



Proton Beam Therapy

Clinical Coverage Criteria

Overview

Proton beam therapy (PBT) is a form of external radiation therapy in which positively charged subatomic particles (protons) are precisely targeted to a specific tissue mass using a sophisticated stereotactic treatment planning and delivery system. The goal of PBT is to deliver a higher target dose with lower normal tissue exposure than is possible with conventional photon irradiation, thereby improving local control of tumors and reducing acute and late complications.

Conventional external beam radiation therapy (EBRT), three-dimensional conformal radiation therapy (3D-CRT), and intensity modulated radiation therapy (IMRT) are delivered via photon beams. Proton beams differ from photon beams mainly in the way they deposit energy in living tissue. Whereas photons deposit energy in small packets all along their path through tissue, protons deposit much of their energy at the end of their path (called the Bragg peak) and deposit less energy along the way. In theory, use of protons should reduce the exposure of normal tissue to radiation, possibly allowing the delivery of higher doses of radiation to a tumor.

Although hundreds of patients have been treated worldwide with PBT, current evidence provides support for limited use outside of research. Fallon Health will continue to monitor evolving studies and literature on PBT using resources such as ASTRO, the American Society for Radiation Oncology.

Clinical trials are used to establish whether new treatments are beneficial to humans. It is clear from limited clinical trials that PBT is not inferior to other radiation therapy techniques for many tumors. What has not been shown is that PBT is superior and that its ability to spare normal surrounding tissue translates to improved patient outcomes (e.g., overall survival, recurrence-free survival, etc.).

Policy

Fallon Health Requires Prior Authorization for Proton Beam Therapy. Coverage Criteria is diagnosis specific as outlined below. These requests must be supported by the treating provider(s) medical records.

Fallon Commercial and Masshealth Plan Members: The below disease sites will be considered for coverage:

Uveal melanoma:

Fallon Health considers proton beam therapy (PBT) medically necessary primary therapy for plan members uveal melanomas (iris, choroid, or ciliary body), with no evidence of metastasis or extrascleral extension, and who are not candidates brachytherapy.

Written documentation must demonstrate why brachytherapy is not an option. Brachytherapy is generally indicated for anterior small (<10 mm in diameter and <3 mm

in height) and medium (10 to 15 mm in diameter and 3 to 5 mm in height) tumors. Tumors as large as 24 mm in diameter and 14 mm in height have been treated with proton beam therapy. Enucleation is indicated for tumors with large extrascleral extensions and extensive iris neovascularization or tumors involving more than 30% of the ocular volume. Fallon Health considers reirradiation for local recurrence of uveal melanoma not medically necessary.

CNS tumors:

Fallon Health considers PBT medically necessary for plan members with chordoma or low-grade (I or II) chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine (with or without biopsy or partial resection). To be eligible for this treatment the member must have a residual localized tumor without evidence of metastasis.

Fallon Health will review any additional requests for Proton Beam Therapy to treat different sites however current evidence does not support it superior clinical outcomes.

Medicare based plans Fallon Health will cover treatment for the following site provided Criteria is met. This is accordance with Medicare Local Coverage Determination (L35075)

PBT is considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient. Examples of such an advantage might be:

1. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to lessen the risk of excessive early or late normal tissue toxicity.
3. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity.
4. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

On the basis of the above medical necessity requirements and published clinical data, disease sites that frequently support the use of PBT include the following:

- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to:
 - Chordoma
 - Chondrosarcomas
 - Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
- Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma,

- medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous
- malformations
 - Primary hepatocellular cancer treated in a hypofractionated regimen
 - Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
 - Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
 - Pituitary neoplasm
 - Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck
 - Malignant lesions of the paranasal sinus, and other accessory sinuses
 - Unresectable retroperitoneal sarcoma.

Additional indications will be reviewed based upon peer reviewed medical literature.

Exclusions

- The use of Proton Beam Therapy for any other diagnosis outlined above without Prior Authorization approval.

Codes

Selection of the correct proton beam delivery code is based on the complexity and compensation of the treatment:

- Simple proton beam therapy delivery to a single treatment area is billed with either CPT 77522 (with compensation) or CPT 77520 (without compensation).
- Intermediate proton beam therapy delivery to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports with custom blocks and compensators is billed with CPT 77523.
- Complex proton beam therapy delivery to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators is billed with CPT 77525.

Proton beam therapy delivery codes are technical component only codes and should only be billed by the facility delivering the treatment.

Code type	Code	Description
CPT	77520	Proton treatment delivery; simple, without compensation
	77522	Proton treatment delivery; simple, with compensation
	77523	Proton treatment delivery; intermediate
	77525	Proton treatment delivery; complex
HCPCS	S8030	Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

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Policy History

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.