Proton Beam Radiotherapy  Part B

FIRST COAST SERVICE OPTIONS  
MAC - PART B   
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33937

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09102 – Florida  
09202 – Puerto Rico  
09302 – Virgin Islands

Contractor Type
MAC – Part B

LCD Title
Proton Beam Radiotherapy

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

N/A

Primary Geographic Jurisdiction
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.

CPT/HCPCS Codes
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77520   Proton treatment delivery; simple, without compensation

77522   simple, with compensation

77523   intermediate

77525   complex

Note: Other CPT/HCPCS codes may be appropriate (i.e., treatment planning, dosimetry, port films, etc.)

ICD-10 Codes that Support Medical Necessity

Group #1 Listing

C40.00 – C41.9  Malignant neoplasm of bone and articular cartilage
C47.0 – C47.9  Malignant neoplasm of peripheral nerves and autonomic nervous system
C49.0 – C49.9  Malignant neoplasm of other connective and soft tissue
C64.1 – C64.9  Malignant neoplasm of kidney, except renal pelvis
C69.00 – C72.9  Malignant neoplasms of eye, brain and other parts of central nervous system
C75.1-C75.3  Malignant neoplasm of other endocrine glands and related structures
C79.31  Secondary malignant neoplasm of brain
C79.49  Secondary malignant neoplasm of other parts of nervous system
D32.0 – D32.9  Benign neoplasm of meninges
D33.0 – D33.7  Benign neoplasm of brain and other parts of central nervous system
D35.2-D35.4  Benign neoplasm of other and unspecified endocrine glands
D42.0 – D42.9  Neoplasm of uncertain behavior of meninges
D43.0-D43.2  Neoplasm of uncertain behavior of brain-and central nervous system
D43.4  Neoplasm of uncertain behavior of spinal cord
D44.3-D44.5  Neoplasm of uncertain behavior of endocrine glands
Q28.2  Arteriovenous malformation of cerebral vessels
Q28.3  Other malformations of cerebral vessels

Group #2 Listing

C01  Malignant neoplasm of base of tongue
C03.0 – C03.1  Malignant neoplasm of gum
C04.0 – C08.1  Malignant neoplasm of lip, oral cavity and pharynx
C09.0 – C14.2  Malignant neoplasm of lip, oral cavity and pharynx
C19-C22.9  Malignant neoplasms of digestive organs
C25.0 – C25.9  Malignant neoplasm of pancreas
C30.0 – C38.2  Malignant neoplasm of respiratory and intrathoracic organs
C44.00 – C44.99  Other and unspecified malignant neoplasm of skin
C48.0  Malignant neoplasm of retroperitoneum
C50.011 – C50.019  Malignant neoplasm of nipple and areola, female
C50.111 – C50.119  Malignant neoplasm of central portion of breast, female
C50.211 – C50.219  Malignant neoplasm of upper-inner quadrant of breast, female
C50.311 – C50.319  Malignant neoplasm of lower-inner quadrant of breast, female
C50.411 – C50.419  Malignant neoplasm of upper-outer quadrant of breast, female
C50.511 – C50.519  Malignant neoplasm of lower-outer quadrant of breast, female
C50.611 – C50.619  Malignant neoplasm of axillary tail of breast, female
C52  Malignant neoplasm of vagina
C53.0 – C53.8  Malignant neoplasm of cervix uteri
C56.4-1 – C56.9  Malignant neoplasm of ovary
C61  Malignant neoplasm of prostate
C67.0 – C67.9  Malignant neoplasm of bladder
C73 Malignant neoplasm of thyroid gland
C75.0 Malignant neoplasm of parathyroid gland
C76.1-C76.3 Malignant neoplasm of other and ill-defined sites
C78.00 -C78.02 Secondary malignant neoplasm of lung
C78.7 Secondary malignant neoplasm of liver and intrahepatic [ ]

Diagnoses that Support Medical Necessity
N/A

ICD-10 Codes that DO NOT Support Medical Necessity
All ICD-10-CM codes not listed under ICD-10-CM codes that Support Medical Necessity

Diagnoses that DO NOT Support Medical Necessity
N/A

Associated Information

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.

Sources of Information and Basis for Decision

FCSO reference LCD number – L29470


American College of Radiation Oncology (ACRO), Practice Management Guide; Proton Therapy in the United States (2004).


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Start Date of Comment Period
N/A

End Date of Comment Period
N/A

Start Date of Notice Period
04/01/2014

Original
Publication: April 2014 Connection

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.
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Related Documents

N/A

LCD Attachments

N/A