

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Proton Beam Therapy Programme
Commissioner Lead	Fiona Marley, Head of Highly Specialised Commissioning
Provider Lead	
Period	1 st April 2016 – 31 st March 2019
Date of Review	October 2017.

1. Population Needs
<p>1.1 National/local context and evidence base</p> <p>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</p> <p>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.</p> <p>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.</p> <p>1.2 Proton Overseas Programme</p> <p>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.</p>

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

- Improve cancer survival and cure rates
- Deliver higher, accurately targeted therapeutic doses of radiation to tumours
- Minimise and reduce the short and long-term side effects of treatment
- Improve the patient experience of treatment
- Develop clear clinical outcome information to support further clinical and service development
- To support development of the UK based service, infrastructure, clinical protocols and pathways of care.

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 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

3.2.1 In addition to the standards required within the NHS Standard 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, Oncology Information Systems.
- be fully integrated with a conventional radiotherapy programme and department
- have a minimum of two rooms and two full gantries
- 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) 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
- 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

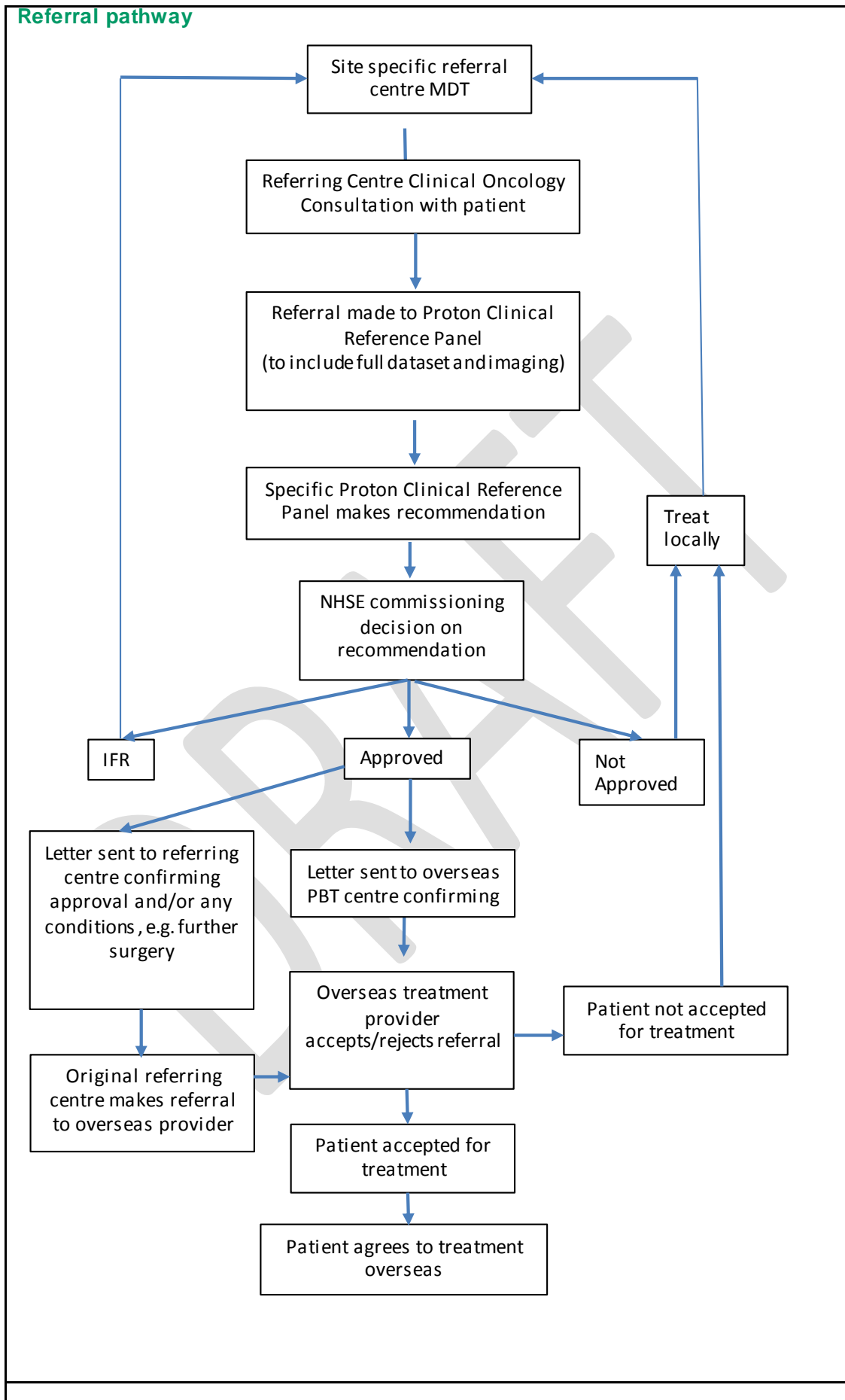
Essential

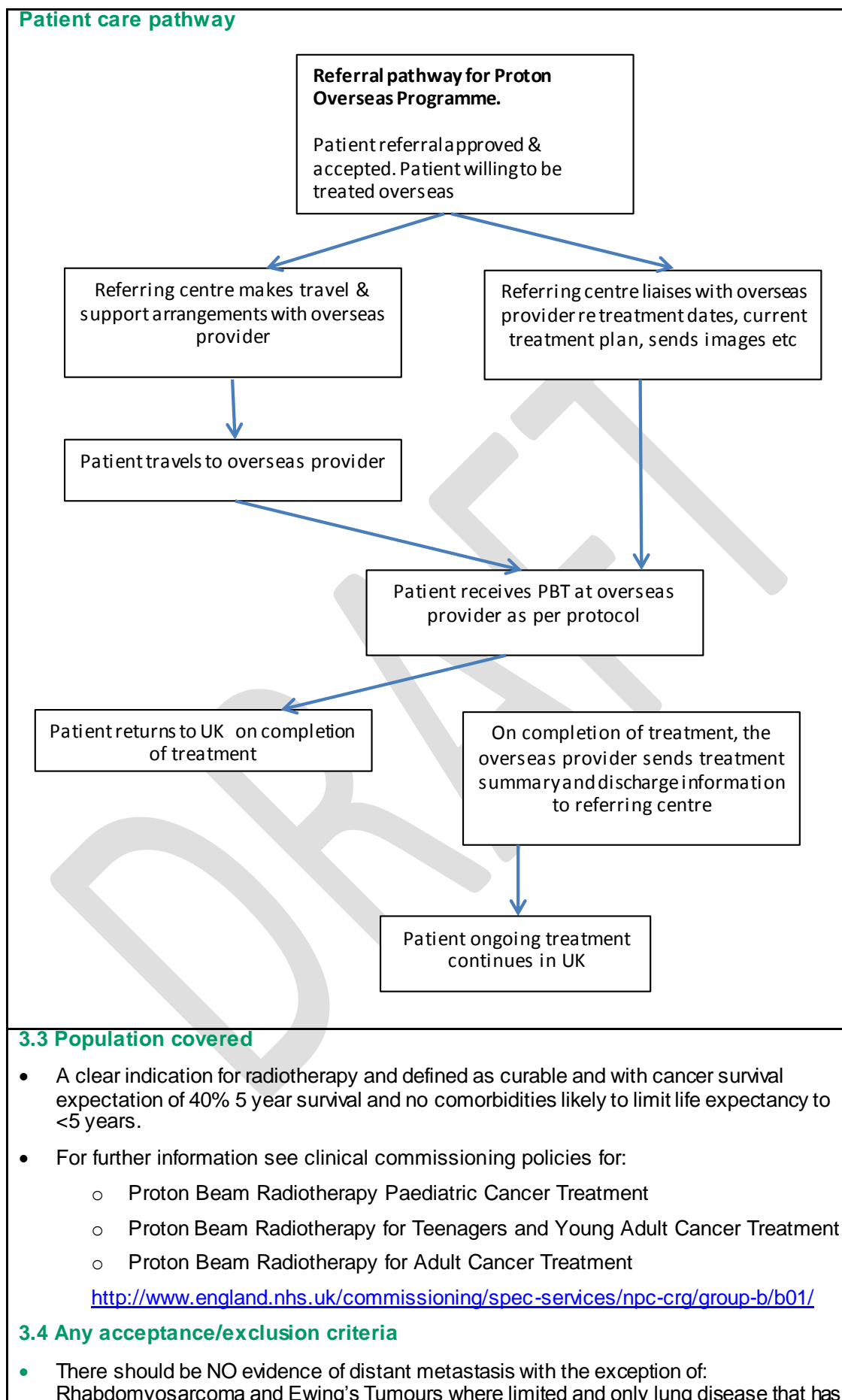
- ensure protection of children and other vulnerable people in line with national standards (equivalent to "Safeguarding Vulnerable People in the Reformed NHS: Accountability and Assurance Framework <https://www.england.nhs.uk/wp-content/uploads/2013/03/safeguarding-vulnerable-people.pdf>)
- have case/patient 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 and over 30 sedated paediatric cases per year
- 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 & 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





a good partial response to the initial radiological reassessment after chemotherapy will be considered for referral and treatment.

- 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/>

3.5 Interdependence with other services/providers

- Oncology – paediatric and adult
- Anaesthesia – paediatric only
- 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
- Support services for patients and carers

- Established links (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 (eg 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>)

<p>4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)</p> <ul style="list-style-type: none"> 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)). <p>4.3 Applicable local standards</p> <p>As above, where appropriate</p>
<p>5. Applicable quality requirements and CQUIN goals</p>
<p>5.1 Applicable Quality Requirements (See Schedule 4A-D)</p> <ul style="list-style-type: none"> 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 <p>5.2 Applicable CQUIN goals (See Schedule 4E)</p> <p>Not applicable</p>
<p>6. Location of Provider Premises</p>
<p>The Provider's Premises are located at:</p>
<p>7. Individual Service User Placement</p>