**Medica Coverage Policy**

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<th>Proton Beam Radiation Therapy</th>
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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Proton beam radiation therapy (PBRT) is **COVERED** for treatment of:

1. Advanced and/or unresectable head and neck cancer
2. Chordomas or chondrosarcomas arising at the base of the skull or along the axial skeleton without distant metastasis
3. Malignant and benign central nervous system tumors, including primary or metastatic spine tumors
4. Hepatocellular/hepatobiliary cancer
5. Ocular tumors, including uveal melanoma (iris, choroid, ciliary body) not amenable to surgical excision or other conventional forms of treatment
6. Paranasal sinus or other accessory sinus tumors
7. Soft tissue sarcomas (e.g., non-metastatic retroperitoneal sarcomas).

PBRT is **COVERED** for other diagnoses not listed above as medically necessary when:

1. Documentation in the medical record indicates that sparing of surrounding healthy tissue cannot be achieved using standard radiation therapy modalities (e.g., intensity-modulated radiation therapy [IMRT]; stereotactic body radiation therapy [SBRT]; selective internal radiation spheres), and
2. Evaluation includes documentation of:
   a. A comparison of treatment plans for PBRT, IMRT and SBRT, and
   b. PBRT’s ability to reduce the dose to adjacent critical structures in a clinically meaningful manner.

PBRT is considered investigative and unproven and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Description**

Proton beam radiation therapy involves directing a beam of accelerated subatomic, electrically charged particles to targeted tumor tissue. To penetrate the body, protons must first be accelerated by cyclotrons and synchrotrons to attain 60% of the speed of light, which results in maximum delivery of energy at a defined depth (e.g., the depth of the targeted tumor). Proton beam radiation therapy has been used alone or in combination with traditional radiation, chemotherapy, and/or as follow-up to surgery to treat malignancies in the abdomen, central nervous system, eye,
lung, head and neck, and prostate, as well as some noncancerous conditions (e.g., arteriovenous malformations, circulatory system defects within the brain).

The primary advantage of using protons therapy over photons therapy is decreased collateral damage to surrounding tissue. Because of the targeted delivery of proton energy, tissue in the beam's path to the targeted tissue receives only a small radiation dose, with tissue around and behind the targeted tissue receiving even less radiation. Decreased exposure of healthy tissue is intended to reduce some of the side effects of radiation therapy (e.g., fatigue, redness/irritation of irradiated tissue, nausea, fistula formation, secondary cancers), including adverse events in pediatric patients who are especially vulnerable to radiation side effects.

The proton beam procedure involves detailed treatment plans with input from clinicians, medical physicists and dosimetrists, who determine the precise angle, proton beam energy for maximum penetration, and the dose per treatment for each individual patient. Three-dimensional PET or CT scans are utilized to ensure the accurate delivery of the proton beam. During the actual treatment session, patients are immobilized with the use of custom made molds which hold the entire body or the head and neck region completely still to prevent any movement that may compromise the accuracy of the proton beam. Treatment typically occurs once daily for five days and up to eight weeks, which divides the total radiation dose over several treatment sessions. Each treatment session typically lasts between 30 and 60 minutes. Patient positioning takes most of this time, while actual delivery of the proton beam lasts only about two minutes.

FDA Approval
Traditional proton therapy accelerators are designed and built on-site and are not subject to U.S. Food and Drug Administration (FDA) premarket approval processes (e.g. the Harvard University Cyclotron Laboratory, are designated as “preamendments devices”). The FDA began regulating proton therapy systems in 1988, and devices receiving FDA approval since introduction of earlier accelerators must demonstrate they are “substantially equivalent” to these previously cleared (e.g., predicate or preamendment) devices. In certain instances, the FDA grants marketing clearance to the center itself, rather than to their system components.

The following hospital-based proton therapy centers receiving marketing clearance include, but not limited to:
1. Loma Linda University Medical Center Proton Beam Therapy System (Loma Linda, CA)
2. Massachusetts General Hospital Francis H. Burr Proton Therapy Center (Boston, MA)
3. Indiana University Cyclotron Proton Therapy System (Bloomington, IN)
4. McLaren Health Care Corp. (Flint, MI).

Many systems have received FDA 510(k) approval including, but not limited to:
1. MEVION S250 Proton Therapy System (Mevion Medical Systems)
2. PT Varian Proton Therapy System (i.e., ProBeam) (Varian Medical Systems)
3. PROBEAT proton therapy system, PROBEAT with MGCS, and PROBEAT proton therapy system with DSSS (Hitachi Ltd.)
4. Proton Beam Therapy System; Conforma 3000 (Optivus Proton Therapy)
5. IBA Proton Therapy System; Proteus 235 (IBA S.A.).

The U.S. Nuclear Regulatory commission licenses and regulates the use of proton beam systems under the U.S. Code of Federal Regulations, Title 10, Part 20, Standards for Protection Against Radiation. The regulation governs ionizing radiation produced by particles, including gamma rays, x-rays, neutrons, and high-speed protons.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.
Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes
- 77520 - Proton treatment delivery; simple, without compensation
- 77522 - Proton treatment delivery; simple, with compensation
- 77523 - Proton treatment delivery; intermediate
- 77525 - Proton treatment delivery; complex

Original Effective Date Coverage Policy: 4/21/2021

Re-Review Date(s) Coverage Policy: 7/21/2021
8/23/2021 – administrative update

Original Effective Date UM Policy: 6/1/2013

Re-Review Date(s) UM Policy: 9/1/2014
12/1/2015
10/1/2016
8/1/2017
6/1/2018
9/1/2019
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