

Subject: Radiation Oncology: Proton Beam Therapy

Medical Policy #: 16.14 Original Effective Date: 11/26/2007

Status: Reviewed Last Review Date: 07-26-2023

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, Centennial 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.

- 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:

- o Short-term palliative procedure.
- Any indication not specifically described as covered.

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

ICD-10 Codes	Description: Not an all inclusive list
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth
C06.2	Malignant neoplasm of retromolar area
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland

ICD-10 Codes	Description: Not an all inclusive list
C08.1	Malignant neoplasm of sublingual gland
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C30.0	Malignant neoplasm of nasal cavity
C30.1	Malignant neoplasm of middle ear
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C31.2	Malignant neoplasm of frontal sinus
C31.3	Malignant neoplasm of sphenoid sinus
C31.8	Malignant neoplasm of overlapping sites of accessory sinuses
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C40.01	Malignant neoplasm of overlapping sites of larytix Malignant neoplasm of scapula and long bones of right upper limb
C40.01	Malignant neoplasm of scapula and long bones of left upper limb
C40.02	
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb Malignant neoplasm of long bones of right lower limb
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C40.22	Malignant neoplasm of long bones of left lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C45.1	Mesothelioma of peritoneum
C45.7	Mesothelioma of other sites
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip

ICD-10 Codes	Description: Not an all inclusive list
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C69.01	Malignant neoplasm of right conjunctiva
C69.02	Malignant neoplasm of left conjunctiva
C69.11	Malignant neoplasm of right cornea
C69.12	Malignant neoplasm of left cornea
C69.21	Malignant neoplasm of right retina
C69.22	Malignant neoplasm of left retina
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.51	Malignant neoplasm of right lacrimal gland and duct
C69.52	Malignant neoplasm of left lacrimal gland and duct
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C69.81	Malignant neoplasm of overlapping sites of right eye and adnexa
C69.82	Malignant neoplasm of overlapping sites of left eye and adnexa
C70.0	Malignant neoplasm of cerebral meninges
C70.1	Malignant neoplasm of spinal meninges
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.21	Malignant neoplasm of right olfactory nerve
C72.22	Malignant neoplasm of left olfactory nerve
C72.31	Malignant neoplasm of right optic nerve

ICD-10 Codes	Description: Not an all inclusive list
C72.32	Malignant neoplasm of left optic nerve
C72.41	Malignant neoplasm of right acoustic nerve
C72.42	Malignant neoplasm of left acoustic nerve
C72.59	Malignant neoplasm of other cranial nerves
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C75.0	Malignant neoplasm of parathyroid gland
C75.1	Malignant neoplasm of pituitary gland
C75.2	Malignant neoplasm of craniopharyngeal duct
C75.3	Malignant neoplasm of pineal gland
C75.4	Malignant neoplasm of carotid body
C75.5	Malignant neoplasm of aortic body and other paraganglia
C75.8	Malignant neoplasm with pluriglandular involvement, unspecified
C76.0	Malignant neoplasm of head, face and neck
C76.1	Malignant neoplasm of thorax
C76.2	Malignant neoplasm of abdomen
C76.41	Malignant neoplasm of right upper limb
C76.42	Malignant neoplasm of left upper limb
C76.51	Malignant neoplasm of right lower limb
C76.52	Malignant neoplasm of left lower limb
C76.8	Malignant neoplasm of other specified ill-defined sites
C79.31	Secondary malignant neoplasm of brain
D16.01	Benign neoplasm of scapula and long bones of right upper limb
D16.02	Benign neoplasm of scapula and long bones of left upper limb
D16.11	Benign neoplasm of short bones of right upper limb
D16.12	Benign neoplasm of short bones of left upper limb
D16.21	Benign neoplasm of long bones of right lower limb
D16.22	Benign neoplasm of long bones of left lower limb
D16.31	Benign neoplasm of short bones of right lower limb
D16.32	Benign neoplasm of short bones of left lower limb
D16.4	Benign neoplasm of bones of skull and face
D16.5	Benign neoplasm of lower jaw bone
D16.6	Benign neoplasm of vertebral column
D16.7	Benign neoplasm of ribs, sternum and clavicle
D16.8	Benign neoplasm of pelvic bones, sacrum and coccyx
D32.0	Benign neoplasm of cerebral meninges
D32.1	Benign neoplasm of spinal meninges
D33.0	Benign neoplasm of brain, supratentorial
D33.1	Benign neoplasm of brain, infratentorial
D33.3	Benign neoplasm of cranial nerves
D33.4	Benign neoplasm of spinal cord
D35.2	Benign neoplasm of pituitary gland
D35.3	Benign neoplasm of craniopharyngeal duct
D35.4	Benign neoplasm of pineal gland
D42.0	Neoplasm of uncertain behavior of cerebral meninges
D42.1	Neoplasm of uncertain behavior of spinal meninges
D43.0	Neoplasm of uncertain behavior of brain, supratentorial
D43.1	Neoplasm of uncertain behavior of brain, infratentorial
D43.4	Neoplasm of uncertain behavior of spinal cord
D44.11	Neoplasm of uncertain behavior of right adrenal gland
D44.12	Neoplasm of uncertain behavior of left adrenal gland
D44.3	Neoplasm of uncertain behavior of pituitary gland
D44.4	Neoplasm of uncertain behavior of craniopharyngeal duct
D44.5	Neoplasm of uncertain behavior of pineal gland

ICD-10 Codes	Description: Not an all inclusive list
D49.7	Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: Gray Clarke MD

Senior Medical Director: <u>David Yu MD</u> Medical Director: <u>Ana Maria Rael MD</u> Date Approved: 07/26/2023

References

- 1. CMS LCD (L36658), Proton Beam Therapy, Revision date: 09-26-2019, Revision number R10. Accessed 06/16/2023.
- 2. CMS LCA (A55315), Billing and Coding for Proton Beam Therapy, Revision date: 10/06/2022, Revision number R10. Accessed 06/16/2023.
- 3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), Prostate Cancer, Version 1.2023 September 16, 2022. See section Principles of Radiation Therapy. [Cited 06/16/2023]
- MCG Health Ambulatory Care 27th Edition, Proton Beam Therapy, ACG: A-0389, last update: 2/1/2023. Accessed 06/16/2023

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.

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.