

Corporate Medical Policy

Charged Particle Radiotherapy (Proton or Helium Ion)

File Name:	charged_particle_radiotherapy-proton_or_helium_ion
Origination:	3/12/96
Last CAP Review:	5/2011
Next CAP Review:	5/2012
Last Review:	5/2011

Description of Procedure or Service

Charged-particle beams consisting of protons or helium ions are a type of particulate radiation therapy. 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 that are 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 D1 [without distant metastases], also classified as T3 or T4).

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.

*****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.**

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.

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

- 1) as primary therapy for patients with 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) as 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 spine (usually cervical). Patients eligible for this treatment have residual localized tumor without evidence of metastasis.

When Charged Particle Radiotherapy is not covered

Charged particle radiotherapy with proton beams using standard treatment doses is considered **not medically necessary** and therefore non covered 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.

Charged particle radiotherapy is considered **investigational** for all other indications not addressed above, including but not limited to use of proton beam therapy for non-small-cell lung cancer (NSCLC) at any stage or for recurrence.

Policy Guidelines

Charged-particle beam radiation therapy has been most extensively studied in uveal melanomas, in which the focus has been to provide adequate local control while still preserving vision. Pooling data from 3 centers, Suit and Urie reported local control in 96% and 5-year survival of 80%, results considered equivalent to enucleation. (1) A recent summary of results from the United Kingdom reports 5-year actuarial rates of 3.5% for local tumor recurrence, 9.4% for enucleation, 61.1% for conservation of vision of 20/200 or better, and 10.0% death from metastasis. (2) The available evidence also suggested that charged-particle beam irradiation is at least as effective as, and may be superior to, alternative therapies including conventional radiation or resection to treat chordomas or chondrosarcoma of the skull base or cervical spine.

In October 2010, the policy was updated following a TEC Assessment on use of proton beam therapy for non-small-cell lung cancer (NSCLC). Since the published data do not allow conclusion about the results of proton beam therapy (PBT) on health outcomes for any stage of non-small-cell lung cancer (NSCLC), this indication is considered investigational.

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Three recent review articles (references) comment that current data do not demonstrate improved outcomes with use of PBT for prostate cancer. In a 2010 review, Kagan and Schulz comment about the lack of data related to improved outcomes and make a number of additional, important comments. (18) They note that while projected dose distribution for PBT suggests reduced rates of bladder and rectal toxicity, toxicity reports for PBT in prostate cancer are similar to those for intensity-modulated radiation therapy (IMRT). They also comment that the role of dose escalation and the optimum doses and dose rates are yet to be established. Finally, they note that the potential for treatment errors with PBT is much greater than with photons. Brada and colleagues reported on an updated systematic review of published peer-reviewed literature for PBT and concluded it was devoid of any clinical data demonstrating benefit in terms of survival, tumor control, or toxicity in comparison with best conventional treatment for any of the tumors so far treated, including prostate cancer. (19) They note that the current lack of evidence for benefit of protons should provide a stimulus for continued research with well-designed clinical trials. In another review article, Efstathiou and colleagues concluded that the current evidence does not support any definitive benefit to PBT over other forms of high-dose conformal radiation in the treatment of localized prostate cancer. (20) They also comment on uncertainties surrounding the physical properties of PBT, perceived clinical gain, and economic viability.

Billing/Coding/Physician Documentation Information

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, and 77525

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.

Charged Particle Radiotherapy (Proton or Helium Ion)

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

Policy Implementation/Update Information

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 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

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- 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)

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.