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The Department of Vermont Health Access Clinical Criteria

Subject: Proton Beam Therapy

Last Review: August 30, 2024*

Past Revisions: May 5, 2023; December 6, 2021; February 18, 2020; June 14, 2017; April 25, 2016; April 25, 2015; 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, radiation dosing is delivered 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. 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 pertain to the member's aid category. Prior Authorization (PA) is] only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services
- 4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services



Coverage Position

Proton beam therapy may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont's Office of Professional Regulation's website*, who is knowledgeable regarding proton beam therapy and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

Coverage Criteria

Proton beam therapy may be covered for members when ordered by a consultant oncologist after the member has been assessed and when the following is met:

- The target volume is in close proximity to one or more critical structure(s), requiring a steep dose gradient outside the target to limit the structure(s)'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.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

The same criteria apply for the initial use.

Type of service or procedure covered

In accordance with the Centers for Medicare and Medicaid (CMS) Local Coverage Determination (LCD) L35075 (2019), DVHA considers proton beam therapy 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:
 - Chordomas
 - Chondrosarcomas
 - 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.
- 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.
- Primary hepatocellular cancer treated in a hypofractionated regimen.
- Primary 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 neoplasms
- Advanced staged (e.g., T4) and unresectable malignant lesions of the head and neck
- Malignant lesions of the paranasal sinus, and other accessory sinuses
- Unresectable retroperitoneal sarcoma

Group 2

Coverage of proton beam therapy for indications below in group 2 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.

Prostate Cancer

Coverage and payments for 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 (https://www.nccn.org/guidelines/category_1));
- b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

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 2 years of life expectancy).

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

Proton beam therapy is not covered for the following indications:

- 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-veal melanoma
- Parotid gland tumor
- Seminoma
- Small bowel adenocarcinoma
- Soft tissue sarcoma
- Squamous cell carcinoma of the tongue/glottis
- Submandibular gland tumor
- Thymoma
- Tonsillar cancer

Coding guidelines

Please see the Medicaid Portal at <http://vtmedicaid.com/#!/feeSchedule> for fee schedules, code coverage, and applicable requirements.

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