MASSACHUSETTS

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Medical Policy

Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions

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Policy Number: 437

BCBSA Reference Number: 8.01.10
NCD/LCD: Local Coverage Determination (LCD): Proton Beam Therapy (L35075)

Related Policies

- Clinical Exception and Notification Form for Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions, #678
- Intensity-Modulated Radiation Therapy (IMRT) of the Breast and Lung #163
- Intensity-Modulated Radiation Therapy (IMRT) of the Prostate #090
- Intensity-Modulated Radiation Therapy (IMRT): Abdomen and Pelvis #165
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- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy #277

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Charged-particle irradiation with proton or helium ion beams may be considered **MEDICALLY NECESSARY** in the following clinical situations*:

- 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;
- Postoperative therapy (with or without conventional high-energy x-rays) in patients who have undergone biopsy or partial resection of 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.
- In the treatment of pediatric central nervous system tumors.

***Please note:** Clinical Exception and Notification form must be filled out and submitted prior to all proton beam therapy treatments.

Other applications of charged-particle irradiation with proton or helium ion beams are considered **INVESTIGATIONAL**. This includes, but is not limited to:

- Clinically localized prostate cancer
- Non-small-cell lung cancer (NSCLC) at any stage or for recurrence,
- Pediatric non-central nervous system tumors,
- Tumors of the head and neck (other than skull-based chordoma or chondrosarcoma).

Clinical Exception and Notification Form*

Providers must submit a request for an exception for a non-covered indication by completing the clinical exception and notification form. Click here for the Proton Beam exception and notification form (#678)

Providers must complete the Clinical Exception and Notification Form when requesting coverage:

- For medically necessary indications described in medical policy 437, Charged-Particle (Proton or Helium Ion) Radiation Therapy.
- For not medically necessary and investigational indications, described in medical policy 437, Charged-Particle (Proton or Helium Ion) Radiation Therapy.

The clinical exception/notification form is not required for Medicare Advantage members.

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Proton Beam Therapy (L35075)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Providers must complete the Clinical Exception and Notification Form prior to service.
Commercial PPO and Indemnity	Providers must complete the Clinical Exception and Notification Form prior to service.
Medicare HMO Blue[SM]	Prior authorization is **not required**.
Medicare PPO Blue[SM]	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

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

Description

Charged-particle beams consisting of protons or helium ions are a type of particulate radiotherapy. They have several unique properties that distinguish them from conventional electromagnetic (ie, photon) radiotherapy, including minimal scatter as particulate beams pass through tissue, and deposition of ionizing energy at precise depths (ie, the Bragg peak). Thus, radiation exposure of surrounding normal tissues is minimized. The theoretical advantages of protons and other charged-particle beams may improve outcomes when the following conditions apply:

- Conventional treatment modalities do not provide adequate local tumor control;
- Evidence shows that local tumor response depends on the dose of radiation delivered; and
- Delivery of adequate radiation doses to the tumor is limited by the proximity of vital radiosensitive tissues or structures.

Summary

For individuals who have uveal melanoma(s) who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. Systematic reviews, including a 1996 TEC Assessment and a 2013 review of randomized and nonrandomized studies, concluded that the technology is at least as effective as alternative therapies for treating uveal melanomas and is better at preserving vision. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a skull-based tumor(s) (ie, cervical chordoma, chondrosarcoma) who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. A 2007 systematic review found a 5-year overall survival rate of 81% with PBT compared with 44% with surgery plus photon therapy. In 2016, a systematic review of observational studies found 5-year survival rates after PBT ranging from 67% to 94%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have pediatric central nervous system tumor(s) who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes case series, nonrandomized comparative studies, and systematic reviews. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. There are few comparative studies, and they tend to have small sample sizes. The available observational studies do not provide sufficient evidence on the efficacy of charged-particle therapy compared with other treatments (eg, intensity-modulated radiotherapy). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pediatric non-central nervous system tumor(s) who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes dosimetric planning studies in a small number

of patients. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. For this population, there is a lack of randomized and observational studies evaluating the efficacy and safety of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have localized prostate cancer who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes 2 RCTs and systematic reviews. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. A 2010 TEC Assessment addressed the use of PBT for prostate cancer and concluded that it had not been established whether PBT improves outcomes in any setting for clinically localized prostate cancer. The TEC Assessment included 2 RCTs, only one of which had a comparison group of patients that did not receive PBT. No data on the use of PBT for prostate cancer published since 2010 would alter the conclusions of the TEC Assessment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have non-small-cell lung cancer who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. A 2010 TEC Assessment, which included 8 case series, concluded that the evidence was insufficient to permit conclusions about PBT for any stage of non-small-cell lung cancer. No subsequent randomized or nonrandomized comparative studies were identified that would alter the conclusions of the TEC Assessment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have head and neck tumors other than skull-based who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes case series and a systematic review. Relevant outcomes are overall survival, disease-free survival, change in disease status, and treatment-related morbidity. The systematic review noted that the studies on charged-particle therapy were heterogenous in terms of the types of particles and delivery techniques used; further, there are no head-to-head trials comparing charged-particle therapy with other treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
9/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
9/2016	BCBSA National medical policy review. Title updated to indicate “for Neoplastic Conditions.” References added. 9/1/2016
8/2016	Updated to include Local Coverage Determination (LCD): Proton Beam Therapy (L35075). Effective 8/22/2016.
5/2016	BCBSA National medical policy review. The second policy statement was corrected to use the same “or helium ion” language as the first policy statement.
12/2015	BCBSA National medical policy review. Charged particle radiotherapy for clinically localized prostate cancer changed from “not medically necessary” to investigational. Title changed from “radiation therapy” to “radiotherapy.” Effective 12/1/2015.
9/2015	Local Coverage Determination (LCD): Proton Beam Therapy (L31617 added.
7/2014	BCBSA national medical policy review. New medical policy describing medically necessary, not medically necessary and investigational indications. Effective 7/1/2014.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process

Medical Technology Assessment Guidelines

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