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Welsh Health Specialised
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Specialised Services Commissioning Policy: CP147

Proton Beam Therapy for adults with cancer

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Document information

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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy.
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Policy Statement

<p>Background</p>	<p>Access to High Energy Proton Beam Therapy (PBT) for selected clinical indications for adults.</p> <p>This policy document outlines the arrangements for funding of this treatment for the population of Wales.</p>
<p>Summary of Access Criteria</p>	<p>Adult patients with selected diagnostic and clinical criteria and meeting the pre-defined criteria as set out in Section 3.</p>
<p>Responsibilities</p>	<p>The responsible clinician (a Consultant Clinical Oncologist) from a relevant specialist cancer multi-disciplinary team (MDT) should refer all suitable patients who meet the pre-defined criteria to the UK National Proton Clinical Reference Panel for approval.</p> <p>Following the panel approval, the clinician will then apply to WHSCC for funding for the treatment.</p> <p>Referrers should:</p> <ul style="list-style-type: none"> • inform the patient that this treatment is not routinely funded outside the criteria in this policy, and • refer via the agreed pathway. <p>The clinician considering treatment should:</p> <ul style="list-style-type: none"> • discuss all of the non-PBT treatment options with the patient • advise the patient of any side effects and risks of the potential treatment • inform the patient that treatment is not routinely funded outside of the criteria in the policy, and • confirm that there is contractual agreement with WHSSC for the treatment. <p>In all other circumstances the responsible clinician should submit an Individual Patient Funding Request (IPFR).</p>

1. Aim

1.1 Introduction

This document has been developed as the policy for the planning of an adult high energy Proton Beam Therapy (PBT) service for people resident in Wales. This service is only commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

PBT is currently delivered through the NHS Proton Overseas Programme, in accordance with the criteria outlined in this document. However, on establishment of a NHS Proton Beam Service for the United Kingdom (currently planned to begin in 2018) the NHS Proton Overseas Programme will be wound down and the indications outlined within this policy will be delivered by the UK service.

The purpose of this document is to:

- define diagnostic and other qualifying clinical indications for access to PBT services
- define referral pathways to PBT treatment centres for patients likely to benefit from PBT
- define the criteria that patients must meet in order to access treatment
- enable all patients in Wales to have equity of access to PBT services.

1.2 Plain language summary

Definitions:

For the sake of clarity, this document distinguishes between **Proton Beam Therapy (PBT)**, and all other types of radiotherapy which are grouped together as **conventional radiotherapy**

Radiotherapy is the use of ionising radiation to treat cancer. Radiotherapy includes Proton Beam Therapy (PBT), which is provided by specialist centres. Radiotherapy also includes treatments provided by all British radiotherapy centres, such as conventional radiotherapy, Intensity Modulated Radiotherapy (IMRT), Image Guided Radiotherapy (IGRT), Stereotactic Radiotherapy (SBRT, SABR), Brachytherapy, Superficial radiotherapy, electron therapy, and Molecular Radiotherapy (i.e. therapeutic radioisotopes such as radioiodine).

Proton Beam Radiotherapy (PBT) refers to the use of high-energy proton beams used instead of conventional radiotherapy to treat cancer and tumours. Like conventional radiotherapy, PBT is capable of being targeted to match a high dose treatment to the shape and position of the tumour area within the body. Because of the characteristic properties of PBT to stop at a precise depth in tissue with little dose beyond that point, it can allow treatment with reduced volumes of irradiated normal tissues in some situations when compared to conventional radiotherapy. It is this property that allows treatment to be delivered with potentially reduced risks of late side effects, and which can permit escalation of radiation dose to radical levels for some tumours situated next to sensitive structures such as the spinal cord or brain, where conventional radiotherapy may be difficult.

Patients who meet the clinical criteria outlined in this policy are eligible for proton beam radiotherapy and should be considered for it by specialised multidisciplinary teams (MDT).

The highly selected adult indications within this policy include rare cancers situated at the skull base or around the spine that present major challenges for conventional radiotherapy as they are situated close to very sensitive normal tissues that limit the dose that can be given. There is evidence that in these situations PBT allows a higher dose to be given to the tumour safely with improved probabilities of local tumour control and potential for cure.

1.3 Relationship with other Policies and Service Specifications

This document should be read in conjunction with the following documents:

- [WHSSC Specialised Services Service Specification: Proton Beam Therapy](#) – CP146
- [WHSSC Commissioning Policy: Proton Beam Therapy for children, teenagers and young adults with cancer](#) – CP148
- All Wales Policy: [Making Decisions on Individual Patient Funding Requests](#) (IPFR).
- NHS England Highly Specialised Commissioning, [Proton Beam Therapy Service \(adults and children\) Service Specification](#)
- Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Paediatric Cancer Treatment](#) – NHS overseas programme
- Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Young Adult Cancer Treatment](#) – NHS overseas programme

- Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Skull Base Tumour Treatment](#) – NHS overseas programme (adult)
- [All Wales National Standards for Teenager and Young People with Cancer aged 16-24 years](#)
- [All Wales National Standards for Children with Cancer aged 0 to 15 years](#)

2. Scope

2.1 Definition

Proton Beam Radiotherapy (PBT) is the use of high-energy proton beams, instead of high energy linear accelerator-generated external beam radiotherapy using X-rays (photons) and electrons, to treat cancer and tumours. In certain situations, PBT may have clinical advantages over conventional radiotherapy techniques because of the distinct depth-dose characteristics of PBT deposition in human tissue, when compared to high energy X-rays and electrons. PBT is given in a number of daily treatments over several weeks.

This policy for adults is linked to those of children and teenagers and young adults (TYA) cancers and is to allow a policy framework for a future UK based service in 2018 onwards. It overlaps with a highly selected group of rare paediatric and TYA cancers for which there is a sufficient evidence of clinical benefit to commission routinely.

2.2 Aims and objectives

This policy aims to define a framework for appropriate adult cancer patients to access proton beam radiotherapy.

The objectives are to:

- ensure appropriate adult cancer patients have access to Proton Beam Radiotherapy and so improved clinical outcomes, especially in terms of late side effects of treatment, and
- in some cases it may also allow opportunities for improved primary cure rates and reduced treatment related second malignancy.

2.3 Codes

There are currently no codes for PBT under Operating Procedure Codes (OPCS) or Healthcare Resource Group (HRG) as the service is not yet available in the UK.

3. Access Criteria

Patients meeting all of the following criteria **and** subject to being approved by the UK National Proton Clinical Reference Panel will be routinely funded for high-energy proton treatment within the Overseas Proton Treatment programme.

This arrangement will be kept under regular review.

In NHS England there is a proposal for two more expansions of clinical indications in 2018 (known as 'Category 1' and 'Category 2').

- Category 1 will be routinely commissioned indications (covering children, TYA and adults) and will be defined through future NHS England clinical commissioning policies.
- Category 2 will be defined through 'commissioning through evaluation' or NHS research funded indications, and this group covers a much wider expansion of the adult indications.

All patients in category 1 and 2 (and treated within the NHS England service) will be part of a prospective programme of evaluation of clinical outcomes.

This policy will be reviewed on an annual basis. The All Wales PBT Advisory Group (AWPROT), a subgroup of the Clinical Oncology Sub-Committee (COSC) of the Welsh Scientific Advisory Committee (WSAC), will be asked to scrutinise any new evidence to help inform WHSSC of any change to the list of indications included in this document.

3.1 Clinical Indications – general principles

Age

Adults are defined as individuals aged 18 years old and over. There is an overlap with the TYA group whose age extends from 16-25 years of age. The age limit applies to the start of treatment. Patients who transition between age groups at any stage during the pathway should be managed according to the original referral criteria assuming this is clinically appropriate.

Ability and willingness to travel

Patients and their accompanying family members need to be willing to travel abroad (or to suitable facilities as these are developed in the UK).

MDT discussion/management

The patient's management should have been fully discussed by the appropriate specialist MDT. Comprehensive diagnosis and staging should have been carried out.

Consultation with the patient and final recommendation for PBT should be made by a Consultant Clinical Oncologist. This is important in order that the general radiotherapeutic issues have been explained. This should include an explanation of the relative merits of PBT compared with high quality conventional radiotherapy.

3.2 Criteria for Treatment

General Criteria

1. A clear indication for radiotherapy and defined as curable and with cancer survival expectation of 40% 5 year survival and no co-morbidities likely to limit life expectancy to <5 years, plus WHO performance status 0-1.
2. There should be **no** evidence of distant metastasis.

Specific Diagnostic Criteria

Base of Skull tumours

Patients with skull base tumours should have had appropriate and maximal safe resection, so that minimal residual disease and adequate clearance from critical dose limiting normal structures (such as brain stem and optic structures) are achieved before referral.

Clinically useful dose escalation with PBT should be reasonably expected compared to photon radiotherapy:

- Chordoma
- Chondrosarcoma
- High naso-ethmoid, frontal and sphenoid tumours with base of skull involvement.
- Adenoid cystic carcinoma with perineural invasion
- Esthesioneuroblastoma

Spinal and Para spinal tumours

Patients with spinal and paraspinal tumours should have had successful maximal resection and adequate clearance from critical dose limiting normal structures.

Patients should have adequate stabilisation without metal placement that will compromise target volume determination or dose distribution.

Clinically useful dose escalation should be reasonably expected compared to photon radiotherapy.

- Spinal and Paraspinal Bone and Soft Tissue Sarcoma
- Spinal Chordoma

The list of commissioned indications will be kept under review by WHSSC and the All Wales PBT Advisory Group (AWPROT). New

indications will be considered for inclusion as new evidence emerges based upon their clinical and cost effectiveness.

Clinical trials

It is recognised that the eligibility criteria for PBT will evolve, partly as the result of clinical research and trials. Trials may be locally developed, national or international. Within the UK, it is assumed that PBT trials will be coordinated by CTRad's (the National Cancer Research Institute's Radiotherapy Clinical and Translational Research Working Group) Proton Beam Therapy Clinical Research Steering Committee (PBT-CRSC). Patients from Wales should have access to appropriate clinical trials. If new PBT indications are supported within NHS England by the Commissioning through Evaluation process, access and funding for Welsh patients should be considered by WHSSC.

3.3 Referral Pathway (see Annex i)

Patients with the cancers listed above must all be considered by appropriate specialist MDT.

Where radiotherapy is considered and patients are eligible according to the criteria as listed above, consideration should be made by the MDT for referral for protons and this should be offered to patients.

The responsible Clinical Oncologist attending the MDT should make the referral to the NHS England Proton Clinical Reference Panel for case review and a recommendation for overseas Proton Treatment.

Following approval from NHS England Proton Clinical Reference Panel, the clinician then should apply to WHSCC for funding approval.

On completion of treatment follow up will be by the referring treatment centre.

Clinical outcomes data is collected on all patients and referring clinicians and teams expected to provide relevant clinical information.

This pathway will be kept under regular review.

3.4 Exclusions

Proton Beam Therapy for children and teenagers and young adults is covered in a separate WHSSC policy (CP148).

The age limit applies to the start of treatment. Patients who transition between the age groups at any stage during the pathway should be managed according to the original referral criteria assuming this is clinically appropriate.

Ocular tumours suitable for low energy PBT are not covered in this policy.

3.5 Exceptions

If the patient does not meet the criteria for treatment an [Individual Patient Funding Request](#) (IPFR) can be made to WHSSC under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted.

Guidance on the IPFR process is available at: www.whssc.wales.nhs.uk

3.6 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effect and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances submit an IPFR request.

4. Putting Things Right: Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- If the patient does not meet the criteria for treatment within this policy and Individual Patient Funding Request (IPFR) can be made by the patient's clinician and will be considered by WHSSC under the guidance of the All Wales Policy: [Making Decisions on Individual Patient Funding Requests](#).
- If an IPFR is declined by the panel the patient and/or their NHS Clinician has the right request information about how the decision was reached. If the patient and their NHS clinician feel **the process** has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken, by the patient's Local Health Board;
- The grounds for the review, which are detailed in the All Wales Policy: [Making Decisions on Individual Patient Funding Requests](#) (IPFR), must be clearly stated.

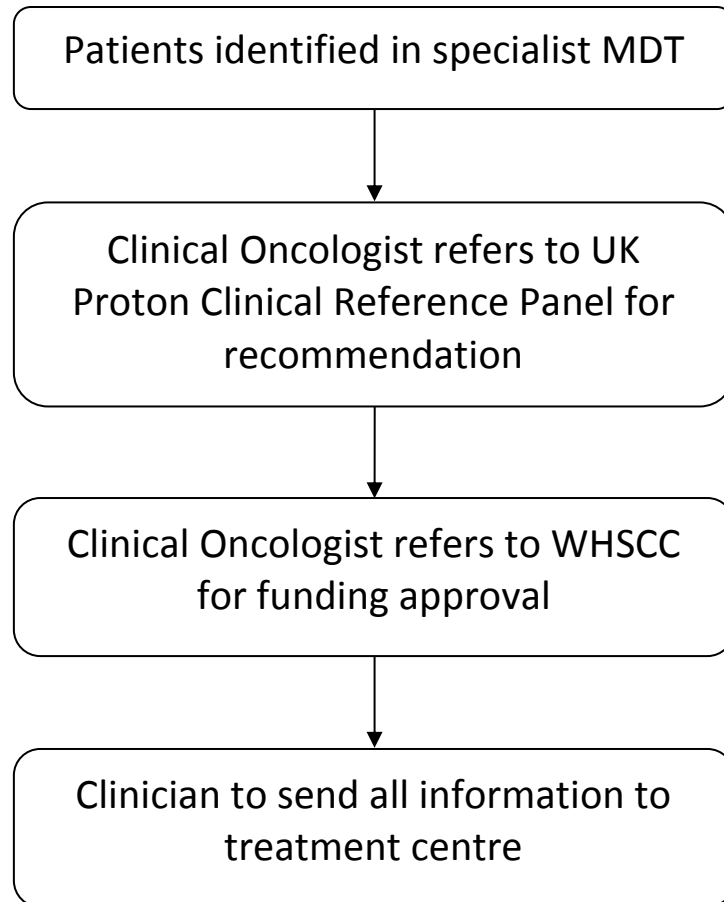
5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex (i) Referral Pathway



Annex (ii) Checklist

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The following checklist should be completed for every patient to whom the policy applies:

- i) Where the patient meets the criteria **and** the procedure is included in the contract **and** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- ii) The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- iii) The patient meets the criteria but wishes to be referred to a non contracted provider. [An Individual Patient Funding Request](#) (IPFR) form must be completed and submitted to WHSSC for consideration.
- iv) The patient does not meet criteria, an [Individual Patient Funding Request](#) (IPFR) form must be completed and submitted to WHSSC for consideration for treatment.