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

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for proton beam therapy. National Government Services, Inc. has an LCD for Proton Beam Therapy (L35075) and an LCA: Billing and Coding: Proton Beam Therapy (A56827) (MCD search 07-02-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

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. Documentation in the medical record must fully support the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Commercial and MassHealth plan members: The following disease sites will be considered for coverage of proton beam therapy (PBT):

Uveal melanoma
Fallon Health considers 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.

Other treatment Sites
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 members: Fallon Health covers proton beam therapy (PBT) for Medicare members, including Medicare Advantage, NaviCare and PACE plan members, in accordance with National Government Services, Inc. Local Coverage Determination (LCD) Proton Beam Therapy (L35075) and Local Coverage Article: Billing and Coding: Proton Beam Therapy (A56827).

LCD Link: **Proton Beam Therapy (L35075)**
LCA link: **Billing and Coding: Proton Beam Therapy (A56827)**

Documentation in the patient medical record must:
1. Support one or more of the four medical necessity requirements for the use of proton beam therapy listed below.
2. Include a treatment prescription that defines the goals of the treatment plan- including specific dose-volume parameters for the target and nearby critical structures- as well as

pertinent details of beam delivery, such as method of beam modulation, field arrangement, and expected positional and range uncertainties.
3. Include a treatment plan, signed by a physician, which meets the prescribed dose-volume parameters for the clinical target volume (CTV) and surrounding organs at risk (OARs) in the presence of expected uncertainties.
4. Describe the target setup verification methodology, including patient positioning, immobilization and use of image guidance.
5. Include verification of planned dose distribution via independent dose calculation or physical measurement.

PBT is considered medically necessary 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.

PBT may offer dosimetric advantages as well as added complexity over conventional radiotherapy, 3D Conformal Radiation Therapy (3-D CRT) or Intensity Modulated Radiation Therapy (IMRT). Before applying PBT techniques, a comprehensive understanding of the benefits and consequences is required. In addition to satisfying at least one of the four medical necessity criteria noted above, the radiation oncologist's decision to employ PBT requires an informed assessment of the benefits and risks including:
- Determination of patient suitability for PBT allowing for reproducible treatment delivery
- Adequate definition of the target volumes and OARs
- Equipment capability, including ability to account for organ motion when relevant
- Physician, physicist and staff training
- Adequate quality assurance procedures.

It is important to note that normal tissue dose volume histograms (DVHs) must be demonstrably improved with a PBT plan to validate coverage. Therefore, coverage decisions must extend beyond ICD-10 codes to incorporate additional considerations of clinical scenario and medical necessity with appropriate documentation. The final determination of the appropriateness and medical necessity for PBT resides with the treating radiation oncologist who should document the justification for PBT for each patient.

<u>Group 1</u>
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 tolerancenmay 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.

Group 2

Coverage of proton beam therapy in Group 2 is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors
- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
- Prostate cancer, without distant metastases
- Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
- Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

Prostate Cancer

Coverage and payments of proton beam therapy for prostate cancer will require:

a. Physician documentation of patient selection criteria (stage and other factors as represented in the NCCN guidelines);
b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

Exclusions

- The use of proton beam therapy for any other diagnosis outlined above without prior authorization.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

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.

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

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2. Hayes Inc. Hayes Directory Proton Beam Therapy for Non-Small Cell Lung Cancer. Published January 19, 2017. Annual Review Completed January 3, 2019.
3. Hayes Inc. Hayes Technology Brief. Proton Beam Therapy for Treatment of Pituitary
4. Adenomas. Published February 5, 2019.
5. American Society for Radiation Oncology (ASTRO) Model Policy: Proton Beam Therapy. Approved June 2017.
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Policy history

Origination date:	11/15/2012
Approval(s):	Technology Assessment Committee: 11/15/2012, 12/03/2014 (updated template, references, criteria expanded) 12/15/2015 (updated references), 03/22/2017 (updated references), 03/28/2018 (updated Medicare plan coverage, updated references), 03/27/2019 (updated references) *07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section*

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.