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.

For 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.

For Medicare based plans Fallon Health will cover treatment for the following site provided Criteria is met. This is accordance with Medicare Local Coverage Determination (L34634)

- Unresectable benign or malignant central nervous system tumors to include but not limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations.
- Intraocular melanomas
- Pituitary neoplasms
- Chordomas and chondrosarcomas
- Advanced staged and unresectable malignant lesions of the head and neck.
- Malignant lesions of the Para nasal sinus, and other accessory sinuses
- Unresectable retroperitoneal sarcoma
- Solid tumors in children

For Treatment of these sites the below criteria must be met:
1. The Dose Volume Histogram (DVH) one or more critical structures or organs protected by the use of Proton Beam Therapy
2. The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue;
3. There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or
4. There is documented clinical rationale that higher levels of precision associated with Proton Beam Therapy compared to other radiation treatments are clinically necessary.

For the treatment of primary lesions, the intent of treatment must be curative. For the treatment of metastatic lesions, there must be
1. The expectation of a long-term benefit (Greater Than 2 Year of life expectancy) that could not have been attained with conventional therapy.
2. The expectation of a complete eradication or improved duration of control of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy The patient’s record demonstrates why Proton beam radiotherapy is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over IMRT or 3- dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

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

<table>
<thead>
<tr>
<th>Code type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
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<tr>
<td></td>
<td>77522</td>
<td>Proton treatment delivery; simple, with compensation</td>
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<td></td>
<td>77523</td>
<td>Proton treatment delivery; intermediate</td>
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<td></td>
<td>77525</td>
<td>Proton treatment delivery; complex</td>
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<td>HCPCS</td>
<td>S8030</td>
<td>Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy</td>
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References


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Effective 04/01/2017

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)

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.