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Proton Beam Therapy for children, teenagers and young adults in the treatment of malignant and non-malignant tumours

Commissioning Policy: CP148

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Abbreviations

IPFR	Individual Patient Funding Request
NWJCC	NHS Wales Joint Commissioning Committee
PBT	Proton Beam Therapy
TYA	Teenagers and Young Adults

Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission Proton Beam Therapy (PBT) for Children, Teenagers and Young Adults in the treatment of malignant and non-malignant tumours in accordance with the criteria outlined in this document.

In creating this document NWJCC has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

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This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed for the planning and delivery of Proton Beam Therapy (PBT) for Children, Teenagers and Young Adults (TYA) in the treatment of malignant and non-malignant tumours for people resident in Wales. This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain Language Summary

*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).*

Children are defined as individuals aged up to their 16th birthday. The age limit applies to the start of treatment. Patients who transition between age groups at any stage during the pathway should have their cancer managed according to the original referral criteria assuming this is clinically appropriate.

TYA patients are defined as individuals aged from their 16th to their 25th birthday. There is an overlap between TYA and adult patients.

Most cancers affecting children differ from those affecting adults. They occur in different parts of the body, appear differently under the microscope and respond differently to treatment. Cancers in teenagers and young adults (aged 16 to around 25 years old) are often 'paediatric-type' pattern of malignancies.

Cancer in children, teenagers and young adults encompasses a wide range of individual diagnoses, each of which is treated according to specific clinical protocols and treatments according to stage (extent of spread) and body site. Around 40% are leukaemias and lymphomas (forms of blood cancer), 25% are brain tumours, with the remainder comprising a wide range of other tumours. Treatment is frequently complex and intensive

but cure rates among children are much higher than for most adult cancers, and overall more than 80% of children are completely cured.¹

Rarely, non-malignant conditions, for example desmoid fibromatosis, may also require radiotherapy as part of their treatment regimens.

PBT refers to the use of high-energy proton beams instead of conventional radiotherapy to treat cancer and tumours. PBT utilises a different method of conformally targeting a high dose to a tumour compared to conventional radiotherapy and may thus allow dose escalation to the treatment volume when compared to conventional treatment. As a result of the characteristic properties of PBT (i.e. 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 nearly all 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.

1.2 Aims and Objectives

This policy aims to define the commissioning position of NWJCC on the use of PBT for children and TYA in the treatment of malignant and non-malignant tumours.

The objectives of this policy are to:

- ensure commissioning for the use of PBT is evidence based
- ensure equitable access to PBT
- define criteria for children and TYA in the treatment of malignant and non-malignant tumours to access treatment
- improve outcomes for children and TYA in the treatment of malignant and non-malignant tumours.

1.3 Epidemiology

Paediatric cancer is relatively rare (less than 1% of all cancers)² with a characteristic pattern of tumour types and incidence.

TYA cancer is also relatively rare (less than 1% of all cancers)³ with a characteristic pattern of tumour types and incidence. Although TYA patients are defined as individuals

¹ [Gan H.-W. & Spoudeas H.A. \(2014\). Long-term follow-up of survivors of childhood cancer \(SIGN Clinical Guideline 132\). Archives of Disease in Childhood – Education and Practice, 99:138-143](#)

² [Children's cancers incidence statistics | Cancer Research UK](#)

³ [Young people's cancers statistics | Cancer Research UK](#)

aged from their 16th to their 25th birthday there is inevitably an overlap between TYA and adult patients.

There is also a spectrum of cancers that are more common in the paediatric age group and occur with less frequency in the TYA definition group but overlap.

1.4 Current Treatment

Standard pathways of care vary depending on the type of cancer and can include chemotherapy, surgery and radiotherapy.

One third of survivors of childhood cancer report severe or life-threatening complications up to 30 years after the diagnosis of cancer. This can be due to side effects of cancer treatment, and radiotherapy is a significant contributing factor.

Late effects of radiotherapy are related to a number of factors, including the age of the child, the total dose of radiation, the volume of tissue treated and the critical structures within the radiation field. Late effects of radiotherapy can include effects on IQ, learning and memory, pituitary dysfunction requiring life-long hormone replacement, risk of vascular sequelae such as stroke, infertility, premature menopause, risk of cardiac, renal and lung toxicity and the risk of secondary radiation induced malignancy. These risks are particularly high in this age range due to the vulnerability of growing tissues compared to mature adults.

1.5 Proposed Treatment

Proton Beam Therapy (PBT) is a potential alternative to conventional radiotherapy. PBT provides radiation by delivering a beam of proton particles rather than X-rays. The physical properties of protons result in a significantly reduced radiation dose being deposited in the normal tissue beyond the tumour. This is in contrast to X-rays where there is dose extension beyond the tumour.

This leads to two main advantages. Firstly, the reduction in the volume of normal tissue irradiated when treating tumours in children, teenagers and young adults is expected lead to an improvement in the quality of survival by reducing the long term side effects of treatment. Secondly, PBT may have the ability to treat tumours which are adjacent to normal tissue where the normal tissue tolerance would prevent X-ray radiotherapy from delivering an effective dose. In this case PBT would be able to deliver an effective dose of radiation to the tumour and avoid irradiating the surrounding normal tissue beyond its tolerance thereby leading to increased cure rates. This is particularly advantageous for radio-resistant tumours where higher doses are required to optimise chance of cure.

1.6 What NHS Wales has decided

NWJCC has carefully reviewed the evidence of PBT for children and TYA in the treatment of malignant and non-malignant tumours. We have concluded that there is enough evidence to fund the use of PBT, within the criteria set out in section 2.1.

1.7 Relationship with other documents

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

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests \(IPFR\)](#).
- **NHS Wales Joint Commissioning Committee policies and service specifications**
 - NWJCC Proton Beam Therapy for adults with cancer, Commissioning Policy (CP147)
 - NWJCC Services for Children with Cancer, Service Specification (SS86)
- **Relevant NHS England policies**
 - [Proton Beam Therapy Service \(All Ages\) Service Specification](#)
 - [Proton Beam Therapy for Children, Teenagers and Young Adults in the treatment of malignant and non-malignant tumours](#)
- **Other published documents**
 - [All Wales National Standards for Teenager and Young People with Cancer aged 16-24 years](#)

2. Criteria for Commissioning

The NHS Wales Joint Commissioning Committee approve funding of Proton Beam Therapy (PBT) for Children, Teenagers and Young Adults (TYA) with malignant and non-malignant tumours in line with the criteria identified in this policy.

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.

This arrangement will be kept under regular review.

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 NWJCC of any change to the list of indications included in this document.

2.1 Inclusion Criteria

Age

This policy is for children, teenagers and young adults up to their 25th birthday.

The age limit applies to the start of treatment. Those who transition between age groups at any stage during the pathway should have their disease managed according to the original referral criteria assuming this is clinically appropriate. There is an overlap between TYA and adult patients.

Prior to Proton Beam Therapy

Prior to PBT, the following should have taken place:

- Discussion by the appropriate specialist MDT
- Comprehensive diagnosis and staging
- Consultation with the children, teenagers and young adults and/or their carer/guardian where general radio-therapeutic issues and the relative merits of PBT compared with high quality conventional radiotherapy have been discussed and explained.

The final decision to offer PBT is made by a consultant clinical oncologist.

2.2 Criteria for Treatment

For Proton Beam Therapy (PBT) to be routinely funded, Children, Teenagers and Young Adults (TYA) need to meet all of the following criteria:

- A principal cancer treatment centre MDT for children and/or TYA has confirmed that treatment with PBT is an appropriate treatment option.
- There is a clear indication for radiotherapy, and defined as curable (leading if cured to normal or near-normal life expectancy) with a reasonable disease specific 5 year survival expectation and no comorbidities likely to limit life expectancy to fewer than 5 years.
- Are under 25 years of age
- There is **no** evidence of distant metastases, with the exception of certain tumours which remain curable when metastatic. For example, metastatic intracranial germinoma, rhabdomyosarcoma and Ewing's Tumours with limited volume lung metastases that have demonstrated a good partial response on radiological reassessment after chemotherapy.
- Adequate performance status and medically sufficiently stable to undergo PBT without a delay which may lead to increased risk of recurrence or a compromise to cure rate and combined treatment pathways.
- If an adult over the age of 25 years is diagnosed with a typical paediatric diagnosis requiring radiotherapy and meeting all other (non-age-specific) criteria as above, they may be referred for PBT and individual cases will be considered by the panel.

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, for example based on clinical trial data or within NHS England through their Evaluated Commissioning Projects, access and funding for Welsh patients should be considered by AWPROT and NWJCC.

2.3 Exclusion Criteria

PBT for adults is covered in a separate NWJCC Policy: Proton Beam Therapy for Adults with Cancer, Commissioning Policy (CP147).

Patients requiring radiotherapy for indications where there is no dosimetric advantage for protons over photons will be excluded (for example, total body irradiation (TBI), whole brain radiotherapy, extremity sarcomas (see Annex ii for further details, although this list

is not exhaustive. Some referrals will need to be discussed with the PBT teams on a case-by-case basis).

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

See Annex ii for indications where patients' life expectancy is unlikely to yield a significant clinical benefit with PBT.

2.4 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.5 Acceptance Criteria

The service outlined in this policy is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP Practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.6 Transition Arrangements

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services, NICE guidance NG43](#) and the [Welsh Government Transition and Handover Guidance](#)

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services. This preparation should start from early adolescence 12-13 year olds. The exact timing of this will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

For the specialised paediatric services it commissions, the JCC will routinely commission treatment up until a patient is 16 years old. The JCC does not commission specialised paediatric services for patients aged 18 years and older. For patients aged 16 or 17 years of age, the JCC will continue to commission ongoing specialised treatment initiated before the patient's 16th birthday and under the ongoing care of a specialised paediatric team.

2.7 Patient Pathway (Annex i)

- Patients with paediatric and TYA cancers should all be considered by appropriate specialist MDTs. For children the relevant MDT will be either the paediatric MDT or the joint adult/paediatric neuro-oncology MDT.
- For TYA patients the referral will be made by the relevant disease site MDT. Patients should be referred to the 'co-ordinating TYA MDT' which will also need to provide support to patients and families at what will be a disruptive time.
- 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 PBT and this should be offered to patients.
- The responsible Clinical Oncologist attending the MDT should make the referral to the relevant PBT National Clinical Panel (via the online referral portal/imaging must be sent via the Image Exchange Portal) for case review and a recommendation for Proton Treatment.
- If approved by the PBT National Clinical Panel:
 - the referral is forwarded automatically via the portal. The proton beam centre will contact the patient's local oncology team to confirm receipt of referral and request any additional information that may be required.
 - PBT treatment will be funded directly by NHS England and recharged to NWJCC.
- On completion of treatment, follow up will be by the referring treatment centre.

2.8 Designated Centres

The Christie NHS Foundation Trust
Wilmslow Road
Manchester
M20 4BX

University College London Hospitals NHS Foundation Trust
235 Euston Road
London
NW1 2BU

2.9 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

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

Further information on making IPFR requests can be found at: [Individual Patient Funding Requests](#)

2.10 Clinical Outcome and Quality Measures

The Provider should work to written quality standards and provide monitoring information to the lead commissioner.

The centre should enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

The PBT programme should aim to deliver the following:

- improved cancer survival and cure rates
- ability to minimise and reduce the short and long-term side effects of treatment
- delivery of accurately targeted therapeutic doses of radiation to tumours
- 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.

The Provider should:

- have a structured clinical outcomes collection and analysis programme
- audit practice to inform change
- report and learn from radiotherapy error and near-miss events, to inform practice
- prospectively collect an RTDS-compatible dataset for routine submission to the Welsh Cancer Intelligence Surveillance Unit or Public Health England
- collect relevant diagnosis specific data on clinical outcome measures

- overall survival
- progression free survival
- tumour local control
- acute and late toxicity
- patient satisfaction data
- describe links to clinical trials, national registries and academic studies.

2.11 Responsibilities

The responsible clinician (a consultant clinical oncologist) from a relevant specialist cancer MDT should refer all suitable patients to the UK National Proton Clinical Reference Panel for approval.

Following the panel approval, the clinician will then apply to NWJCC for funding for the treatment.

Referrers should:

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

Clinicians considering treatment should:

- discuss all the non-PBT treatment options with the patient and/or their parent or guardian;
- advise the patient and/or their parent or guardian of any side effects and risks of the potential treatment
- inform the patient and/or their parent or guardian that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with NWJCC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Evidence

NWJCC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

3.1 References

The indications for PBT described in this policy (section 2.1) are supported by a comprehensive evidence review conducted by NHS England⁴.

There is extensive literature describing the dosimetric advantages of PBT compared to conventional radiotherapy, which leads to less irradiation of normal surrounding tissue. Particularly in young patients, who have many years in which to accumulate and live with late radiotherapy toxicities, this offers a great theoretical advantage. Due to this, PBT for young people is internationally considered to be the treatment of choice. PBT has been used for many years across the world safely, including within services commissioned by the NHS Wales via the overseas programme. Given the uncertainties regarding definite long term clinical gain (due to lack of long term follow up data from randomised controlled trials in this group of patients), clinicians and patients/guardians will discuss the pros and cons of PBT versus PRT using a decision-making aid, which will offer a structured format for discussion.

3.2 Date of Review

This document is scheduled for review every three years, unless information is received which indicates that the policy requires revision.

If an update is carried out the policy will remain extant until the revised policy is published.

⁴ <https://www.england.nhs.uk/wp-content/uploads/2020/10/proton-beam-therapy-evidence-review.pdf>

4. Equality Impact and Assessment

The Equality Impact Assessment (EWLIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning 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.

5. Listening to People:

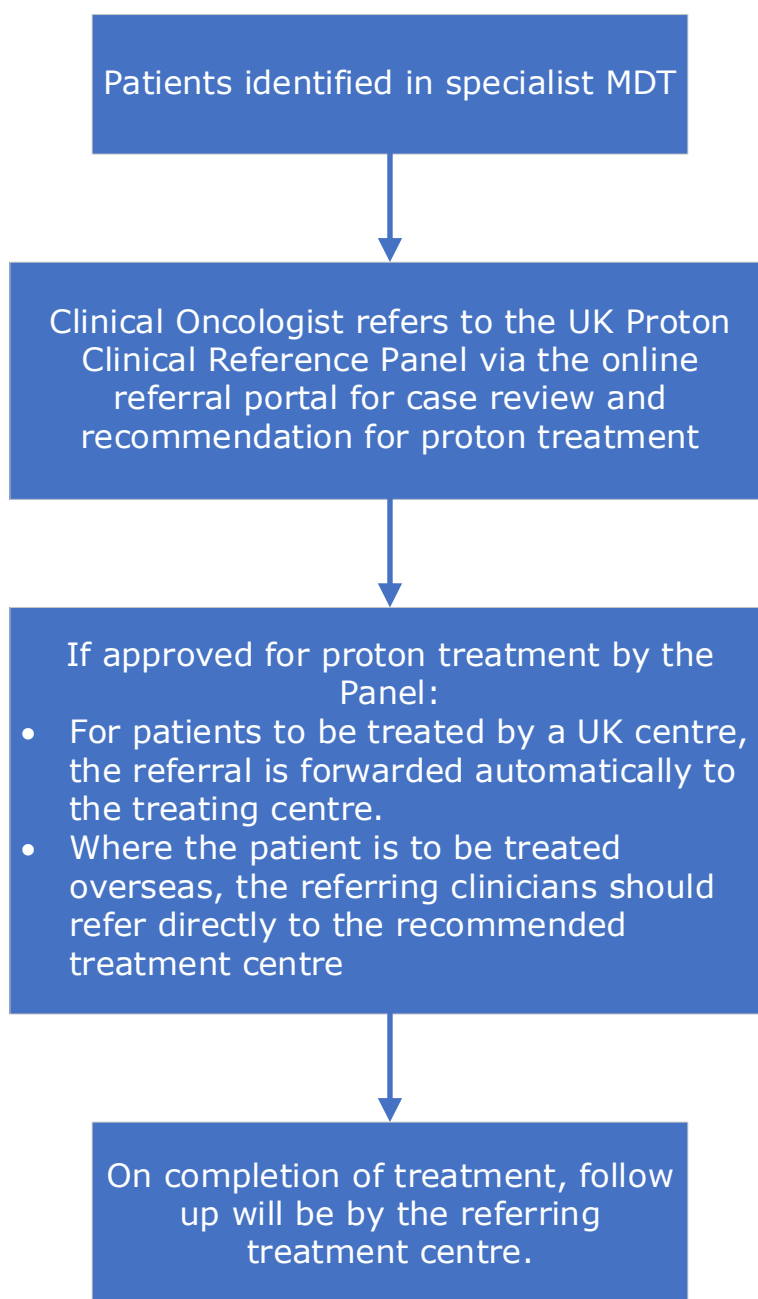
5.1 Complaints, Incidents and Redress Process

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 a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to [Listening to People, The NHS Wales Complaints, Incidents and Redress Process – People’s Guidance 2026](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to NWJCC.

Annex i Patient Pathway



Annex ii Paediatric indications suitable for conventional radiotherapy (photons or electrons)

Indications where patients' life expectancy unlikely to yield a significant clinical benefit with PBT	
Patients with biologically aggressive diseases with poor prognoses	Diffuse Midline Glioma (Including Diffuse Intrinsic Pontine Glioma - DIPG) High Grade Glioma CNS Atypical Teratoid Rhabdoid Tumour (ATRT) (incompletely resected, recurrent, poor performance status or unstable on chemotherapy)
Patients with extensive metastatic disease treated with purely palliative intent (i.e. for symptom control only) with limited life expectancy	Any anatomical site Variable number of fractionation regimes
Radical, Adjuvant and Palliative Indications where the anatomical site location and/or an extensive Radiotherapy Target volume renders PBT unlikely to yield a clinical benefit (no significant Organs at Risk sparing and/or integral dose benefit)	
Distal limb primary sites (without pelvic or thoracic extension)	e.g. Ewing's/Rhabdomyosarcoma/ Osteosarcoma Adult-type sarcomas Fibromatosis
Extensively wide RT Target volume	Total Body Irradiation (pre BMT conditioning- all disease indications) Total Nodal Irradiation Whole Brain RT e.g. Cranial Boost with TBI -CML/ALL BMT Primary Cerebral Lymphoma Palliative WBRT Whole Lung Irradiation (in absence of additional focal boost to e.g. chest wall/mediastinum/spine etc) e.g. Ewing's sarcoma RMS Wilms tumour Hodgkin's lymphoma

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	Whole abdominal/Pelvic Irradiation e.g. Ruptured Wilms tumour Desmoplastic small round blue cell tumour
Superficial RT volume (preferentially treatable with Electrons or Orthovoltage radiation modalities)	e.g. Cutaneous/scalp lesions (includes benign (e.g. keloid) and malignant conditions)

Annex iii Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Principal cancer treatment centre

The principal treatment centre provides expertise and experience in the management of an individual patient's particular type of cancer, which includes the provision of multidisciplinary care, the coordination of an individual's care with other appropriate locations and access to clinical trials and research. Such centres will have defined clinical governance structures and clear policies for transition to age-appropriate environments and specialist teams.

Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

Email:

NWJCC consultation mailbox – NWJCC.Consultation@wales.nhs.uk

Telephone:

General Enquiries – 01443 433112

Website:

[Contact us - NHS Wales Joint Commissioning Committee](#)

Writing:

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

South Wales Offices

Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ

Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

North Wales Offices

Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY

Preswylfa, Hendy Road, Mold, CH7 1PZ