A PRESBYTERIAN

Subject: Radiation Oncology: Proton Beam Therapy

Medical Policy #: 16.14

Status: Reviewed

Original Effective Date: 11/26/2007 Last Annual Review Date: 08/21/2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Proton Beam Therapy is a type of radiation therapy that utilizes protons to deliver ionizing damage to a target. In conventional radiation, the greatest energy release is at the surface of the tissue and decreases exponentially the farther the radiation travels. Thus, the tissue beyond the target invariably receives a low to moderate radiation dose. In contrast, the energy of a proton beam is released at the end of its path, a region called the Bragg peak. Since the energy release of the proton beam is confined to the narrow Bragg peak, collateral damage to the surrounding tissues should be reduced, enabling an increased dose of radiation to be delivered to the tumor.

Proton beam therapy is of particular value in those tumors located close to vital organs (or organs at risk) where a small local overdose can cause severe complications such as tumors close to the spinal cord. Irregular shaped lesions near critical structures are well suited for protons beam therapy. In general, proton beam radiotherapy is not indicated for cancers that are widely disseminated, such as leukemias or malignancies with hematogenous metastases or as a short-term palliative procedure.

Proton beam therapy is also not indicated in the treatment of very radiosensitive tumors such as lymphomas or germ cell neoplasms. **The intent of treatment should be curative.** If proton beam radiotherapy is used for a patient with metastatic disease, evidence should be provided to justify the expectation of a long-term benefit (> 2y), as well as evidence of a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy. Due to the reduction in integral dose with protons, the most important benefits can be expected for pediatric patients. In adults, proton beam therapy should be reserved to treat patients that have clinically apparent disease (by exam or medical imaging).

The proton beam therapy system must be FDA approved.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Coverage applies to Commercial, Medicaid and Medicare.

Presbyterian considers Proton Beam Radiotherapy medically reasonable and necessary when <u>ALL</u> (a, b, c) of the following criteria are met:

- a. Patient with diagnosis of **1 or more** of the following conditions:
 - Unresectable benign or malignant CNS tumors (e.g., variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, arteriovenous malformation)
 - Intraocular melanomas
 - Pituitary neoplasms
 - Chordomas and chondrosarcoma
 - Advanced stage and unresectable malignant lesions of head and neck
 - Malignant lesions of para-nasal sinus and other accessory sinuses
 - Unresectable retroperitoneal sarcoma
 - Solid tumors in children under the age of 18 (requires a "case-by case" review for solid tumors).
- b. Patient's record demonstrates the need for proton beam radiotherapy, by indicating the treatment of choice for patient, as indicated by **1 or more** of the following:
 - Dose volume histogram illustrates one or more critical structures or organs are protected by use of proton beam therapy.
 - Dose to control or treat tumor cannot be delivered without exceeding tolerance of normal tissue.
 - Documented clinical rationale that doses generally thought to be above level otherwise attainable with other radiation methods might improve control rates.

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001].

- Documented clinical rationale that higher levels of precision associated with proton beam therapy compared to
 other radiation treatments are clinically necessary.
- c. Proton beam radiotherapy is for 1 or more of the following:
 - For primary lesions, intent of treatment is curative.
 - For metastatic lesions, 1 or more of the following are met:
 - Expectation of long-term benefit (>2 years of life expectancy) that could not have been attained with conventional therapy, or
 - Expectation of complete eradication or improved duration of control of metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy

Limitation:

Proton Beam Radiotherapy is **NOT COVERED** for **ANY** of the following:

- Short-term palliative procedure.
- Any indication not specifically described as covered.
- Prostate cancer is considered investigational. It should only be performed within the context of a clinical trial or registry per NCCN guideline

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	The proton delivery codes are technical component only codes and can only be billed by the facility delivering the treatment
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex
For medical necessary diagnosis, please see LCA (A55315)	

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): <u>Clinton White MD</u> Senior Medical Director: <u>Jim Romero</u> Date Approved: 08/21/2024

References

- 1. CMS LCD (L36658), Proton Beam Therapy, Revision date: 10/05/2023, Revision number R11. Accessed 05/30/2024.
- 2. CMS LCA (A55315), Billing and Coding for Proton Beam Therapy, Revision date: 11/16/2023, Revision number R12. Accessed 05/30/2024.
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), Prostate Cancer, Version 4.2024 May 17, 2024. See section Principles of Radiation Therapy. [Cited 06/20/2024]
- MCG Health Ambulatory Care 28th Edition, Proton Beam Therapy, ACG: A-0389, last update: 03/14/2024. Accessed 06/20/2024
- 5. Hayes, Proton Beam Therapy for Prostate Cancer, Health Technology Assessment Mar 4, 2020 | Annual Review: Apr 11, 2023. [Cited 06-20-2024]
- 6. New Mexico <u>Senate Bill 246</u>, 2024 Regular Session, Title: Capital Outlay Reauthorizations, Sponsor Nancy Rodriquez, Final Version, 03/06/2024 [Cited 06-20-2024]
- 7. UpToDate, External beam radiation therapy for localized prostate cancer, Literature review current through: May 2024, This topic last updated: Oct 05, 2023.
- 8. Aetna, Proton Beam, Neutron Beam, and Caron Ion Radiotherapy, Number 0270, Last Review: 05/15/2024, Effective: 07/16/1998, Next Review: 03/13/2025. [Cited 06-20-2024]

Publication History

- 11-26-07: Benefit/Technology Alert for Proton Beam Therapy for Prostate Cancer
- 04-22-09: Transitioned to Medical Policy for Proton Beam Therapy, Revision
- 04-28-10: Annual Review and Revision
- 09-22-10: Transition to HealthHelp Radiation Oncology Guidelines
- 02-22-12: Review and revise
- 01-30-13: Review and Revise
- 01-29-14: Presbyterian Policy Retired

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001].

- 01-29-14: Presbyterian now uses MCG Criteria A-0389
- 07-27-16: Annual Review. Accessed MCG 07-18-16. Criteria A-0389 last updated 01-28-16. No changes.
- 07-26-17: Annual Review. Accessed MCG A-0389 21st Edition 7/13/17. No changes.
- 01-23-19: Annual Review. Accessed CMS LCD L36658
- 04-04-19: Correction to Exclusion section. Changed to reflect Clinical Trail.
- 07-22-20: Annual review. Reviewed by PHP Medical Policy Committee on 05/20/20. Committee agreed to continue coverage for all LOBs using LCD L36658. Criteria updated to include a "case-by case" review for solid tumors for children up to age 18. Clinical trial instructions removed and noted to see LCD L36658, Group 2 section for defined provisions as well as A55315. Prior authorization for 77520, 77522, 77523, 77525, and S8030 will continue.
- 07-28-21 Annual review. Reviewed by PHP Medical Policy Committee on 08/04/2021. No change in LCD L36658, since 09/262019. Added the entire criteria from LCD L36658, related to the (Group II) clinical trial to the policy. Continue PA for: 77520, 77522, 77523 and 77525. Removed ICD-10 codes and provided Local Coverage Article: Billing and Coding: Proton Beam Therapy (A55315) for the current listing of covered ICD-10.
- 07-27-22 Annual review. Reviewed by PHP Medical Policy Committee on 06-29-2022. Change. PHP will no longer follow LCD (L36658) and have developed our own criteria. The coverage determination guideline language has been revised and covered ICD-10 codes were added. Coverage will continue to be for all LOB. Continue PA for: 77520, 77522, 77523 and 77525.
- 07-26-23 Annual review. Reviewed by PHP Medical Policy Committee on 06-16-2023. Continue with criteria for ALOB. Continue PA for 77520, 77522, 77523 and 77525. Non-Metastatic Prostate covered only when part of a clinical trial, registry or both, per NCCN and LCD L36658. Continue with the listed diagnosis.
- 08-21-24 Annual review. Reviewed by PHP Medical Policy Committee on 06-26-2024. Continue to follow the criteria extracted from CGS LCD (L36658). Added Prostate cancer is considered investigational and experimental and should only be performed within the context of a clinical trial or registry per NCCN guideline. The listing of ICD-10 was removed and replaced to see the hyperlink to the related LCA (A55315).

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: <u>Click here for Medical Policies</u>

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.