Proton Beam Therapy

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

DISCUSSION

Proton beam therapy (PBT) is a form of external beam radiotherapy that uses particles instead of an X-ray beam. The benefit of proton therapy is that there is little to no radiation dose beyond the treatment area.[1] Proton therapy allows delivery of radiation a second time or a higher dose of radiation for certain tumors involving the base of the skull.[1] A proton beam deposits relatively less radiation energy upon entering the body compared to a photon beam.[2] The energy deposition of the proton beam then rapidly increases over a narrow range of tissue at a desired depth to produce an intense dose distribution pattern called the Bragg peak. Beyond the Bragg peak, energy and dose deposition rapidly decrease, resulting in the absence of any significant exit dose deposited in normal tissue beyond the target.[2]

Proton delivery methods can be described in one of two forms: scattering or scanning. In scattered deliveries, the beam is broadened by scattering devices, beam energies are combined by mechanical absorbers and the beam is shaped by placing material such as collimators and compensators into the proton path. In scanning deliveries, the beam is swept laterally over the target with magnets instead of with scattering devices. Collimators and range compensators are still sometimes used for lateral and distal beam shaping, but field specific hardware is not always required because the scanning magnets allow the lateral extent of the beam to be varied with each energy level, a technique sometimes called intensity-modulated proton therapy (IMPT).[2]

The basic requirement for all forms of PBT treatment delivery is that the technology must accurately produce the calculated dose distribution described by the PBT plan. PBT dose distributions are sensitive to changes in target depth and shape and thus, changes in patient anatomy during treatment may require repeat planning. Such a change must be documented. Precise delivery is vital for proper treatment. Therefore, imaging techniques such as stereoscopic X-ray or CT scan (collectively referred to as Image Guided Radiation Therapy or IGRT) should be utilized to verify accurate and consistent patient and target setup for every treatment fraction.[2]

Proton therapy has several advantages over conventional photon radiotherapy. Protons are useful in two scenarios that apply to a large proportion of cancer patients. These two scenarios are: the lack of exit dose allows for delivery of a therapeutic radiation dose to tumors in challenging anatomic locations; and reduction in integral dose (low-dose bath) to normal tissues that may reduce the risk of late toxicities and secondary cancers. Current evidence is limited for proton therapy and more phase 3 randomized clinical trials are needed to determine its appropriate use.[2]

Proton therapy is considered medically necessary for the following conditions when being treated with definitive intent.

- Chordoma or Chondrosarcoma of the skull base or spine
- Tumors of the paranasal sinuses
- Ocular melanoma with no distant metastases

- Unresectable primary hepatocellular cancer treated in a hypofractionated regimen with 15 or less fractions in curative setting
- Primary or benign solid tumors in members < 20 years old

Proton therapy may be covered for other indications in selected cases. These requests will be evaluated on a case-by-case basis and may include evaluation of comparison treatment plans which document a clinical dosimetric benefit between proton therapy and standard therapy with photons.[2]

DEFINITIONS

- **Bragg Peak -** The energy deposition of the proton beam rapidly increasing over a narrow range of tissue at a desired depth.
- **Image-guided radiation therapy (IGRT) -** Image-guided radiation therapy (IGRT) is the use of imaging during radiation therapy to improve the precision and accuracy of treatment delivery. Radiation therapy machines are equipped with imaging technology to allow your doctor to image the tumor before and during treatment. By comparing these images to the reference images taken during simulation, the patient's position and/or the radiation beams may be adjusted to more precisely target the radiation dose to the tumor. To help align and target the radiation equipment, some IGRT procedures may use fiducial markers, ultrasound, MRI, X-ray images of bone structure, CT scan, 3D body surface mapping, electromagnetic transponders, or colored ink tattoos on the skin.
- **National Comprehensive Cancer Network® (NCCN®) -** An alliance of 32 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

POLICY

Please see all the below related anatomical policy that includes proton beam radiation therapy as a treatment for medical necessity.

- Bone Cancer, Primary
- Head and Neck Cancer
- Liver and Biliary Tract Cancers
- Soft Tissue Sarcoma
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REFERENCES

1. LaRiviere MJ, Santos PMG, Hill-Kayser CE, Metz JM. Proton Therapy. *Hematology/Oncology Clinics of North America*. 2019;33(6):989-1009.
2. Proton beam therapy. ASTRO Model Policies. https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/ASTROPBTModelPolicy.pdf. Accessed May 20, 2022.
3. Dictionary of cancer terms. National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/. Accessed May 20, 2022.
4. Billing and coding: Proton beam therapy (A55315). CMS.gov. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55315&ver=12&. Accessed May 20, 2022.

CODING [ICD-10, HCPCS]*

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C00.0-C14.8	Malignant neoplasm of external upper lip - Malignant neoplasm of overlapping sites of lip, oral cavity, and pharynx
C30.0-C32.9	Malignant neoplasm of nasal cavity - Malignant neoplasm of larynx, unspecified
C40.00-C40.82	Malignant neoplasm of scapula and long bones of unspecified upper limb - Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C41.0-C41.2	Malignant neoplasm of bones of skull and face - Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum, and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C45.1	Mesothelioma of peritoneum
C45.7	Mesothelioma of other sites
C47.0	Malignant neoplasm of peripheral nerves of head, face, and neck
C48.0	Malignant neoplasm of retroperitoneum
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face, and neck
C64.1-C64.9	Malignant neoplasm of right kidney, except renal pelvis - Malignant neoplasm of unspecified kidney, except renal pelvis
C69.00-C72.9	Malignant neoplasm of unspecified conjunctiva - Malignant neoplasm of central nervous system, unspecified
C75.0	Malignant neoplasm of parathyroid gland
C75.1-C75.3	Malignant neoplasm of pituitary gland - Malignant neoplasm of pineal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C7A.8	Other malignant neuroendocrine tumors
C76.0-C76.8	Malignant neoplasm of head, face, and neck - Malignant neoplasm of other specified ill-defined sites
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
D32.0-D33.9	Benign neoplasm of cerebral meninges - Benign neoplasm of central nervous system, unspecified
D35.2-D35.4	Benign neoplasm of pituitary gland - Benign neoplasm of pineal gland
D35.6	Benign neoplasm of aortic body and other paraganglia
D42.0-D43.2	Neoplasm of uncertain behavior of cerebral meninges - Neoplasm of uncertain behavior of brain, unspecified
D43.4	Neoplasm of uncertain behavior of spinal cord

Code	Description
D44.10-D44.12	Neoplasm of uncertain behavior of unspecified adrenal gland - Neoplasm of uncertain behavior of left adrenal gland
D44.3-D44.5	Neoplasm of uncertain behavior of pituitary gland - Neoplasm of uncertain behavior of pineal gland
D44.6-D44.7	Neoplasm of uncertain behavior of carotid body - Neoplasm of uncertain behavior of aortic body and other paraganglia
D49.6-D49.7	Neoplasm of unspecified behavior of brain - Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system
G95.20-G95.29	Unspecified cord compression - Other cord compression
G95.9	Disease of spinal cord, unspecified
Q28.2-Q28.3	Arteriovenous malformation of cerebral vessels - Other malformations of cerebral vessels

REVISION AND REVIEW HISTORY

No.	Description	Metadata
1	Original Effective Date:	5/2022
2	Policy Review Dates:	5/23/2022, 5/24/2022, 6/1/2022, 7/20/2022
3	Policy Revision Dates:	5/23/2022, 5/24/2022, 6/1/2022, 7/20/2022
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	5/24/2022, 6/1/2022
6	Revision Changes:	