

Corporate Medical Policy

Charged Particle Radiotherapy

File Name: charged_particle_radiotherapy
Origination: 3/12/96
Last CAP Review: 5/2019
Next CAP Review: 5/2020
Last Review: 5/2019

Description of Procedure or Service

Charged-particle beams consisting of protons or helium ions are a type of particulate radiation therapy (RT). They contrast with conventional electromagnetic (i.e., photon) radiation therapy due to several unique properties including minimal scatter as particulate beams pass through tissue, and deposition of ionizing energy at precise depths (i.e., 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.

The use of proton or helium ion radiation therapy has been investigated in two general categories of tumors/abnormalities. However, advances in photon-based radiation therapy (RT) such as 3-D conformal RT, intensity-modulated RT (IMRT), and stereotactic body radiotherapy (SBRT) allow improved targeting of conventional therapy.

1. Tumors located near vital structures, such as intracranial lesions or lesions along the axial skeleton, such that complete surgical excision or adequate doses of conventional radiation therapy are impossible. These tumors/lesions include uveal melanomas, chordomas, and chondrosarcomas at the base of the skull and along the axial skeleton.
2. Tumors associated with a high rate of local recurrence despite maximal doses of conventional radiation therapy. One tumor in this group is locally advanced prostate cancer (i.e., Stages C or D [without distant metastases], also classified as T3 or T4).

Advances in photon-based RT such as 3-dimensional conformal radiotherapy, intensity-modulated radiotherapy, and stereotactic body radiotherapy allow improved targeting of conventional therapy.

Proton beam therapy can be given with or without stereotactic techniques. Stereotactic approaches are frequently for uveal tract and skull-based tumors. For stereotactic techniques, 3 to 5 fixed beams of protons or helium ions are used.

Related Policies:

Epiretinal Radiation Therapy for Age-Related Macular Degeneration

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

BCBSNC will provide coverage for Charged Particle Radiotherapy (Proton or Helium Ion) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Charged Particle Radiotherapy is covered

Charged particle irradiation with proton or helium ion beams may be considered medically necessary for the following clinical indications:

- 1) 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 millimeters in largest diameter and 14 millimeters in height.
- 2) Post-operative therapy (with or without conventional high energy X-rays) in patients who have undergone biopsy or a 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.
- 3) In the treatment of pediatric central nervous system (CNS) tumors.

When Charged Particle Radiotherapy is not covered

Charged particle irradiation is considered **investigational** for all other indications not addressed above under, "When Charged Particle Radiotherapy" is covered, including but not limited to, use of proton beam therapy for:

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

Policy Guidelines

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 non-randomized 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have skull-based tumor(s) (ie, cervical chordoma and 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 2016 systematic review of observational studies

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found 5-year survival rates after proton beam therapy ranging from 67% to 94%. The evidence is sufficient to determine qualitatively 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, a few 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 studies tended to have small sample sizes. The available observational studies do not provide sufficient evidence on the efficacy of sample sizes. The available observational studies do not provide sufficient evidence on the efficacy of charged-particle therapy compared with other treatments eg, IMRT. 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 CNS tumors has the potential to reduce long-term adverse effects, such as damage to nearby normal CNS tissue and 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. There is a lack of randomized and observational studies evaluating the efficacy and safety of the 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 has not yet been established whether PBT improves outcomes in any setting for clinically localized prostate cancer. The TEC Assessment included 2 RCTs, only 1 of which included a comparison group of patients who did not receive proton-beam therapy. No data on the use of PBT for prostate cancer have been published since 2010 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 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 included 8 case series and concluded that the evidence is insufficient to permit conclusions about proton beam therapy for any stage of non-small cell lung cancer. No subsequent randomized or non-randomized comparative studies have been published. 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 evidence is insufficient to determine the effects of the technology on health outcomes. The systematic review noted that the studies no charged-particle therapy were heterogenous in terms of type of particle and delivery techniques, and that there are no head to head trials comparing charged-particle therapy to other treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 77520, 77522, 77523, 77525, S8030

Charged Particle Radiotherapy typically consists of a series of CPT codes describing the individual steps used. CPT codes 77520, 77522, 77523, and 77525 may be used for treatment delivery of proton beam therapy.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

National Association TEC Review - 1/96

BCBS Association Medical Policy Reference Manual - 7/96

Medical Policy Advisory Group Review 3/99

BCBS Association Medical Policy Reference Manual - 11/99

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

Specialty Matched Consultant Advisory Panel - 6/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.10, 4/29/2003.

Specialty Matched Consultant Advisory Panel - 5/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.10, 4/1/2005.

Specialty Matched Consultant Advisory Panel - 3/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.10, 2/14/08.

Specialty Matched Consultant Advisory Panel - 3/2008

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 2/11/2010

Specialty Matched Consultant Advisory Panel 5/2010

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Proton Beam Therapy for Non-Small-Cell Lung Cancer. 2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.10, 10/8/2010.

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 1/13/2011

Specialty Matched Consultant Advisory Panel 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 10/4/11

Specialty Matched Consultant Advisory Panel 5/2013

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BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 3/14/13
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 3/13/14
Specialty Matched Consultant Advisory Panel 6/2014
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 4/23/15
Specialty Matched Consultant Advisory Panel 5/2015
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 7/9/15
Medical Director review 7/2015
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 3/10/16
Specialty Matched Consultant Advisory Panel 5/2016
Sr. Medical Director review 7/2016
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 7/14/16
Specialty Matched Consultant Advisory Panel 5/2017
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 7/13/17
Specialty Matched Consultant Advisory Panel 5/2018
Medical Director review 5/2018
BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.10, 7/12/18
Specialty Matched Consultant Advisory Panel 5/2019

Policy Implementation/Update Information

For Policy titled "Charged Particle Radiotherapy (Proton or Helium Ion)"

3/96 Local policy issued.
11/96 Reaffirm: National Association issued policy 7/96.
3/99 Reaffirm
6/99 Reformatted, Definition of Procedure or Service revised, Medical Term Definitions added.
10/00 Specialty Matched Consultant Advisory Panel review. References to the cervical spine changed to "spine (usually cervical)". System coding changes. Medical Policy Advisory Group review. No further changes to criteria.
12/00 77520, 77522, 77523, and 77525 added to coding section. System coding changes.
11/01 Coding format change.
6/02 Specialty Matched Consultant Advisory Panel. No changes. Approve.
1/04 Benefits Application and Billing/Coding sections updated for consistency.
6/10/04 Specialty Matched Consultant Panel review. No changes to policy. Resources added. Notification given 6/10/2004. Effective date 8/12/2004.
4/10/06 Specialty Matched Consultant Advisory Panel review 3/15/2006. Added additional indications to "When covered" section to include; "B. Charged particle radiotherapy may be considered medically necessary for treatment of arteriovenous malformations (AVM) or

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acoustic neuromas that meet the following criteria: the lesion is unresectable **and** the lesion is too large (>3cm) and irregularly shaped to be treated with standard radiotherapy. C. Charged particle radiotherapy may be considered medically necessary for treatment of pituitary adenomas and nasopharyngeal carcinoma that is recurrent after standard radiation therapy." Rationale added to "Policy Guidelines" section. References added.

- 8/28/06 Medical Policy changed to Evidence Based Guideline.
- 6/02/08 Specialty Matched Consultant Advisory Panel review 3/17/08. Added additional indication to "When covered section: "D. Charged particle radiotherapy may be appropriate using standard treatment doses in patients with clinically localized prostate cancer." Removed this indication from the "When not covered" section. References added. (btw)
- 6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/2010. Updated "Description section". Added additional indication to "When not covered section: C. "In patients with clinically localized prostate cancer, because the clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy, yet proton beam therapy is generally more costly than these alternatives." Removed this indication from the "When covered section." References added. (lpr)
- 11/9/10 Evidenced Based Guideline changed to Medical Policy. Under When Covered section: removed B "Charged particle radiotherapy may be appropriate for treatment of arteriovenous malformations (AVM) or acoustic neuromas that meet the following criteria— lesion is unresectable and lesion is too large (>3cm) and irregularly shaped to be treated with standard radiotherapy; also removed C. Charged particle radiotherapy may be appropriate for treatment of recurrent pituitary adenomas and nasopharyngeal carcinoma following standard radiation therapy. Under When Not Covered section: removed A. For indications other than those listed above, B. For melanoma outside the eye, chondrosarcoma, or chordoma at sites other than the skull base or spine." Under When Not Covered" section: added including but not limited to use of proton beam therapy for non-small-cell lung cancer (NSCLC) at any stage or for recurrence. Rationale updated in "Policy Guidelines" section. References added. "Notification given 11/9/10. Effective date 2/15/11. Reviewed with Senior Medical Director. (lpr)
- 6/7/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. References added. (lpr)
- 5/29/12 Revised Policy Guidelines section and reference added. Specialty Matched Consultant Advisory panel review 5/16/2012. (lpr)
- 4/30/13 Revised Policy Guidelines section. Under When Covered; added medically necessary indication for pediatric CNS tumors. Under When Not Covered section: added investigational statements for pediatric non-CNS tumors and for tumors of the head and neck, other than skull based chordoma or chondrosarcoma. Added HCPCS code S8030 to the Billing/Coding section. Reference added. Medical director review 3/2013. Notification given 4/30/13 for effective date 7/30/13. (lpr)
- 7/29/14 Specialty Matched Consultant Advisory Panel review meeting 6/24/2014. No change to policy statement. Reference added. (lpr)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. Reference added. No change to policy statement. (lpr)
- 9/1/15 Under "When Covered" section: charged particle radiotherapy for clinically localized prostate cancer changed from not medically necessary to investigational. Senior medical director review 7/2015. Reference added. (lpr)

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- 7/26/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Reference added. No change to policy statement. Updated Policy Guidelines section. Changed policy title from “Charged Particle Radiotherapy (Proton or Helium Ion)” to “Charged Particle Radiotherapy.” Sr. Medical Director review 7/2016. (lpr)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. No change to policy statement. (lpr)
- 8/25/17 Reference added. No change to policy statement. (lpr)
- 6/8/18 Specialty Matched Consultant Advisory Panel review 5/2018. No changes to policy statements. Medical Director review 5/2018. (mco)
- 5/28/19 Specialty Matched Consultant Advisory Panel review 5/15/2019. No changes to policy intent. Reference added. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.