PROTON BEAM RADIATION THERAPY

Policy Number: 2016M0022B  Effective Date: February 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This medical policy describes the use of Proton Beam Therapy (PBT), a form of external radiotherapy in which positively charged subatomic particles (protons) are precisely targeted to a specific tissue mass using a sophisticated treatment planning and delivery system. PBT is used to reduce recurrence of a tumor after surgical excision or as a primary treatment for an inoperable mass. The goal is to deliver higher target doses to the tissue than is possible with conventional photon irradiation while improving local control of tumors and reducing acute and late complications.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

A. Proton Beam Radiation Therapy (PBT) is considered MEDICALLY NECESSARY for the treatment of:
   1. Pediatric, adolescent, or adults with radiosensitive tumor sites that may be considered for Proton Beam Radiotherapy:
      a. Those requiring craniospinal irradiation
      b. Central nervous system tumors or lesions:
         1) Ependymomas
         2) Craniopharyngiomas
         3) Primitive neuroectodermal tumors
         4) Low grade gliomas (astrocytoma, glioblastoma)
         5) Medulloblastomas
         6) Benign and atypical meningiomas
         7) Neuromas
      c. Non-central nervous system tumors:
         1) Chordomas and chondrosarcomas
         2) Rhabdomyosarcomas
         3) Retroperitoneal sarcoma
         4) Malignant lesions of the paranasal sinus and nasal cavity tumors
         5) Advanced staged and unresectable malignant lesions of the head and neck
         6) Solid tumors in children
         7) Ewing’s sarcoma
         8) Pineal tumors
   2. Intracranial arteriovenous malformations (AVMs)
   3. Melanoma of the uveal tract (iris, ciliary body and choroid), not amenable to surgical excision or other conventional forms of treatment
   4. Spinal cord tumors

B. Proton Beam Radiation Therapy (PBT) is considered INVESTIGATIONAL for the conditions listed below, however it would be covered by CMS when the therapy is part of a clinical trial, registry or both.
   1. Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
   2. Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
   3. Left breast tumors
   4. Unresectable pancreatic and adrenal tumors
   5. Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
6. Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
7. Prostate cancer, non-metastatic

Presence of an Institutional Review Board (IRB) review is expected. Physician documentation of patient selection criteria and patient informed consent are also required.

Note: There is as yet no good comparative data to determine whether or not Proton Beam Therapy for these conditions is superior, inferior, or equivalent to external beam radiation, IMRT, or brachytherapy in terms of safety or efficacy. Comparative effectiveness studies including randomized controlled trials are needed to document the theoretical incremental advantages of PBT over other radiotherapies in many common cancers. It is not known whether the higher precision of PBT actually translates to better clinical outcomes. Therefore, PBT is considered a form of external beam radiation therapy, non-preferentially to other forms of external beam radiation.

C. Proton Beam Radiation Therapy is considered EXPERIMENTAL/INVESTIGATIONAL for the treatment of other indications, including but not limited to:
1. Age-related macular degeneration (AMD)
2. Bladder cancer
3. Carotid body tumor
4. Cavernous hemangioma
5. Choroidal hemangioma
6. Esophageal cancer
7. Germ cell tumors
8. Lymphoma
9. Non-uveal melanoma
10. Small bowel adenocarcinoma
11. Tumors of the vestibular system
12. Thymoma
13. Intracranial and skull base tumors that have metastasized from another primary site

There is inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature to support the use of PBT on these conditions.

D. Proton beam radiation therapy used in conjunction with intensity-modulated radiation therapy (IMRT) is considered EXPERIMENTAL/INVESTIGATIONAL.

Clinical evidence is insufficient to support the combined use of these technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy.

Clinical Considerations:
Alternatives to PBT include, but may not be limited to, the following:
- Chemotherapy
- Electron beam radiation therapy (EBRT)
- Endovascular embolization
- Surgical excision.

Physician documentation of patient selection criteria is required.
The patient's record demonstrates why proton beam radiotherapy is considered the treatment of choice for the individual patient.

For the treatment of primary lesions, the intent of treatment must be curative.

There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates.

There is documented clinical rationale that higher levels of precision associated with proton beam therapy compared to other radiation treatments are clinically necessary.

For the treatment of metastatic lesions, there must be:

- The expectation of a long-term benefit (greater than 2 years of life expectancy) that could not have been attained with conventional therapy.
- The expectation of a complete eradication of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy (IMRT or 3-D radiation therapy).

**BACKGROUND:**

Unlike other types of radiation therapy that use x-rays or photons to destroy cancer cells, proton beam therapy (PBT) uses a beam of special particles (protons) that carry a positive charge. There is no significant difference in the biological effects of protons versus photons; however, protons can deliver a dose of radiation in a more confined way to the tumor tissue than photons. After they enter the body, protons release most of their energy within the tumor region and, unlike photons, deliver only a minimal dose beyond the tumor boundaries (American College of Radiology website, 2012).

The greatest energy release with conventional radiation (photons) is at the surface of the tissue and decreases exponentially the farther it travels. In contrast, the energy of a proton beam is released at the end of its path, a region called the Bragg peak. Since the energy release of the proton beam is confined to the narrow Bragg peak, collateral damage to the surrounding tissues should be reduced, while an increased dose of radiation can be delivered to the tumor.

Because of these physical properties, it has been theorized that PBT may be especially useful for cancers located in areas of the body that are highly sensitive to radiation and/or where damage to healthy tissue would be an unacceptable risk to the patient. In addition, PBT may also benefit patients with tumors that are not amenable to surgery. Theoretically, the use of protons and other charged-particle beams may improve outcomes when the following conditions apply:

1. Conventional treatment modalities do not provide adequate local tumor control;
2. Evidence shows that local tumor response depends on the dose of radiation delivered; and
3. Delivery of adequate radiation doses to the tumor is limited by the proximity of vital radiosensitive issues or structures.

PBT has been used in stereotactic radiosurgery of intracranial lesions. The gamma knife and linear accelerator have also been used in stereotactic radiosurgery. Proton beam radiotherapy has been shown to be particularly useful in treating radiosensitive tumors that are located next to vital structures, where complete surgical excision or administration of adequate doses of conventional radiation is difficult or
impossible. Examples include uveal melanomas, chordomas and chondrosarcomas at the base of the skull, and inoperable arterio-venous malformations.

To date, there are no published, controlled, comparative studies describing outcomes from patients treated with proton beam radiotherapy versus other therapies; thus the advantage of protons over conventional photon therapy is based on the dosimetric advantage of protons over photons for tumors that are in immediate proximity to critical structures. The majority of the published literature is in the form of prospective or retrospective case series and cohort studies; there is also significant variation in the types and stages of cancer for which treatment with proton beam radiotherapy has been reported, as well as the reported doses and fractionation schedules. Published reports focus mainly on toxicity, and include pediatric, adolescent, and adult patients treated with proton beam radiotherapy primarily for ocular cancers, spine or skull base chordomas and chondrosarcomas, spinal and paraspinal bone and soft tissue sarcomas, head and neck cancers, and brain tumors. In addition, there is some literature reporting the use of proton beam radiotherapy for patients with lymphoma, non-small cell lung cancer, prostate cancer, and some gastrointestinal cancers.

As of April 2013, there are 41 facilities worldwide that offer treatment with proton beam radiotherapy. In North America, there are currently 12 facilities in operation, and 8 more are under development or being constructed.

**Device:** The proton beam facility involves an accelerator-synchrotron system, a beam transport system, a beam delivery system, and a patient alignment and imaging system (treatment planning system), all under the operation of a facility control system. Protons are generated by an ion source and then accelerated by a linear accelerator up to approximately 2 million electron volts (MeV). The beam then enters the synchrotron; as the protons complete each trip around the synchrotron, their energy is increased to the desired level by the addition of radiofrequency energy. The desired energy level would be that required to position the Bragg peak into the cancerous tissue. The beam transport system consists of additional magnets that focus and direct the beam from the synchrotron to the delivery system, which is located in one of several treatment rooms. The beam delivery system that is used for treatment of tumors in locations other than the head and neck or the eye is mounted on very large steel gantries. These gantries can rotate 360° around the patient, thus providing great flexibility in exact delivery of the proton beam. Several components serve to spread and shape the beam so that it fits the target irradiation volume. Computed tomography (CT) scans, magnetic resonance imaging (MRI), and positron emission tomography (PET), along with conventional x-rays, can be utilized to construct a digital three-dimensional model of the cancerous tissue for treatment planning (MacDonald et al., 2006; Optivus, 2006).

**Treatment:** Precise targeting of the Bragg peak is of utmost importance in PBT because there is a sudden release of energy within the Bragg peak, but minimal energy release proximal to it and virtually none distal to it. Additional margins are added to the gross tumor volume to define a clinical target volume and a planning target volume, thus allowing a small margin of noncancerous tissue to be irradiated. Multiple tumors are encompassed within a single target volume. Penetration depth is controlled by the initial energy selected for the beam. Proton dose is measured in cobalt gray equivalents (CGE), which are calculated by multiplying the amount of energy delivered, measured in grays (Gy), times a relative biological effectiveness (RBE) ratio. The RBE expresses the relative effect of a test radiation compared with the same energy delivered as photon radiation. For proton beams, the RBE is usually considered to be 1.1. As with conventional radiation therapy, PBT usually uses fractionation of dose and multiport beam entry to limit exposure to the skin and other non-target tissue. The patient’s positioning must be consistent for...
consecutive treatment sessions. Patient immobilization is also an essential component of precise targeting and is often accomplished by placing the patient in a polyvinyl mold. A technique referred to as respiration gating may be used to help avoid irradiation beyond the planned volume because of organ motion that occurs during breathing. In some patients, conformal photon irradiation may be administered in conjunction with PBT (Bush et al., 2004a; Chiba et al., 2005; Levin et al., 2005; Hata et al., 2006a; MacDonald et al., 2006; Nihei et al., 2006).

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

   Radiation therapy is a procedure and, therefore, is not subject to FDA regulation. However, the accelerators and other equipment used to generate and deliver proton beam radiation therapy are regulated by the FDA.

   Proton beam therapy systems are approved by the FDA 510(k) process as a “medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation” (FDA, 2006).

   Examples of such systems are the Optivus Proton Beam Therapy System (Optivus Technology Inc., Loma Linda, CA) and the Probeat (Hitachi, Ltd., Power Systems Group, Tokyo, Japan) (FDA, 2006; FDA, 2000).

   The following devices have received 510(k) clearance for PBT of tumors and other medical conditions susceptible to proton radiation therapy:
   - The Harvard University Cyclotron Laboratory Beam Therapy system is a pre-amendment (pre-1976) device (FDA, 2001a; FDA, 2001b).
   - The Loma Linda University Proton Beam Therapy system received 510(k) clearance on February 22, 1988 (FDA, 1998).
   - The Optivus Proton Beam Therapy System (Optivus Technology, Inc, Loma Linda, CA) received 510(k) clearance on July 21, 2000 (FDA, 2000).
   - The Proton Therapy System (Ion Beam Applications S.A., Louvain-la-Neuve, Belgium; distributed in the U.S. by Ion Beam Applications, Philadelphia, PA) received 510(k) clearance on July 12, 2001 (FDA, 2001a).
   - The Northeast Proton Therapy Center (Massachusetts General Hospital, Boston, MA) received FDA 510(k) clearance on July 20, 2001 (FDA, 2001b).
   - Hitachi Probeat (Hitachi, Ltd., Power Systems Group, Tokyo, Japan) received FDA 510(k) clearance (FDA, 2006b).


2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

   No National Coverage Determination (NCD) for Proton Beam Therapy exists.

   Local Coverage Determinations (LCDs) exist for Proton Beam Therapy (PBT) and compliance with the policy is required. LCD ID Number: L31617. Minnesota. Accessed November 13, 2015.

Proton therapy is of particular value in those tumors located close to vital organs (or organs at risk).
where a small local overdose can cause fatal complications such as tumors close to the spinal cord. Irregular shaped lesions near critical structures are well suited for protons. In general, proton beam radiotherapy is not indicated for cancers that are widely disseminated, such as leukemias or malignancies with hematogenous metastases or as a short term palliative procedure. Proton beam therapy is also not indicated in the treatment of very radiosensitive tumors such as lymphomas or germ cell neoplasms. The intent of treatment should be curative. If proton beam radiotherapy is used for a patient with metastatic disease, evidence should be provided to justify the expectation of a long-term benefit (> 2y), as well as evidence of a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy. Due to the reduction in integral dose with protons, the most important benefits can be expected for pediatric patients. In adults, proton beam therapy should be reserved to treat patients that have clinically apparent disease (by exam or medical imaging).

Indications:
Proton beam therapy will be considered medically reasonable and necessary for the following conditions:

**Group 1**
1. 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,
2. Intraocular melanomas,
3. Pituitary neoplasms,
4. Chordomas and chondrosarcomas,
5. Advanced stage and unresectable malignant lesions of the head and neck,
6. Malignant lesions of the para-nasal sinus, and other accessory sinuses,
7. Unresectable retroperitoneal sarcoma,

In addition to the criteria in Group I, Proton Beam Therapy indications must demonstrate that:
- The Dose Volume Histogram (DVH), one or more critical structures or organs, are protected by the use of Proton Beam Therapy;
- The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue;
- There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or
- There is documented clinical rationale that higher levels of precision associated with Proton Beam Therapy compared to other radiation treatments are clinically necessary.

**Group 2**
This section defines conditions that are still under investigation and would be covered when part of a clinical trial, registry or both.
1. Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers,
2. Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix,
3. Left breast tumors,
4. Unresectable pancreatic and adrenal tumors,
5. Skin cancer with macroscopic perineural/cranial nerve invasion of skull base,
6. Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum,
7. Prostate cancer, non-metastatic.

Note: There is as yet no good comparative data to determine whether or not Proton Beam Therapy for prostate cancer is superior, inferior, or equivalent to external beam radiation, IMRT, or brachytherapy in terms of safety or efficacy. Physician documentation of patient selection criteria is required.

For the treatment of primary lesions, the intent of treatment must be curative.

For the treatment of metastatic lesions, there must be:

- The expectation of a long-term benefit (greater than 2 years of life expectancy) that could not have been attained with conventional therapy,
- The expectation of a complete eradication or improved duration of control of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for proton beam radiotherapy over other forms of radiation therapy,
  - The patient’s record demonstrates why proton beam radiotherapy is considered the treatment of choice for the individual patient,
  - The presence of an Institutional Review Board (IRB) review when appropriate and patient informed consent are also expected.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding PBT in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

The Agency for Healthcare Research and Quality (AHRQ) published a report on particle beam therapy for treating a variety of cancers. More than half of the publications the AHRQ identified described treatment of ocular cancers (uveal melanoma in particular), and cancers of the head and neck (brain tumors, and tumors arising from skull base, cervical spine and nearby structures). In order of decreasing number of studies, the following types of malignancies were also described: gastrointestinal (esophageal cancer, hepatocellular carcinomas of the liver, pancreatic cancer), prostate, lung, spine and sacrum, bone and soft tissue, uterine (cervix and corpus), bladder, and miscellaneous (skin cancer or a compilation of a center’s experience with a variety of cancers treated there).

According to the AHRQ report, there are many publications on particle (mainly proton) beam therapy for the treatment of cancer. However, they typically do not use a concurrent control, focus on heterogeneous populations and they employ different definitions for outcomes and harms. These studies do not document the circumstances in contemporary treatment strategies in which radiotherapy with charged particles is superior to other modalities. Comparative effectiveness studies including randomized controlled trials are needed to document the theoretical advantages of charged particle radiotherapy to specific clinical situations. At present, there is very limited evidence comparing the safety and effectiveness of PBBT with other types of radiation therapies for cancer. Therefore, it is not possible to draw conclusions about the comparative safety and effectiveness of PBBT at this time (AHRQ, 2009).

Several systematic reviews (Terasawa, 2009; Brada, 2009; Lodge, 2007; Olsen, 2007) previously reported the lack of evidence supporting proton beam therapy and the need for well-designed prospective studies.
comparing proton beam therapy to other forms of radiation therapy.

**APPLICABLE CODES:**

**UNDER DEVELOPMENT:** This section will host claim payment and billing instructions to be used by Claims and Customer Service staff. Content in this section is to be developed cooperatively by multiple departments, and reviewed by the Medical Policy Group.

*Note: The contents of this section are confidential and are not to be shared externally. When printing a copy of a policy for external distribution, this section should be excluded.*

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<tr>
<td>0073T</td>
<td>Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session</td>
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<tr>
<td>0197T</td>
<td>Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment</td>
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<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
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<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan</td>
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<td>77418</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
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<td>Proton treatment delivery; simple, without compensation</td>
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<td>Proton treatment delivery; simple, with compensation</td>
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<td>Proton treatment delivery; intermediate</td>
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<td>158.0</td>
<td>Malignant neoplasm of retroperitoneum [soft tissue sarcomas not amenable to other radiotherapy]</td>
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<td>170.0</td>
<td>Malignant neoplasm of bones of skull and face, except mandible</td>
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<td>170.2</td>
<td>Malignant neoplasm of vertebral column, excluding sacrum and coccyx</td>
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<td>185</td>
<td>Malignant neoplasm of prostate</td>
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<td>190.0</td>
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D43.4 Neoplasm of uncertain behavior of spinal cord
D49.6 Neoplasm of unspecified behavior of brain
Q28.3 Other malformations of cerebral vessels
Q28.2 Arteriovenous malformation of cerebral vessels

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<tr>
<td>S8030</td>
<td>Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy</td>
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</table>

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REFERENCES:


62. Slater JD, Rossi CJ, Jr., Yonemoto LT, et al. Proton therapy for prostate cancer: the initial Loma Linda University


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ATTACHMENTS: