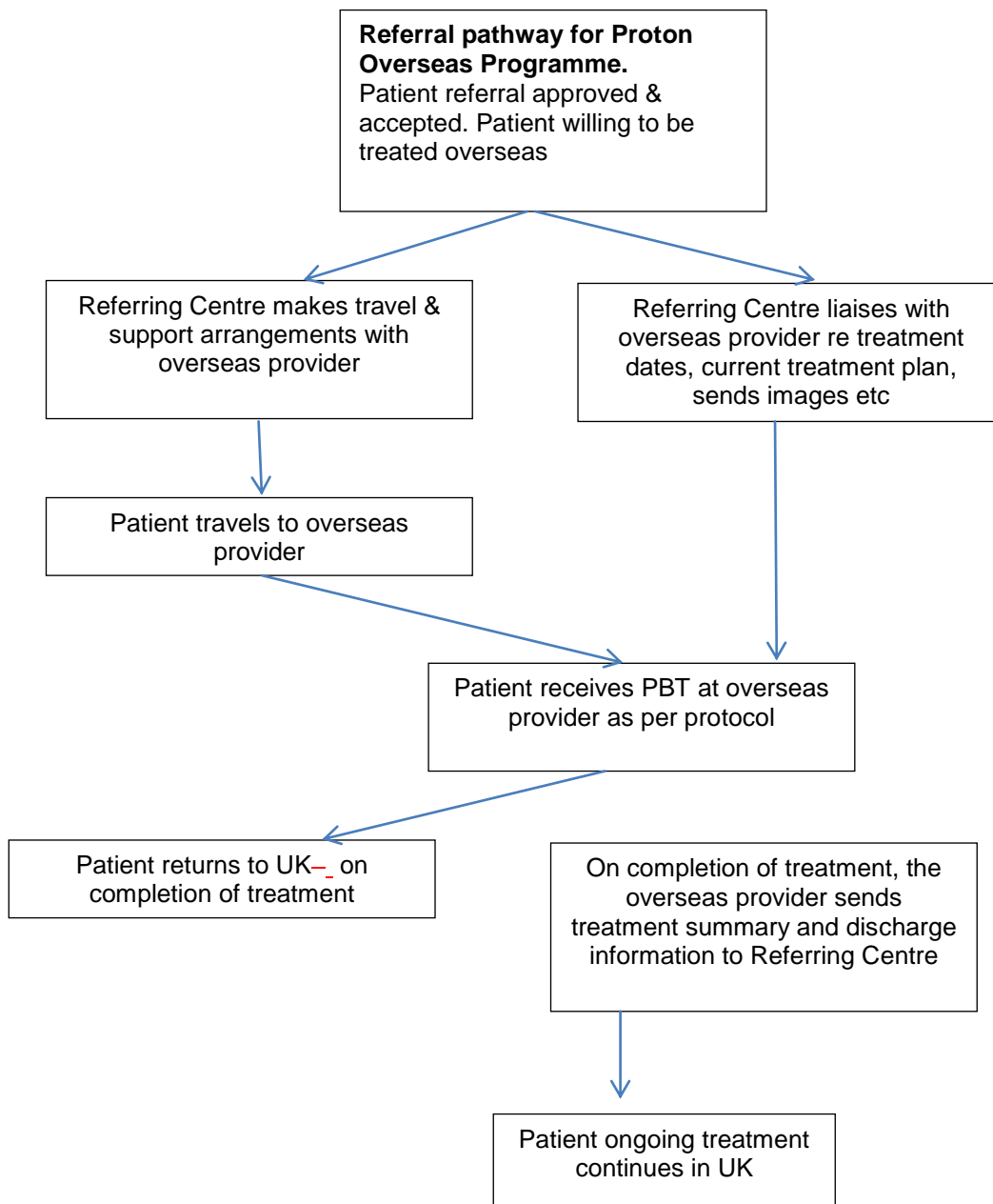
- For further information see clinical commissioning policies for:
 - Proton Beam Radiotherapy Paediatric Cancer Treatment
 - Proton Beam Radiotherapy for Teenagers and Young Adult Cancer Treatment
 - Proton Beam Radiotherapy for Adult Cancer Treatment
- The provider may withdraw treatment and refer the patient back to the referring centre if the

patient is considered not to be complying with their treatment regime. Prior to any treatment withdrawal, the provider must have discussed this with the patient and the referring centre, explaining the reasons for treatment withdrawal and actions the patient and/or referring centre need to take. The provider must inform NHS England when treatment is withdrawn and actions taken to prevent and mitigate this action.

Referral Pathway



Patient Care Pathway



3.5 Interdependencies with other services/providers

- Oncology – paediatric and adult
- Anaesthesia – paediatric only (minimum throughput of over 30 sedated paediatric cases per annum)
- Endocrinology
- Head & neck surgery
- Neurosurgery
 - Paediatric neurosurgery
 - Specialist skull-based neurosurgical unit
 - Specialist spinal surgical unit
- Chemotherapy
- Emergency Care
- Play therapy – paediatric only
- Accommodation for patients and carers

See Clinical commissioning policy – funding policy for travel and accommodation proton overseas programme
<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b01/>

- Support services for patients and carers
- Established links with (or part of) University/Academic centre.

4. Applicable Service Standards

Refer to section 3.2 service description for service standards

- Demonstrate processes for the management of risk to patients and staff
- The provider will notify the Chair of the Proton Overseas Panel of any 'never events' or serious untoward incidents (see main contract body for definitions) within 48 hours of the event occurring.

4.1 Applicable national standards e.g. NICE

- Equivalent national standards where applicable for Radiation Protection
- Services should match international standards for Radiotherapy, that are consistent with the Cancer Reform Strategy Commitment to develop World Class services and the NHS England Vision for Radiotherapy Services (2014)
- Be accredited by national and/or state regulatory board

- Provide treatment to patients in accordance with the nationally agreed (NCRI, CCL, CSG and NHRC) clinical trial protocols within the UKCRN Study Portfolio and guidelines (CCLG) where these exist
 - Ensure protection of children and other vulnerable people in line with national standards (equivalent to “Safeguarding Vulnerable People in the Reformed NHS: Accountability and Assurance Framework <https://www.england.nhs.uk/wp-content/uploads/2013/03/safeguarding-vulnerable-people.pdf>).
- 4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**
- Meet the national standards of the relevant professional bodies (equivalent to for example Royal College of Radiologists (RCR), Society and College of Radiographers (SCoR) and Institute of Physics and Engineering in Medicine (IPEM)).

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

Refer to section 3.2 service description for service standards

- recognised UK clinical oncology experts to visit and assess clinical quality including patterns of integrated care
- the provider will have a recognised system to demonstrate service quality and standards
- the service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site
- the quality system and its treatment protocols will be subject to regular clinical and management audit
- the provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

Not applicable

6. Location of Provider Premises

The Provider’s Premises are located at:

N/A

Appendix Two

Quality standards specific to the service using the following template:

Proton Beam Quality Indicators

These should be read in conjunction with the national service specification and extended version of the indicators.

Structure & Process			
<i>Number</i>	<i>Indicator</i>	<i>Data source</i>	<i>Domains</i>
PBT-16-001	Process for the commissioning of new equipment	Self declaration	1,2
PBT-16-002	Use of equipment and technologies	Self declaration	5
PBT-16-003	Treatment capacity	Self declaration	5
PBT-16-004	There is a minimum of 2 treatment rooms	Self declaration	5
PBT-16-005	There are contingency plans for technical interruptions /breakdown	Self declaration	5
PBT-16-006	Access to conventional radiotherapy	Self declaration	5
PBT-16-007	Access to inpatient and outpatient care	Self declaration	5
PBT-16-008	Provision of interdisciplinary care	Self declaration	3, 5
PBT-16-009	Provision of supportive services	Self declaration	3, 5
PBT-16-010	Communication pathways	Self declaration	4, 5
PBT-16-011	Staffing levels and training	Self declaration	5
PBT-16-012	Dedicated site specialised teams	Self declaration	1,2,3
PBT-16-013	The service is delivered according to national and international standards	Self declaration	5
PBT-16-014	Treatment protocols	Self declaration	5

PBT-16-015	National/state regulatory accreditation	Self declaration	5
PBT-16-016	Quality assurance	Self declaration	5
PBT-16-017	Risk management	Self declaration	5
Outcomes/quantitative indicators			
Number	Indicator	Data source	Domains
PBT-16-018	Participation in clinical audit	Self declaration	2
PBT-16-019	Research and academic practice	Self declaration	2
Patient Experience			
Number	Indicator	Data source	Domains
PBT-16-020	Safeguarding of children and vulnerable people	Self declaration	4, 5
PBT-16-021	Patient management/ concierge service	Self declaration	4
PBT-16-022	Patient information	Self declaration	4
PBT-16-023	Care settings	Self declaration	4
Paediatric Specific Structure & Process			
Number	Indicator	Data source	Domains
PBT-16-024	Minimum activity	Self declaration	5
PBT-16-025	Outpatient specialist paediatric anaesthesia	Self declaration	5
PBT-16-026	Play Therapy	Self declaration	4

PBT-16-027	Access to paediatric oncology	Self declaration	5
PBT-16-028	Specialised paediatric oncologist provision	Self declaration	5
Outcomes/quantitative indicators			
<i>Number</i>	<i>Indicator</i>	<i>Data source</i>	<i>Domains</i>
PBT-16-029	Research and academic links	Self declaration	2