

MEDICAL POLICY



SUBJECT: PROTON BEAM RADIATION THERAPY	EFFECTIVE DATE: 07/02/99
POLICY NUMBER: 6.01.11	REVISED DATE: 04/19/01, 07/18/02, 07/17/03, 06/17/04, 05/18/05, 03/16/06, 01/18/07, 12/20/07, 01/15/09, 03/18/10, 03/17/11, 02/16/12, 02/21/13, 02/20/14, 06/19/14, 02/19/15, 04/21/16, 06/15/17, 04/19/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and review of the peer-reviewed literature charged particle irradiation with proton ion beams has been medically proven to be effective and therefore, a **medically appropriate** treatment for the following indications:
 - A. Primary therapy for *melanoma of the uveal tract* (iris, choroid, or ciliary body), with no evidence of metastasis or extrascleral extension, and with tumors up to 24 mm in largest diameter and 14 mm in height; or
 - B. Post-operative therapy (with or without conventional high-energy x-rays) in patients who have undergone biopsy or partial resection of the *chordoma* or *low-grade* (I or II) *chondrosarcoma* of the basisphenoid region (*skull-base chordoma* or *chondrosarcoma*) or *cervical spine*. Patients eligible for this treatment have residual localized tumor without evidence of metastasis; or
 - C. Localized unresectable hepatocellular carcinoma, when considered preferential to Stereotactic Body Radiation Therapy (SBRT) or radiofrequency ablation; or
- II. Based on our criteria and review of the peer reviewed literature charged particle irradiation with proton ion beams is considered **not medically necessary** for the treatment of *prostate cancer*.
- III. Based upon our criteria and review of the peer reviewed literature charged particle irradiation with proton ion beams has not been medically proven to be effective and is therefore considered **not medically necessary** for all other indications, including but not limited to non-small-cell lung cancer, and esophageal cancer.

Refer to Corporate Medical Policy #6.01.12 regarding Stereotactic Radiosurgery and Stereotactic Radiotherapy.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

Refer to Corporate Medical Policy #11.01.13 regarding Out of Area/Out of Network Services.

POLICY GUIDELINES:

This technology is limited to specialized centers. There are twenty-five operating in the USA and an additional eleven being planned or under construction (please refer to the National Association of Proton Centers (<http://proton-therapy.org/find-a-facility/>)).

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Charged particle beams consisting of protons or helium ions are an alternative to conventional x-rays, and other types of photon irradiation in the treatment of malignant disease. When positively charged atomic particles called protons travel through tissue, they have a limited range, depending on the power of the proton beam. As they reach the end of their range, protons release a burst of energy within a very limited area. Controlling the power of the beam allows delivery of radiation to the tumor, but not to tissues lying behind the tumor, thereby minimizing radiation exposure to surrounding

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normal tissue. Proton beam radiation requires specialized equipment in the form of accelerators (cyclotrons, synchrotrons, synchrocyclotrons, or linear accelerators) that can generate a beam of particles (protons or helium ions). They also require accurate localization of the malignancy by using tomographic scanning (with x-ray and/or magnetic resonance imaging), and precise and reproducible positioning (relative to the beam) and immobilization of the patient during both tomographic scanning and treatment.

Proton beam radiation is a form of radiation therapy that can be used for either stereotactic radiosurgery or conventional fractionated radiation therapy. It can also be used without stereotactic guidance.

Radiation therapy with charged-particle beams such as protons proposes clinical gains when:

- I. Conventional treatment modalities do not provide adequate local tumor control;
- II. The likelihood of metastasis prior to radiotherapy is small to nonexistent;
- III. There is evidence that local tumor response depends on the dose of radiation delivered; or
- IV. Delivery of an adequate radiation dose to the tumor is limited by the proximity of vital radiosensitive tissues or structures.

RATIONALE:

Radiotherapy is a procedure and therefore is not subject to U.S. Food and Drug Administration (FDA) regulations. However, the accelerators and other equipment used to generate and deliver charged particle radiation are devices, and thus do require FDA approval. The equipment used to deliver proton beam therapy is approved as a Class II, 510(k) device by the FDA.

Uveal melanoma, chordoma, chondrosarcoma of skull base or cervical spine. Clinical evidence supports that proton beam radiation improves health outcomes for patients with uveal melanoma and chordoma or chondrosarcoma of the skull base or cervical spine. Most of these patients have few other treatment options. A small case series of patients with recurrent uveal melanoma indicated a second course of proton beam radiation therapy (PBT) was associated with a relatively good probability of local control and a low enucleation rate.

Hepatocellular cancer. In hepatocellular cancer, radiation therapy plays a role in unresectable cancers and in those not amenable to radiofrequency ablation. SBRT has been used as well as PBT. The larger PBT series are from Japan suggesting excellent local control rates and modest 2-5 year survival rates. Four retrospective (360 patients) and 2 prospective studies (64 patients) of PBT in patients with hepatocellular cancer show results similar to those achieved with SBRT. In patients with unresectable hepatocellular cancers who are not optimally treated with radiofrequency ablation or SBRT, PBT will be considered medically necessary.

Seminoma

Prostate cancer. Data published concerning use of proton beam therapy in localized prostate cancer report that treating large numbers of patients demonstrate results comparable to those obtained with alternative techniques. A 2008 comparative effectiveness review of therapies for clinically localized prostate cancer from the Agency of Healthcare Research and Quality (AHRQ) indicated that, based on nonrandomized comparisons, the absolute rates of outcomes after proton radiation appear similar to other treatments. However, the clinical utility of dose escalation using proton beam therapy (PBT), to doses similar to those currently used in IMRT (e.g., 79-81 Gy), is still not known and further studies are needed. A 2010 BlueCross BlueShield TEC Assessment addressed the use of proton beam therapy for prostate cancer, and concluded that it has not yet been established whether proton beam therapy improves outcomes in any setting in prostate cancer. The American Society for Radiation Oncology (ASTRO) published a position statement in February 2013 which states the following: “At the present time, ASTRO believes the comparative efficacy evidence of proton beam therapy with other prostate cancer treatments is still being developed, and thus the role of proton beam therapy for localized prostate cancer within the current availability of treatment options remains unclear.” In September 2013, as part of its national “Choosing Wisely” initiative, ASTRO listed PBT for prostate cancer as one of 5 radiation oncology practices that should not be routinely used because they are not supported by evidence.

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Other indications. Case series with small sample sizes addressing proton beam radiotherapy in the treatment of hepatocellular carcinoma, nonsmall-cell lung cancer and invasive bladder carcinoma indicate favorable results, but these studies have limitations of small sample size and short follow-up period. Small retrospective studies indicate the use of proton beam radiotherapy appears promising for the treatment of Stage I non-small-cell lung cancer; however, prospective clinical trials with larger study populations and longer follow-up periods are needed. A 2010 BlueCross BlueShield TEC Assessment addressed the question of how health outcomes (overall survival, disease-specific survival, local control, disease-free survival, and adverse events) with proton beam therapy (PBT) compare with outcomes observed for stereotactic body radiotherapy (SBRT), which is an accepted approach for using radiation therapy to treat NSCLC. The report concluded that the evidence is insufficient to permit conclusions about the results of PBT for any stage of NSCLC.

In May 2014, the American Society for Radiation Oncology (ASTRO) published a model policy for proton beam therapy (PBT). PBT is considered reasonable 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. The policy lists four examples of when PBT might be preferred over conventional radiotherapy. In addition to meeting criteria in the one of the four listed examples, the radiation oncologist must determine the patient's suitability for PBT allowing for reproducible delivery, adequate definition of the target volumes and organs at risk, equipment capability, physician, physicist and staff training, and adequate quality assurance procedures. Normal tissue dose volume histograms (DVHs) must be demonstrably improved with a PBT plan to validate coverage. Coverage decisions must extend beyond ICD-9 and ICD-10 codes to incorporate considerations of clinical scenario and medical necessity with appropriate documentation. The final determination of the appropriateness and medical necessity for PBT resides with the treatment radiation oncologist who should document the justification for PBT for each patient. On the basis of the 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 the skull (e.g., chordoma, chondrosarcomas), primary or metastatic tumors of the spine (where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has been previously irradiated), 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 four example criteria is met, patients with genetic syndromes making total volume of irradiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients. PBT would be considered as part of "coverage with evidence development" (CED) for the following indications (but not limited to): head and neck malignancies, thoracic malignancies, abdominal malignancies, pelvic malignancies, including genitourinary, gynecological, and gastrointestinal carcinomas. In the treatment of prostate cancer, the use of PBT is evolving as the comparative efficacy evidence is still being developed. Proton beam therapy for primary treatment of prostate cancer should only be performed within the context of a prospective clinical trial or registry.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	77520	Proton treatment delivery; simple, without compensation
	77522	Proton treatment delivery; simple, with compensation
	77523	Proton treatment delivery; intermediate
	77525	Proton treatment delivery; complex

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HCPCS: No code

ICD10: C30.0-C31.9	Malignant neoplasm of nasal cavity and middle ear (code range)
C40.80-C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of limb (code range)
C40.90-C40.92	Malignant neoplasm of unspecified bones and articular cartilage of limb (code range)
C41.0-C41.2	Malignant neoplasm of bone and articular cartilage of other and unspecified sites (code range)
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C61	Malignant neoplasm of prostate
C69.30-C69.42	Malignant neoplasm of choroid or ciliary body (code range)
C72.20-C72.9	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system (code range)
C78.30-C78.39	Secondary malignant neoplasm of other and unspecified respiratory organs (code range)
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40-C79.49	Secondary malignant neoplasm of other and unspecified parts of nervous system (code range)
C79.51-C79.52	Secondary malignant neoplasm of bone or bone marrow (code range)
D02.3	Carcinoma in situ of other parts of respiratory system
D07.5	Carcinoma in situ of prostate

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KEY WORDS: Charged particle radiation therapy, conformal proton beam radiation, proton beam radiation, proton beam therapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Proton Beam Therapy. Please refer to the following LCD website for Medicare members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35075&ver=22&CtrctrSelected=298*1&Ctrctr=298&s=41&DocType=Active&bc=AggAAAQBAAAA&