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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: 8.01.VT10
Origination: 11/2019
Last Review: 10/2024
Next Review: 10/2025
Effective Date: 11/01/2024

Description/Summary

Proton beam therapy (PBT) is a form of external radiation therapy consisting of protons, precisely targeted to a specific tissue mass. Also known as charged-particle radiotherapy, such treatment 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.

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 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 with hepatocellular carcinoma (HCC), there is a growing body of evidence supporting use of proton beam therapy. However, it remains unresolved whether these outcomes could be achieved with other approaches (including TACE with RT or stereotactic RT).^[6] Per Hiroshi and colleagues, by systematic review, charged particle therapy for HCC was associated with good local control with limited probability of severe morbidities.

In 2022, the American Society for Radiation Oncology (ASTRO) updated their Model Policy on the use of Proton Beam Therapy. The policy was developed as a means to efficiently communicate what ASTRO believes to be correct coverage policies for radiation oncology services.

Policy

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

- treatment of benign or malignant central nervous system cancers that cannot be completely resected;
- treatment of advanced staged and/or unresectable malignant lesions of the head and neck;
- treatment of ocular tumors, including intraocular/uveal melanoma, with no evidence of metastasis or extrascleral extension, and with tumors up to 24 mm in largest diameter and 14 mm in height;
- treatment of paranasal sinus and nasopharyngeal tumors;

- treatment of skull-based tumors (including chordomas and chondrosarcomas);
- treatment of hepatocellular carcinoma (localized, unresectable) with curative intent, when use of standard radiation therapies would be contraindicated or not technically feasible;
- treatment of malignancies in children (21 years of age and younger);
- treatment of primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated;
- re-irradiation cases, for repeat irradiation of previously treated fields where the dose tolerance of surrounding structures would be exceeded by standard radiation therapies.

Other applications of charged-particle irradiation with proton or helium ion beams are considered **investigational** for all other indications in adults (over age 21). This includes, but is not limited to:

- clinically localized prostate cancer
- non-small-cell lung cancer at any stage or for recurrence

Coding Information

Click the links below for attachments, coding tables & instructions.

[Attachment I](#)

Policy Guidelines

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).

Per 2017 ASTRO Model Policy for Proton Beam Therapy, treatment 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. Examples of such an advantage might be:

1. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose “hotspot” within the treated volume to lessen the risk of excessive early or late normal tissue toxicity.
3. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity.
4. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

Documentation in the patient medical record must include:

1. Documentation supporting one or more clinical indications above.
2. A comprehensive list of therapies and medications used in the member’s cancer

treatment, including chemotherapy history and/or history of previous radiation therapy to the same or an immediately adjacent area.

3. A treatment prescription that defines the goals of the treatment plan, including specific dose-volume parameters for the target and nearby critical structures as well as pertinent details of beam delivery.

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.
2. Blue Cross Blue Shield Association Medical Policy Manual, Policy Number: 8.01.10 - Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions. Last reviewed June 2024. Policy reactivated May 2023. Accessed October 2024.
3. American Society for Radiation Oncology (ASTRO). Proton beam therapy. ASTRO Model Policies. Approved 2022. Reviewed October 2024.
4. UpToDate - Radiation Therapy Techniques in Cancer Treatment. Literature review current through September 2024. Accessed October 2024.
5. UpToDate - External Beam Radiation Therapy for Localized Prostate Cancer. Literature review current through September 2024. Accessed October 2024.
6. UpToDate - Overview of Treatment Approaches for Hepatocellular Carcinoma. Literature review current through July 2023. Accessed August 2023.
7. Igaki H, Mizumoto M, Okumura T, Hasegawa K, Kokudo N, Sakurai H. A systematic review of publications on charged particle therapy for hepatocellular carcinoma. *Int J Clin Oncol*. 2018 Jun;23(3):423-433. doi: 10.1007/s10147-017-1190-2. Epub 2017 Sep 4. PMID: 28871342.
8. Institute for Clinical and Economic Review. Technology Assessment. Proton beam therapy. March 2014. <https://icer.org/assessment/proton-beam-therapy-2008/> . Accessed January 2021

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.
06/2021	Policy reviewed. Expansion of clinical indications. References updated. Added codes 77520, 77522, 77523, 77525 as requiring prior approval.
10/2022	Policy reviewed. Added indication of hepatocellular carcinoma as indication with criteria. References updated.
09/2023	Policy reviewed. References updated. Minor formatting changes. No change to policy statement.
10/2024	Policy reviewed. No change to policy statement. References updated.

Eligible providers

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

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
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
CPT®	77520	Proton treatment delivery; simple, without compensation	Requires Prior Approval
CPT®	77522	Proton treatment delivery; simple, with compensation	Requires Prior Approval
CPT®	77523	Proton treatment delivery; intermediate	Requires Prior Approval
CPT®	77525	Proton treatment delivery; complex	Requires Prior Approval