The Department of Vermont Health Access Medical Policy

Subject: Proton Beam Therapy

Last Review: June 14, 2017*

Past Revisions: April 25, 2016, April 25, 2015 and August 26, 2015

*Please note: Most current content changes will be highlighted in yellow.

Description of Service or Procedure

Proton beam therapy is a type of radiation therapy that utilizes high energy protons to treat cancer. Protons are energized by a device called a synchrotron or a cyclotron, and it is the speed at which these protons are sped up to that determines how deep the protons will penetrate in the body. Protons with higher energy levels will travel deeper inside the body than lower energy ones. An advantage of proton beam therapy is that these protons can be targeted to a specific place in the body, thus deliver their radiation dosing into the tumor and not beyond. Therefore, this form of radiation therapy reduces the amount of radiation delivered to healthy tissue next to the tumor. Moreover, since proton beam therapy spares healthy tissue, it is well suited for treating irregularly shaped lesions located near critical structures, tumors in children, and large tumors near any critical organ.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the beneficiary’s aid category. Prior Authorization (PA) is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid Rules can be found at http://humanservices.vermont.gov/on-line-rules
7102.2 Prior Authorization Determination
7103 Medical Necessity

Coverage Position

Proton beam therapy may be covered for beneficiaries:

• When the proton beam therapy is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice in accordance with Vermont
State Practice Act, who is knowledgeable in the use of proton beam therapy and who provides medical care to the beneficiary AND

- When the clinical guidelines below are met.

**Coverage Criteria**

Proton beam therapy may be covered for beneficiaries who meet the following and the referral is from the consultant oncologist who has seen and assessed the beneficiary:

- Target volume is close to a critical structure, requiring a steep dose gradient outside the target to limit the structure's exposure. AND
- A decrease in dose inhomogeneity in a large treatment volume is required to avoid an excessive "hotspot" within the target volume. AND
- Use of photon-based therapy carries an increased risk of clinically meaningful normal-tissue toxicity. AND
- The same area or an adjacent area has been previously irradiated, increasing the need for sculpting to limit the cumulative radiation dose. AND
- Utilizes FDA approved Devices.

**Clinical guidelines for repeat service or procedure**

The same criteria apply as for the initial use.

**Type of service or procedure covered**

Proton beam therapy 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:

**Group 1**

- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to:
  - Chordoma
  - Chondrosarcomas
- Primary hepatocellular cancer treated in a hypofractionated regimen
- 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
- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
- Pituitary neoplasm
- Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck
- Malignant lesions or tumors of the paranasal sinus, and other accessory sinuses
- Unresectable retroperitoneal sarcoma
  - *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

- Lung cancers, especially NSCLC
- Gastrointestinal tract tumors
- Urinary tract tumors
- Tumors of the female pelvic organs

Group 2

Coverage is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors
- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal, and rectum
- Prostate cancer, without distant metastases**
- Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
- Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

**Please note: 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.

Limitations

- Proton beam therapy is generally not indicated for cancers that are widely disseminated or have hematogenous metastases.
- For the treatment of primary lesions, the intent of treatment should be curative.
- For the treatment of recurrent or metastatic lesions, there should be the expectation at the time of treatment of a long-term benefit (greater than 12 months of life expectancy).

Type of service or procedure not covered (this list may not be all inclusive)

- Adenoid cystic carcinoma
- Age-related macular degeneration
- Bladder cancer
- Carotid body tumor
- Cavernous hemangioma
- Cholangiocarcinoma
- Dermatofibrosarcoma protuberans
• Desmoid fibrosarcoma
• Esophageal cancer
• Ewing's sarcoma
• Fibrosarcoma of the extremities
• Gastrointestinal cancers, including esophageal and pancreatic
• Kidney cancer
• Laryngeal
• Leiomyosarcoma of the extremities
• Nasopharyngeal tumor
• Non-uveal melanoma
• Parotid gland tumor
• Seminoma
• Small bowel adenocarcinoma
• Soft tissue sarcoma
• Squamous cell carcinoma of the tongue/glottis
• Submandibular gland tumor
• Thymoma
• Tonsillar cancer

References


This document has been classified as public information.