Clinical Commissioning Policy: Proton Beam Radiotherapy (High Energy) for Skull Base Tumour Treatment – NHS Overseas Programme (Adult)

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Contents

Policy Statement

NHS England will commission High Energy Proton Radiotherapy for a specific subset of Adult cancers. Initially this activity will be provided through the NHS Proton Overseas Programme, in accordance with the criteria outlined in this document. However, on establishment of a proton beam service for the United Kingdom (UK) (currently planned to begin in 2018) the indications outlined within this policy will delivered by the UK service. There is currently insufficient evidence to support routine commissioning abroad in other indications for radiotherapy for adult cancer where there is a policy supporting the routine commissioning of conventional photon radiotherapy.

In creating this policy NHS England 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.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Proton Beam Therapy (PBT) Radiotherapy refers to the use of high-energy proton beams used instead of conventional X-Rays to treat cancer. It is capable of being targeted to match a high dose treatment to the shape and position of the tumour area within the body. However, because of its characteristic properties to stop at a precise depth in tissue with no dose beyond that point, it can allow treatment with significantly reduced volumes of irradiated normal tissues. There is strong evidence that risks of late side effects of treatment can be reduced by the use of proton beam radiotherapy as well as the risks of radiotherapy induced second cancers later in life as it allows the partial or complete avoidance of radiation dose to normal tissues.

These highly selected adult indications 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 very good evidence that protons allow a significantly higher dose to be given to the tumour safely which gives higher rates of local tumour control and potential for cure.

1. Introduction

Proton Beam Radiotherapy (PBT) is a specific type of radiotherapy delivery with unique properties that make it suitable for the treatment of a subset of those patients treated by radiotherapy with curative intent. The main factors separating this subset relates to the ability of protons to:

a) Reduce dose to critical normal tissues, thereby reducing late side effects; and/or
b) Allowing an increase in delivered dose to the tumour target, especially where this is close to dose limiting normal tissues, and thereby increasing local control and cure rates.

It is relatively expensive compared to conventional radiotherapy and also not available in the UK at present. The indication for treatment abroad in any individual patient has to take into account the complex medical pathways of these rare cancers, the social and personal context and the likelihood of any improved clinical outcomes.

The NHS must be mindful of value for money and justify high cost treatments based on selecting only patients who are likely to benefit and where a sufficient evidence base is available.

2. Definitions

Proton Beam Radiotherapy: is the use of high-energy proton beams used instead of conventional X-Rays to treat cancer. It is capable of being precisely targeted using imaging to match a high dose treatment volume to the shape and position of the tumour area within the body. However, because of its characteristic properties to stop at a precise depth in tissue with, no dose beyond that point, it can deliver treatment with significantly reduced volumes of unnecessarily irradiated normal tissues. It is given in a number of daily treatments over several weeks.

3. Aim 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 equitable access to Proton Beam Radiotherapy and so improved clinical outcomes, especially in terms of improved local control and cure rates with potentially reduced levels of late side effects of treatment.
- In some cases it may also allow opportunities for reduced treatment related

second malignancy.

4. Epidemiology and needs assessment

The tumours within these policy criteria are a combination of different rare cancers and clinical situations with similar characteristics requiring high radiotherapy dose to achieve local control and being very close anatomically to sensitive normal tissue structures that limits treatment with conventional radiotherapy.

Chordoma: This is a rare slow growing tumour arising from remnants of the embryonic notochord and is most common in the skull base or sacrum. It has an incidence of 1 per million of the population per annum and accounts for 3% of bone tumours. It can occur at any age but the average age for skull base tumours is 49 whereas for sacral tumours is 69 It rarely spreads with metastatic disease, particularly if from the most common skull base site. It is best treated by maximal safe surgical resection followed by high dose radiotherapy.

Chondrosarcoma: This is a rare cancer arising from cartilage producing cells. It can arise at any age and represents 30% of skeletal system cancers, affecting the axial skeleton including the spine and skull base, where it represents 6% of tumours at this site. Treatment consists of primary surgery where possible but radiotherapy is particularly useful to improve local control and PBT in particular for tumours situated at the skull base

Although difficult to get accurate figures it is estimated that up to 100 patients per annum may have chordoma and chondrosarcoma and be suitable for PBT.

Primary bone sarcoma are rare (500 cases per annum in the UK) and treated at specialist treatment centres. Soft tissue sarcomas are rare and account for less than 1% of all cancers and can occur at any age but have a highest incidence in younger patients under 25 or above 50. **Primary bone and soft tissue sarcomas arising in the paraspinal regions** are even rarer and may give rise to 100 cases per annum eventually in the UK, but only a very small proportion of these will be suitable for PBT abroad. They may require highly complex surgery and metal stabilisation.

Tumours arising in the **Nasal Cavity and Paranasal Sinuses** are uncommon with an incidence of about 5.6 cases per million. The most common type of cancer is Squamous cell cancer (52%) but other rare types occur and include **Adenocarcinoma, Adenoid Cystic Carcinoma** and **Esthesioneuroblastoma** (arising from the olfactory epithelium). Overall therefore this group of tumours would have an incidence of about 310 case per annum in England. Treatment is usually by surgery but local recurrence rates with surgery alone are high so radiotherapy is added as an adjuvant therapy. These can also be localised but inoperable and

primary radiotherapy used.

Invasion of the skull base is particularly problematic in this group of tumours as it brings similar technical limitations and problems for conventional radiotherapy in that the close proximity of critical structures such as optic apparatus and the brain limit doses.

PBT allows safe dose escalation and improved local control in a proportion of these patients. This may be up to 100 cases per annum but it is estimated that under half of these patients from this group may be suitable for treatment abroad due to prolonged post-operative recovery, care needs or other limiting comorbidities.

5. Evidence base

Because of the large number of possible indications for radiotherapy and PBT, the degree of variation in clinically important patient and disease parameters, and the limited experience in commoner cancers, it is extremely difficult to evaluate the clinical effectiveness of PBT for every potential clinical condition.

The National Radiotherapy Advisory Group recommendations in 2007 (incorporated into the Cancer Reform Strategy are based on clinical consensus and well referenced, although the level of the evidence is generally poor, being based largely on case series. Other more recent National PBT Programmes and National Frameworks have consistent conclusions on the clinical benefit for PBT in the selected cancers and clinical situations contained within the PBT policies and for treatment abroad within the Overseas Programme e.g. American Society for Therapeutic Radiology and Oncology (ASTRO) and Dutch, Danish and Swedish National Policies.

There is good clinical evidence for the ability to safely deliver dose escalated radiotherapy with PBT in specific clinical situations to achieve high local control rates and in other areas to avoid unnecessary radiotherapy dose to normal tissues and so reduce the risk of important side effects and risks of radiotherapy induced second malignancy.

There is good evidence of improved 5 year local control from PBT is these adult cancers treated with PBT in high quality case series.

There is relatively little published evidence as to the cost-effectiveness of PBT in all different cancer types.
NHS England is including a detailed program of evidence review and policy development for PBT within its work program for both the Overseas Programme and the UK PBT National Service.

6. Rationale behind the policy statement

PBT is a highly complex and expensive form of radiotherapy. The evidence base for many cancers is not clear-cut so a formal process for approval and funding is required to ensure appropriate patients with an ability to gain are selected and costs justified. Because treatment is delivered overseas other factors may need to be taken into account so that overall outcomes can be balanced and cure rates not compromised.

Patients have been receiving PBT abroad within the previous highly specialised commissioning structure since 2008. This policy brings that guidance within the current NHS framework and updates the clinical indications to reflect new evidence and processes.

This policy for adults is linked to those of Paediatric and 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.

Low energy PBT has been used in England since 1989 with highly successful results for ocular malignancy but the energy available at Clatterbridge is too low for use in other cancers.

7. Criteria for commissioning

Adult (16 or over) Clinical Indications

Patients meeting all of the following criteria AND subject to being approved by the NHS England National Proton Clinical Reference Panel will be routinely funded for high-energy proton treatment within the Proton Overseas Programme.

1. General

1.1 A clear indication for radiotherapy, defined as curable, with cancer survival expectation of at least 40% 5 year survival and no comorbidities likely to limit life expectancy to <5 years plus WHO Performance Status 0-1.

1.2 There should be NO evidence of distant metastasis.

2. Specific Diagnostic Criteria

2.1 Base of Skull

2.1.1 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).

2.1.2 Dose escalation should be possible compared to conventional RT

2.1.3 Chordoma

2.1.4 Chondrosarcoma
2.1.5 High Naso-ethmoid, frontal and sphenoid tumours with Base of Skull Involvement.
2.1.6 Adenoid Cystic Carcinoma with perineural invasion
2.1.7 Esthesioneuroblastoma

2.2 Spinal and Para-spinal

2.2.1 Patients should have had successful maximal resection so that minimal residual disease and adequate clearance from critical dose limiting normal structures
2.2.2 Patients should have adequate stabilisation but without metal placement that will compromise target volume determination or dose distribution
2.2.3 Dose escalation should be possible compared to conventional RT
2.2.4 Spinal & Para-spinal Bone and Soft Tissue Sarcoma
2.2.5 Spinal Chordoma

8. Patient pathway

Patients with the rare cancers below are all considered by specialist MDTs. Treatment may consist of a variable combination of surgery, chemotherapy and radiotherapy in complex pathways, and in many cases within the context of clinical studies or trials.

It is essential that any surgery should have been carried out within expert specialised units to ensure adequate imaging, multidisciplinary care and quality of resection to allow best outcomes of combined modality care required for many of these tumours.

Where radiotherapy is considered and patients are eligible according to these criteria consideration should be made by the MDT for referral for protons and this offered to parents and patients. There may be complex and good medical or social reasons why PBT is not considered to be possible or the best treatment for individual patients. Reasons for patients not being referred should be documented.

Patients will be referred to the NHS England National Proton Clinical Reference Panel for case review and a recommendation on approval for funding to NHS England commissioners. The panel reviews all relevant clinical details and imaging with a target response time for a decision of within 10 working days of receiving a complete application.

On approval a patient can be referred to the designated proton treatment centre abroad. Clinical details and a formal clinician to clinician referral is then made by the referring clinical oncologist to the proton treatment centre following direct

consultation with parents and patient about the aims and objectives of treatment. Imaging may be sent by the Proton Administration team directly to the treatment centre abroad by secure image exchange portal.

If accepted for treatment the practical travel and accommodation arrangements should be made by the referring centre team in conjunction with the proton treatment centre. Travel and accommodation costs will be paid by NHS England in accordance with the published policy (B01/P(HSS)a 2013).

The patient will travel to the proton treatment centre abroad for the duration of assessment, planning and proton treatment. The proton and associated treatment costs will be met by NHS England.

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 is a continuance of that of the past National Specialised Commissioning Team (NSCT) agreed pathway.

9. Governance arrangements

The referral process specifies detailed information required from referring clinicians and teams to allow clinical decisions on treatment and care to be made abroad.
As there are currently no high-energy PBT facilities in the UK, NHS England currently commissions proton beam therapy services from three providers, two in the USA and one in Switzerland.

Full treatment details and summaries are communicated directly to referring clinical teams.

PBT aligns with the general principles, concepts and governance linked to the Radiotherapy Clinical Reference group as described in the general radiotherapy service specification for services within England.

10. Mechanism for funding

PBT, as a highly complex service with treatment delivered overseas is funded through NHS England Specialised services directly. Treatment costs are funded directly through NHS England to treatment centres abroad. Travel and accommodation costs may be met through patients referring centres and hospitals or directly.

Individual funding requests outside of this policy requires specialised knowledge and

the Proton Overseas Programme National Clinical Reference Panel will be used to support and inform commissioning decisions.

11. Audit requirements

The Proton Administrative team will keep data on activity and treatment and high-level clinical outcomes. It is expected that follow up information will be returned from referring centres. A more detailed late effects scheme is proposed linking into proposals for a UK based service.

12. Documents which have informed this policy

Cancer Reform Strategy 2007

http://www.nhs.uk/NHSEngland/NSF/Documents/Cancer_Reform_Strategy.pdf

Improving Outcomes: A strategy for Cancer 2011

https://www.gov.uk/government/publications/the-national-cancer-strategy

13. Links to other policies

All other policies, clinical guidelines and patient information is available at:

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

This policy links to other policies within the Proton Overseas Programme. Most specifically it links directly to the Proton Beam Radiotherapy (High Energy) for Paediatric and Adult Cancer Treatment – NHS Overseas Programme.

The transport and accommodation Policy for PBT is available as above.

Low energy PBT is available for the treatment of rare ophthalmic cancers in England within the ocular malignancy service specification.

http://www.england.nhs.uk/wp-content/uploads/2013/06/d12-ocular-oncology-ad.pdf

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

To be added