Coverage Indications, Limitations, and/or Medical Necessity

Proton beam radiotherapy is a type of particle beam radiation therapy that delivers high dose radiation to a localized site. Proton beams theoretically 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. Historically, proton beam radiotherapy has most commonly been used for tumors that are difficult or dangerous to treat with surgery or for tumors that are located next to vital structures, where administration of adequate doses of conventional radiation is difficult or impossible.

In general, proton beam radiotherapy is not indicated for cancers that are widely disseminated, such as leukemias, have hematogenous metastases or as a short term palliative procedure. 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.

Proton beam therapy will be considered medically reasonable and necessary for the following conditions (Group #1 of ICD-10-CM Codes that Support Medical Necessity):

**Group #1 Conditions**

- Benign or malignant conditions otherwise not suitable for intensity modulated radiation therapy (IMRT) or 3-dimensional conformal therapy involving the base of the skull or axial skeleton, including but not limited to chordomas and chondrosarcomas.
- Solid tumors in children up to age 18.
- Benign or malignant central nervous system tumors to include primary and variant forms of medulloblastoma, astrocytoma, glioblastoma, arteriovenous malformations, acoustic neuroma craniopharyngioma, benign and atypical meningiomas and pineal gland tumors.
- Intraocular melanomas
Because many radiological oncologists believe that proton beam therapy is a legitimate treatment option in certain circumstances where 3-dimensional conformal or intensity modulated radiation therapy (IMRT) is deemed medically necessary, proton beam therapy will be considered as medically reasonable and necessary for certain other conditions (i.e., Group #2 of ICD-10-CM Codes that Support Medical Necessity) not listed above, as long as the following criteria are met:

Either #1, #2, or #3 must be present and

Either #4 or #5 must be present and

#6 must always be present.

1. When dose constraints to normal tissues limit the total dose of radiation safely deliverable to the tumor with other indicated methods

2. When there is a reason to believe that doses generally thought to be above the level otherwise attainable with other methods might improve control rates

3. In circumstances when the higher levels of precision associated with proton beam therapy as compared to other radiation methods are necessary, i.e clinically relevant

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

5. For the treatment of metastatic lesions, there must be

   a. the expectation of a long-term benefit (> 2y) 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

6. 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 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 review, when appropriate, and patient informed consent are also expected.

Proton beam treatment of the following conditions may be considered medically reasonable and necessary only if the above criteria are met as specified (see Group #2 of the ICD-10 Codes that Support Medical Necessity).

Group #2 Conditions

- Malignant lesions of the head and neck when the intent of treatment is to be curative.
- Malignant lesions of the Para nasal sinus, and other accessory sinuses
- Malignant lesions of the prostate
- Malignant advanced stage, non-metastatic tumors of the bladder
- Advanced pelvic tumors including malignant lesions of the cervix
- Left breast tumors
- Pancreatic and adrenal tumors
- Skin cancer with perineural/cranial nerve invasion
- Unresectable retroperitoneal sarcoma and extremity sarcoma
- Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
- Malignant lesions of the liver, biliary tract, anal canal and rectum

Note: All other indications are not considered reasonable and necessary and will be denied.

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.

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

Documentation Requirements

Documentation must support that the services were performed, including the condition requiring proton beam therapy and why this technology was medically necessary as opposed to conventional radiation therapy. The medical record must support that all requirements listed under Indications and Limitations of Coverage and/or Medical Necessity have been met. The medical record should contain all of the necessary information to process a claim for these services including supporting information about the indications for a particular procedure.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. Services performed in excess of established parameters are subject to denial.

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