“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

In conventional external beam radiation therapy (EBRT), the targeted tissue usually receives 95-100% of the intended dose. A major limitation of EBRT is that in some situations, because critical normal tissues cannot be completely protected from the radiation, a curative dose cannot be used.

Proton Beam radiotherapy is a form of conformal external beam radiation treatment. Protons are positively charged atomic particles and have similar biological effects as conventional x-ray beams, but have very different energy disposition or physics profiles. Conventional x-ray beams give off the most energy a short distance below the skin surface (entrance dose) and continue to deposit some dose throughout the path of the beam even beyond the target (exit dose). Conventional EBRT delivers radiation to a more broad range of diseased and normal tissues with targeted tissue receiving approximately 95-100% of the intended dose but a larger volume of normal/unintended tissue receiving a significantly higher dose of radiation that is approximately 20-60% of the dose. In short, there is a higher integral dose to the normal tissue with conventional external beam therapy. In contrast, proton particles deposit a smaller amount of radiation energy as they enter the body (lower entrance dose), culminating in an intensity dose peak, also called the Bragg Peak. There is no further energy deposition beyond the Bragg peak (no exit dose). The depth of the peak can be controlled by the amount of the proton’s energy. While the unaltered Bragg Peak is measured in millimeters, it can be spread out to encompass whole or partial volumes of a tumor. Like other conformal radiation modalities, proton beams can be precisely delivered to the tumor volume without harming surrounding healthy tissue or critical organs. Proton beams typically deposit less radiation in normal non-targeted tissues than conventional radiation therapy and have been used to escalate the radiation dose to diseased tissues while minimizing damage to adjacent normal tissues. Proton beam therapy will typically have a significantly lower integral dose (dose to the whole body of the patient) compared to conventional x-ray therapy. Intensity-modulated radiation therapy (IMRT), gives integral radiation dose to normal tissues compared to proton beam therapy. Due to reduction in integral dose with protons the most important benefits can be expected for pediatric...
patients.

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).

Protons provide a dosimetric advantage compared to x-rays for many tumor treatment sites. In general, x-rays give 1.5 to 3 times more integral dose outside the target volume than protons, primarily in the low and medium dose range. There is no benefit to irradiating normal tissues outside of the intended treatment volume, and treatment to larger volumes of normal tissues is associated with increased toxicity, including an increased risk of second malignancies.

Stereotactic techniques are sometimes used with proton beam therapy especially for skull based, uveal tract tumors and others.

The proton beam therapy system must be FDA approved.

**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 staged 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

8. Solid tumors in children

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 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.

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

a. the expectation of a long-term benefit (greater than 2 year of life expectancy) that could not have been attained with conventional therapy,

b. 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. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

- If the above provisions are met and the patient is treated in a protocol that is designed for evidence development and for future publication, it is expected that future published data will support an outcome advantage for Medicare patients for continued coverage of the specific diagnosis. The protocol in and by itself does not constitute criteria for coverage. The presence of an Institutional Review Board (IRB) review when appropriate and patient informed consent are also expected.
Group 2
This section defines conditions that are still under investigation and would be covered when part of a clinical trial, registry or both. (See details in coding section)

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.

Prostate Cancer
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.

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.

Coverage and payments of 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); and

b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication, clinical trials.

In addition to the criteria in Group II, Proton Beam Therapy indication must demonstrate that:
• T and N Staging must be documented by CT or MRI scan findings;
• The Dose Volume Histogram (DVH) illustrates one or more critical structures or organs 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.

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

For the treatment of metastatic lesions, there must be:

a. the expectation of a long-term benefit (greater than 2 year of life expectancy) that could not have been attained with conventional therapy;

b. 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). An IMRT or 3-D radiotherapy plan will need to be generated and compared to the Proton plan for target volume coverage and toxicity analysis.

The patient's record demonstrates why Proton beam radiotherapy is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

If the above provisions are met and the patient is treated in a protocol that is designed for evidence development and for future publication, it is expected that future published data will support an outcome advantage for Medicare patients for continued coverage of the specific diagnosis. The protocol in and by itself does not constitute criteria for coverage. The presence of an Institutional Review Board (IRB) review when appropriate and patient informed consent are also expected.

If the patient cannot clearly meet the criteria for coverage but desires Proton beam radiotherapy based on a marketed theoretical advantage, the claim should be billed with the appropriate modifier appended to the treatment delivery code. (See Coding Guidelines).

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not
apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0333 Radiology - Therapeutic and/or Chemotherapy Administration - Radiation Therapy

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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*Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity*

**Documentation Requirements**

1. All documentation must be maintained in the patient’s medical record and available to the contractor upon request.

2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the physician or non-physician practitioner responsible for and providing the care of the patient.

3. The submitted medical record should support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. Each claim must be submitted with ICD-10-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-10-CM codes will be returned.

5. Documentation in the patient medical record must support the reasonable and necessary requirements as outlined under the coverage and limitations sections of this LCD.

6. Documentation must include the planned course of therapy, type and delivery of treatment, level of clinical management involved and ongoing documentation of any changes in the course of treatment, and DHV as noted in the covered indications section.

Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer