Medical Policy
Charged-Particle (Proton or Helium Ion) Radiation Therapy

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Policy Number: 437
BCBSA Reference Number: 8.01.10

Related Policies
- Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy #277
- 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): Cancer of the Head and Neck or Thyroid #164
- Intensity-Modulated Radiation Therapy (IMRT): Abdomen and Pelvis #165

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

Charged-particle irradiation with proton or helium ion beams may be 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.

Charged-particle irradiation with proton beams using standard treatment doses is considered NOT MEDICALLY NECESSARY 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.
Other applications of charged-particle irradiation with proton beams are INVESTIGATIONAL. This includes, but is not limited to:

- 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.

*For Medicare members, providers are expected to follow the coverage guidelines according to the Medicare LCD below. The clinical exception/notification form is not required for Medicare Advantage members.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

**Indications**

Proton beam therapy will be considered medically reasonable and necessary for the following conditions:

**Group 1**

1. Unresectable benign or malignant central nervous system tumors to include but not limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations.
2. Intraocular melanomas
3. Pituitary neoplasms
4. Chordomas and chondrosarcomas
5. Advanced staged and unresectable malignant lesions of the head and neck.
6. Malignant lesions of the Para nasal sinus, and other accessory sinuses
7. Unresectable retroperitoneal sarcoma
8. Solid tumors in children

In addition to the criteria in Group I, Proton Beam Therapy indications must demonstrate that:

- The Dose Volume Histogram (DVH) one or more critical structures or organs protected by the use of Proton Beam Therapy;
- The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue;
- There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or
- There is documented clinical rationale that higher levels of precision associated with Proton Beam Therapy compared to other radiation treatments are clinically necessary.

For the treatment of primary lesions, the intent of treatment must be curative. For the treatment of metastatic lesions, there must be:

a. the expectation of a long-term benefit (Greater Than 2 Year of life expectancy) that could not have been attained with conventional therapy
b. the expectation of a complete eradication or improved duration of control of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy.

- The patient's record demonstrates why Proton beam radiotherapy is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

If the above provisions are met and the patient is treated in a protocol that is designed for evidence development and for future publication, it is expected that future published data will support an outcome advantage for Medicare patients for continued coverage of the specific diagnosis. The protocol in and by itself does not constitute criteria for coverage. The presence of an Institutional Review Board (IRB) review when appropriate and patient informed consent are also expected.

Group 2
This section defines conditions that are still under investigation and would be covered when part of a clinical trial, registry or both.
2. Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
3. Left breast tumors
4. Unresectable pancreatic and adrenal tumors
5. Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
6. Unresectable Malignant lesions of the liver, biliary tract, anal canal and rectum
7. Prostate Cancer, Non-Metastatic.

Prostate Cancer
There is as yet no good comparative data to determine whether or not Proton Beam Therapy for prostate cancer is superior, inferior, or equivalent to external beam radiation, IMRT, or brachytherapy in terms of safety or efficacy.

The prostate cancer should be locally contained and not be an advanced prostate cancer (i.e. T3 or T4 where the tumor has spread through the capsule or has invaded seminal vesicles or other structures) and not any N disease (i.e. no spread to lymph nodes or there has been spread to the pelvic lymph nodes). Note: spread into pelvic lymph nodes is considered metastatic disease.

Coverage and payments of Proton Beam Therapy for prostate cancer will require:
   a. Physician documentation of patient selection criteria (stage and other factors as represented in the NCCN guidelines);
   b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication, clinical trials.

In addition to the criteria in Group II, Proton Beam Therapy indication must demonstrate that:
   - T and N Staging must be documented by CT or MRI scan findings.
   - The Dose Volume Histogram (DVH) illustrates one or more critical structures or organs protected by the use of Proton Beam Therapy;
   - The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue;
There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or

There is documented clinical rationale that higher levels of precision associated with Proton Beam Therapy compared to other radiation treatments are clinically necessary:
  o For the treatment of primary lesions, the intent of treatment must be curative
  o For the treatment of metastatic lesions, there must be:
    a. the expectation of a long-term benefit (Greater Than 2 Year of life expectancy) that could not have been attained with conventional therapy
    b. the expectation of a complete eradication of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy (IMRT or 3-D radiation therapy). An IMRT or 3-D radiotherapy plan will need to be generated and compared to the Proton plan for target volume coverage and toxicity analysis.

Local Coverage Determination (LCD): Proton Beam Therapy (L31617)

Prior Authorization Information
Medicare Members: HMO Blue℠
Prior authorization is NOT required.

Medicare Members: PPO Blue℠
Prior authorization is NOT required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. 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.

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<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
</tr>
<tr>
<td>77522</td>
<td>Proton treatment delivery; simple with compensation</td>
</tr>
<tr>
<td>77523</td>
<td>Proton treatment delivery; intermediate</td>
</tr>
<tr>
<td>77525</td>
<td>Proton treatment delivery; complex</td>
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Description
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.
Background
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 RT. 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 used for uveal tract and skull-based tumors. For stereotactic techniques, 3 to 5 fixed beams of protons or helium ions are used.

Summary
- Studies on the use of charged-particle beam radiation therapy to treat uveal melanomas have shown local control and survival rates considered equivalent to enucleation. Therefore, it is considered medically necessary for this indication.
- Available evidence suggests 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. Therefore, it is considered medically necessary for this indication.
- For pediatric central nervous system (CNS) tumors, there is a small body of literature on long-term outcomes with the use of proton beam therapy. This modality of treatment of pediatric CNS tumors has the potential to reduce long-term side effects, as dosimetric studies of proton therapy compared with best available photon-based treatment have shown significant dose-sparing to developing normal tissues. Clinical input uniformly supported this use of proton beam therapy. Therefore, proton beam therapy may be considered medically necessary in the treatment of pediatric CNS tumors.
- For pediatric non-CNS tumors, scant data exists and consists of dosimetric planning studies and a few case series in a small number of patients. Therefore, this indication is considered investigational.
- Results of proton beam studies for clinically localized prostate cancer have shown similar results and outcomes when compared to other radiation treatment modalities. Given these conclusions, along with information that proton beam therapy is generally more costly than alternative treatments, proton beam therapy is considered not medically necessary for treating prostate cancer.
- In treating lung cancer, definite evidence showing superior outcomes with proton beam radiation therapy versus stereotactic body radiation therapy (an accepted approach for treating lung cancer with radiation), is lacking. Therefore, this indication is considered investigational.
- In treating head and neck cancer (other than skull-based tumors), the data are scant and support from clinical input was mixed. Therefore, this indication is considered investigational.

Policy History

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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
References

4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Charged particle (proton or helium ion) irradiation for uveal melanoma and for chordoma or chondrosarcoma of the skull base or cervical spine. TEC Assessments 1996; Volume 11, Tab 1.