Proton Beam Radiation Therapy

Policy # 00187
Original Effective Date: 01/26/2006
Current Effective Date: 12/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Central Nervous System Lesions

Arteriovenous Malformation (AVM)
Based on review of available data, the Company may consider proton beam therapy for arteriovenous malformation (AVM) to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility for proton beam therapy for arteriovenous malformation (AVM) may be considered when ANY of the following criteria are met:

- Intracranial arteriovenous malformation (AVM) not amenable to surgical excision or other conventional forms of treatment; OR
- Adjacent to critical structures such as the optic nerve, brain stem or spinal cord.

Central Nervous System (CNS) Tumors (in adults age 21 and older)
Based on review of available data, the Company may consider proton beam therapy for central nervous system (CNS) tumors to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility for proton beam therapy for central nervous system (CNS) tumors in adults may be considered when ALL of the following criteria are met:

- Central nervous system (CNS) tumors, such as gliomas (both must be met)
  - When adjacent to critical structures such as the optic nerve, brain stem, or spinal cord; AND
  - When other standard radiation techniques such as intensity-modulated radiotherapy (IMRT) or standard stereotactic modalities would not reduce the risk of radiation damage to the critical structure.

Chordoma, Chondrosarcoma
Based on review of available data, the Company may consider proton beam therapy for chordoma, or chondrosarcoma to be eligible for coverage.
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**Patient Selection Criterion**
Coverage eligibility for proton beam therapy for chordoma, or chondrosarcoma may be considered when the following criterion is met:

- As postoperative therapy for individuals who have undergone biopsy or partial resection of a chordoma or low-grade (I or II) chondrosarcoma of the basisphenoid region (e.g. skull-base chordoma or chondrosarcoma), cervical spine, or sacral/lower spine and have residual, localized tumor without evidence of metastasis.

**Ocular Melanoma**

Based on review of available data, the Company may consider proton beam therapy for ocular melanoma to be eligible for coverage.

**Patient Selection Criterion**
Coverage eligibility for proton beam therapy for ocular melanoma may be considered when the following criterion is met:

- As primary therapy for melanoma of the uveal tract (including the iris, choroid, or ciliary body) involving tumors of up to 24 mm in largest diameter and 14 mm in height, and with no evidence of metastasis or extrascleral extension

**Tumors in Pediatric Patients**

**All Tumor Types**
Based on review of available data, the Company may consider proton beam therapy for all tumor types in pediatric patients to be eligible for coverage.

**Patient Selection Criterion**
Coverage eligibility for proton beam therapy for all tumor types in pediatric patients may be considered when the following criterion is met:

- Age < 21.

**When Services Are Considered Not Medically Necessary**
The use of proton beam when patient selection criteria are not met is considered to be not medically necessary.**

**Background/Overview**
Proton beam radiation therapy (PBRT), also known as proton radiation therapy or proton radiotherapy, is a type of external radiation treatment. Using a stereotactic planning and delivery system, positively charged subatomic particles (protons) are targeted to a specific tissue mass. A focused dose of radiation is delivered to the target area while surrounding healthy tissue receives minimal radiation. PBRT is an active area for clinical investigations, and recommendations for its use continue to evolve.
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PBRT should be administered as monotherapy.

PBRT may be appropriate in circumstances where IMRT or stereotactic would potentially damage critical structures. This technique of radiation delivery is being actively studied in other clinical scenarios, and its role in treatment for these situations remains unclear.

Therefore, PBRT should only be used for treating other malignancies in the context of a clinical trial, including:

- Breast cancer
- Lung cancer
- Pancreatic cancer
- Hepatocellular carcinoma
- Head and Neck cancer

Proton beam therapy has been evaluated in comparison to IMRT for the treatment of Prostate Cancer. Studies did not demonstrate superiority of protons over photons and some studies showed a greater risk of gastrointestinal toxicity. Given the lack of superiority in the context of greater toxicity and greater cost, the role of protons for prostate cancer treatment remains unclear, and is not recommended or supported outside of the context of a clinical trial at this time.

PBRT may be appropriate for pediatric patients who are at high risk of developing secondary malignancies. PBRT is not recommended for the treatment of neovascularization secondary to age-related macular degeneration (AMD).

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)
Radiotherapy is a procedure and, therefore, is not subject to U.S. FDA regulations. However, the accelerators and other equipment used to generate and deliver charged-particle radiation (including proton beam) are devices that require FDA oversight. Senior staff at the FDA’s Center for Devices and Radiological Health have indicated that the proton beam facilities constructed in the United States prior to enactment of the 1976 Medical Device Amendments were cleared for use in the treatment of human diseases on a “grandfathered” basis, while at least one that was constructed subsequently received a 510(k) marketing clearance. There are 510(k) clearances for devices used for delivery of proton beam therapy and devices considered to be accessory to treatment delivery systems, such as the Proton Therapy Multileaf Collimator (which was cleared in December 2009). Since 2001, several devices classified as medical charged-particle radiation therapy systems have received 510(k) marketing clearance. FDA product code LHN.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
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Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

Policy History
Original Effective Date: 01/26/2006
Current Effective Date: 12/01/2017
10/05/2005 Medical Director review
12/20/2005 Medical Policy Committee review
01/26/2006 Quality Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/20/2006 Medical Policy Committee approval. Coverage eligibility changed for the treatment of prostate cancer from not medically necessary to “eligible for coverage”.
12/06/2006 Medical Director review
02/13/2008 Medical Director review
02/20/2008 Medical Policy Committee approval
02/04/2009 Medical Director review
02/19/2009 Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010 Medical Policy Committee review
02/17/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility. Rationale replaced.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. New investigational statement added.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013 Medical Policy Committee review
02/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014 Medical Policy Committee review
02/19/2014 Medical Policy Implementation Committee approval. Added that proton radiotherapy may be considered eligible for coverage with criteria for the treatment of pediatric central nervous system tumors. Investigational statements added for pediatric non-central nervous system tumors and head and neck tumors (non-skull based).
02/05/2015 Medical Policy Committee review
02/18/2015 Medical Policy Implementation Committee approval. No change to coverage.

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08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
02/04/2016 Medical Policy Committee review
02/17/2016 Medical Policy Implementation Committee approval. Title change
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017 Medical Policy Committee review
02/15/2017 Medical Policy Implementation Committee approval. No change to coverage.
09/07/2017 Medical Policy Committee review
09/20/2017 Medical Policy Implementation Committee approval. Changed policy title from “ Charged-Particle (Proton or Helium Ion) Radiotherapy” to “Proton Beam Radiation Therapy” to adopt the title from AIM Guidelines. Coverage changed to follow AIM Guidelines.
11/15/2017 Coding update

Next Scheduled Review Date: 09/2018

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)®, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
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**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;  
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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