Subject: Radiation Oncology: Proton Beam Therapy

Medical Policy #: 16.14

Original Effective Date: 11/26/2007

Status: Reviewed

Last Annual Review Date: 08-27-2025

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. Since the energy release of the proton beam is confined, 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 to support the advantage for proton beam radiotherapy over other forms of radiation therapy.

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 for the following:

A. Patient with diagnosis of 1 or more of the following conditions:

GENERAL

- Benign or malignant tumors or hematologic malignancies in children aged 21 years and younger treated with curative intent and occasionally palliative intent treatment of childhood tumors, when at least one of the criteria in section B applies.
- Benign or malignant tumors or hematologic malignancies in the adolescent/young adult (AYA) population aged 22 years to 39 years treated with curative intent when at least one of the criteria in section B applies.
- Genetic syndromes making total volume of radiation minimization crucial, such as but not limited to NF-1 patients, deleterious ATM mutations, Li-Fraumeni, retinoblastoma patients, and patients with known genetic mutations. In addition, patients with other genetic mutations who are at increased risk of developing second cancers at or near the same body location such as but not limited to BRCA 1/2, Lynch syndrome, etc.
- Medically inoperable patients with a diagnosis of cancer typically treated with surgery where dose escalation is required due to the inability to receive surgery
- Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)
- Primary malignant or benign bone tumors

CENTRAL NERVOUS SYSTEM

- Ocular tumors, including intraocular melanomas
- Skull-based tumors, including but not limited to:
    - Chordomas and chondrosarcoma
        - Malignant neoplasm of bones of skull and face, mandible, vertebral column;
        - Malignant neoplasm of other endocrine glands and related structures;
        - Benign neoplasm of bone;
        - Benign neoplasm of craniopharyngeal duct

- Malignant and benign primary CNS tumors, including but not limited to:
    - 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)
    - Malignant neoplasm of meninges, brain, cranial nerves, spinal cord, pineal gland;
    - Benign neoplasm of meninges, brain, cranial nerves, spinal cord
- Primary spine or spinal cord tumors or metastatic tumors to the spine or spinal cord where organ at risk tolerance may be exceeded with photon treatments, including but not limited to:
    - Malignant neoplasm of bones of vertebral column, sacrum, and coccyx;
    - Malignant neoplasm of spinal meninges;
    - Malignant neoplasm of spinal cord and cauda equina;
    - Benign neoplasm of vertebral column, sacrum, coccyx, spinal meninges, spinal cord
- Primary and metastatic tumors requiring craniospinal irradiation, including but not limited to:
    - Malignant neoplasm of meninges, brain, cranial nerves, spinal cord, pineal gland

HEAD AND NECK

- Pituitary neoplasms
- Advanced stage and unresectable malignant lesions of head and neck
- Malignant lesions of para-nasal sinus and other accessory sinuses, , including but not limited to:
    - Cancers of the nasopharynx, nasal cavity, paranasal sinuses and other accessory sinuses

THORACIC

- Primary cancers of the esophagus
- Primary tumors of the mediastinum, including thymic tumors, mediastinal tumors, mediastinal lymphomas and thoracic sarcomas
- Malignant pleural mesothelioma

ABDOMINAL

- Unresectable and non- metastatic retroperitoneal sarcoma
- Hepatocellular cancer and intra-hepatic biliary cancers

PELVIC

- Advanced and unresectable pelvic tumors with significant pelvic and/or peri-aortic nodal disease

B. Patients' record demonstrates the need for proton beam radiotherapy, by indicating the treatment of choice for patients, 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.
- There is 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.
- Palliative intent treatment of childhood tumors, when at least one of the three criteria in section B applies.
- 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

D. 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): Clinton White MD
Senior Medical Director: Jim Romero
Medical Director: Kresta Antillon
Date Approved: 08/27/2025

References

1. CMS LCD (L36658), Proton Beam Therapy, Revision date: 10/03/2024, Revision number R12. Accessed 07/15/2025.
2. CMS LCA (A55315), Billing and Coding for Proton Beam Therapy, Revision date: 11/16/2023, Revision number R12. Accessed 07/15/2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), Prostate Cancer, Version 2.2025 – April 16, 2025. See section Principles of Radiation Therapy. [Cited 07/15/2025]
4. NCCN, Hepatocellular Carcinoma, Version 1.2025, Principles of Radiation Therapy [Accessed 07/15/2025]
5. American Society for Radiation Oncology, ASTRO Model Policies, Proton Beam Therapy, Copyright © 2025 American Society for Radiation Oncology. [Cited 07/15/2025]
6. MCG Health Ambulatory Care 29 Edition, Proton Beam Therapy, ACG: A-0389, last update: 1/25/2025. Accessed 07/15/2025
7. Hayes, Proton Beam Therapy for Prostate Cancer, Health Technology Assessment Mar 4, 2020 | Annual Review: Apr 11, 2023. [Cited 07/15/2025]
8. New Mexico Senate Bill 246, 2024 Regular Session, Title: Capital Outlay Reauthorizations, Sponsor Nancy Rodriquez, Final Version, 03/06/2024 [Accessed 07/15/2025]
9. UpToDate, External beam radiation therapy for localized prostate cancer, Literature review current through: Jun 2025, This topic last updated: May 30, 2025. Accessed: 07/15/2025
10. Aetna, Proton Beam, Neutron Beam, and Caron Ion Radiotherapy, Number 0270, Last Review: 07/08/2025, Effective: 07/16/1998, Next Review:03/12/2026. [Cited 07/15/2025]

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
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).

08-27-25 Annual review. Reviewed by PHP Medical Policy Committee on 07/18/2025. Removed LCD (L36658) and applied homegrown criteria recommended by American Society for Radiation Oncology (ASTRO) for ALOB. Updated the policy according to the recommendation outlined in the ASTRO, making the policy to be less restrictive than CMS Proton Beam Therapy which provided limited conditions, whereas ASTRO model PBT policy provides more conditions. As a result, additional conditions were listed under these body areas: General, CNS, Head and Neck, Thoracic and Pelvic as follows:

GENERAL:

- Age changed from 18 to 21 years and younger for treatment w/curative intent and occasionally palliative intent treatment of Benign or malignant solid tumors
- Added: Treatment with curative intent for benign or malignant tumors or hematologic malignancies in aged 22 years to 39 years
- Added: Genetic syndromes making total volume of radiation minimization crucial, such as but not limited to NF-1 patients, deleterious ATM mutations, Li-Fraumeni, retinoblastoma patients
- Added: Inoperable patients with a diagnosis of cancer typically treated with surgery where dose escalation is required due to the inability to receive surgery
- Added: Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)
- Added: Primary malignant or benign bone tumors

CNS

- Added examples of conditions under Skull-based tumors for chordomas and chondrosarcoma
- Added examples of conditions under Malignant and benign primary tumors
- Added: Primary spine or spinal cord tumors and metastatic tumors with examples
- Added: Primary and metastatic tumors requiring craniospinal irradiation with examples

HEAD AND NECK

- Added a list of areas to be affected for para nasal sinus

THORACIC

- Added: Primary cancer of the esophagus
- Added: Primary tumors of the mediastinum, including thymic tumors, mediastinal tumors, mediastinal lymphomas and thoracic sarcomas
- Added Malignant pleural mesothelioma

ABDOMINAL

- Added: Hepatocellular cancer and intra-hepatic biliary cancers

PELVIC

- Added: Advanced and unresectable pelvic tumors with significant pelvic and/or peri-aortic nodal disease

Continue PA for 77520, 77522, 77523 and 77525 to safeguard that the proper person/patient who will benefit from PBT is selected.

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: ***Click here for Medical Policies***

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.