



**BlueCross BlueShield  
of Vermont**

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## Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions Corporate Medical Policy

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

File Code: UM.SURG.26

Origination: New Policy

Last Review: 11/2019

Next Review: 11/2020

Effective Date: 04/01/2020

### Description/Summary

Charged-particle beams consisting of protons or helium ions are a type of particulate radiotherapy. Treatment with charged-particle radiotherapy is proposed for a large number of tumors that would benefit from the delivery of a high dose of radiation with limited scatter.

For individuals who have uveal melanoma(s) who receive charged-particle (proton or helium ion) radiotherapy, the evidence includes randomized controlled trials 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 proton beam therapy (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.

Clinical input obtained in 2013 strongly supported the use of charged-particle radiotherapy for treating pediatric central nervous system tumors. This modality of treatment of pediatric central nervous system tumors has the potential to reduce long-term adverse events (eg, damage to nearby normal central nervous system tissue, development of radiation-induced secondary tumors).

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 randomized controlled trials 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 randomized controlled trials, 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

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.

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

- pediatric non-central nervous system tumors,
- clinically localized prostate cancer,
- non-small-cell lung cancer at any stage or for recurrence,

tumors of the head and neck (other than skull-based chordoma or chondrosarcoma).

## Coding Information

[Click the links below for attachments, coding tables & instructions.](#)

[Attachment I](#)

## Policy Guidelines

Evidence is lacking on the definition of age parameters for the use of proton beam therapy in pediatric patients. Some studies using proton beam therapy in pediatric central nervous system tumors have mostly included patients younger than 3 years of age. However, experts cite the benefit of proton beam therapy in pediatric patients of all ages (<21 years of age).

## Reference Resources

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Proton beam therapy for prostate cancer. TEC Assessments 2010; Volume 25: Tab 10.

### Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

### Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

## Administrative and Contractual Guidance

### Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the

employer benefit plan documents takes precedence over medical policy when there is a conflict.

**Policy Implementation/Update information**

11/2019	New Policy Codes: 61796, 61797, 61798, 61799, 63620, 63621 require prior approval.
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**Eligible providers**

Qualified healthcare professionals practicing within the scope of their license(s).

**Approved by BCBSVT Medical Directors**

**Date Approved**

Joshua Plavin, MD, MPH, MBA  
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP  
Senior Medical Director

Attachment I

Code Type	Number	Description	Policy Instructions
<b>The following codes will be considered as medically necessary when applicable criteria have been met.</b>			
CPT®	61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion	Requires Prior Approval
CPT®	61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)	Requires Prior Approval
CPT®	61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	Requires Prior Approval
CPT®	61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)	Requires Prior Approval

CPT®	63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion	Requires Prior Approval
CPT®	63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)	Requires Prior Approval