Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Proton Beam Therapy

Policy Number: HS-140

Original Effective Date: 11/5/2009

Revised Date(s): 8/12/2011; 4/5/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

External beam radiation is used to reduce recurrence of a tumor after surgical excision or as a primary treatment for an inoperable mass. The ability of radiation therapy to eradicate a tumor largely depends on the dose delivered to the cancer; the necessity of delivering high radiation doses to improve local control rates has been demonstrated for a variety of tumor types. However, high-energy photon beams from x-rays or gamma rays used for conventional radiotherapy are characterized by a near-exponential decay of dose with depth. This property results in delivery of a significant dose to structures in the exit region of individual beams, and structures in the entrance region receive an equal or greater dose than the target volume. The collateral dose to normal tissues can cause serious, debilitating, or even fatal side effects. In addition, the radiation dose to the proximal region of the target volume is greater than in the distal region, resulting in non-homogeneous treatment, particularly for larger lesions.

In contrast, proton beam radiation therapy (PBT) deposits the energy of the proton beam at the end of its path; this region of maximum energy release is known as the Bragg peak. Since the depth of penetration of the proton beam can be controlled, the radiation can be targeted almost exclusively to the tumor volume, with minimal exposure of surrounding tissue. Thus, the improved dose distribution possible with PBT has the potential to permit the delivery of higher tumor doses while delivering less radiation to sensitive normal tissues. The relative biologic effect (RBE) of protons is similar to that of x-rays and cobalt gamma rays, and is considered appropriate for treatment of human tissues and tumors.

Device Specifications

The proton beam facility involves a synchrotron, a beam transport system, a beam delivery system, isocentric gantries, and a patient alignment and imaging system, all under the operation of a facility control system. The synchrotron is a particle accelerator, which increases the velocity of the protons to a level sufficient to position the Bragg peak into the cancerous tissue. It is composed of a large ring of magnets that operate in a vacuum. Protons are generated by an ion source and then accelerated up to approximately 2 million electron volts (MeV) in a radiofrequency quadripole. The beam then enters the synchrotron where, as the protons complete each trip around the synchrotron, the proton's energy is increased by the addition of radiofrequency energy. The magnetic field of the synchrotron is likewise increased to maintain the protons in a constant radial orbit. Energy levels when the beam leaves the synchrotron and enters the transport system are between 70 and 250 MeV. The beam transport system consists of additional magnets that focus and direct the beam from the synchrotron to the delivery system. The beam delivery system is mounted on very large steel gantries capable of rotating 360° around the patient, thus providing great flexibility in exact delivery of the proton beam. Because it is essential that the patient's position not change during the procedure, the patient is immobilized in a polyvinyl mold. Computed tomography (CT) scans, magnetic resonance imaging (MRI), and positron emission tomography (PET), along with conventional x-rays, can be utilized to visualize the tumor, and a computer generated, three-dimensional (3D) model of the cancerous tissue is constructed. This model, the digitally reconstructed radiograph (DRR), is used to decide the plan of treatment.

POSITION STATEMENT

Proton beam therapy **is considered medically necessary** for the following conditions:

- **190.0, 190.6** Melanoma of the uveal tract (iris, choroid, or ciliary body) not amenable to surgical excision or other forms of conventional treatment; involving tumors of up to 24 mm in diameter and 14 mm in height with no evidence of metastasis or extrascleral extension; **OR,**
- **747.81** Intracranial arteriovenous malformations not amenable to surgical excision; **OR,**
- **213.9, 239.2** Chordromas **OR**
- **170.0, 170.2** Chondrosarcomas at the base of the skull or along the axial skeleton; **OR,**
- **194.3, 227.3, 237.0** Pituitary neoplasms; **OR,**

Original Effective Date: 11/5/2009 - Revised: 8/12/2011, 4/5/2012

- **191.0 -192.8** Central nervous system tumors located near vital structures not suitable for intensity-modulated radiation therapy

Proton beam therapy for certain other conditions not listed above **is considered medically necessary** IF the following criteria are met:

- When dose constraints to normal tissues limit the total dose of radiation safely deliverable to the tumor with other indicated methods; **OR,**
- 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; **OR,**
- In circumstances when the higher levels of precision associated with proton beam therapy as compared to other radiation methods are necessary

AND

- 140.0 - 195.8 For the treatment of primary lesions, the intent of treatment must be curative; **OR,**
- 196.0 - 198.89 For the treatment of metastatic lesions there must be:
  - The expectation of a long-term benefit (> two years) that could not have been attained with conventional therapy; **AND,**
  - 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 therapy over other forms of radiation therapy

AND

- The member's record demonstrates why proton beam therapy is considered the treatment of choice for the individual. 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 the reduced normal tissue toxicity and/or improved tumor control must be maintained.

Proton beam therapy **is considered medically necessary** for the following conditions if the above criteria are met:

- **160.9 & 195.0** Malignant lesions of the Para nasal sinus and other accessory sinuses; **OR,**
- **185** Malignant lesions of the prostate; **OR,**
- **188.0 - 188.8** Malignant advanced stage, non-metastatic tumors of the bladder; **OR,**
- **195.8 -** Advanced pelvic tumors **including**
- **180.0 - 180.8** Malignant lesions of the cervix; **OR,**
- **174.0 - 175.9, 233.0, 198.81, 198.2** Left breast tumors; **OR,**
- **157.0 - 157.8** Pancreatic and adrenal tumors; **OR,**
- **173.0 - 173.8** Skin cancer with perineural/cranial nerve invasion; **OR,**
- **158.9** Unresectable retroperitoneal sarcoma **and**
- **195.4 - 195.5, 195.8** Extremity sarcoma; **OR,**
- **162.0 - 162.8** Cancers of the lung and upper abdominal/peri-diaphragmatic cancers; **OR,**
- **155.0 - 156.9** Malignant lesions of the liver, biliary tract;
- **154.2** Anal canal, **and**
- **154.1** Rectum

Proton beam therapy **is considered experimental and investigational** for the following conditions:

- **362.50 - 362.52** Age-related macular degeneration; **OR,**
- **155.0 - 155.2** Hepatocellular carcinoma; **OR,**
- **228.09** Choroidal hemangioma; **OR,**
- **150.0 - 150.9** Esophageal cancer; **OR,**
- **160.1, 160.8, 238.8, 212.0** Tumors of the vestibular system; **OR,**
- All other indications not listed above in the medically necessary sections

CODING

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

ICD-9-CM Procedure Codes

92.24 Teleradiotherapy using photons

HCPCS Codes

S8030 Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

Covered ICD-9-CM Diagnosis Codes when the above criteria has been met:

140.0 - 195.8 For the treatment of primary lesions, the intent of treatment must be curative
154.1 Rectum
154.2 Anal canal
155.0 - 156.9 Malignant lesions of the liver, biliary tract
157.0 - 157.8 Pancreatic and adrenal tumors
158.9 Retroperitoneal Sarcoma
160.9 & 195.0 Malignant lesions of the Para nasal sinus and other accessory sinuses
162.0 - 162.8 Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
170.0 Malignant neoplasm of bones of skull and face, except mandible
170.2 Malignant neoplasm of vertebral column, excluding sacrum and coccyx
173.0 - 173.8 Skin cancer with perineural/cranial nerve invasion
174.0 - 175.9 Left Breast tumors
233.0 Carcinoma of Left Breast
180.0 - 180.8 Malignant lesions of the cervix
185 Malignant neoplasm of prostate
188.0 - 188.8 Malignant advanced stage, non-metastatic tumors of the bladder
190.0 Malignant neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid (e.g., uveal tract) [confined to globe - not distant metastases]
190.6 Malignant neoplasm of choroid
191.0 - 192.8 Malignant neoplasm of brain and other parts of the central nervous system
194.3 Malignant neoplasm of pituitary gland and craniopharyngeal duct
195.4 & 195.5 Sarcoma of extremities

195.8	Sarcomas; i.e., advanced pelvic tumors
196.0 - 198.89	Secondary or metastatic lesions
213.9	Chordromas
225.0	Benign neoplasm of brain
225.1	Benign neoplasm of cranial nerves
225.2	Benign neoplasm of cerebral meninges
225.3	Benign neoplasm of spinal cord
227.3	Benign neoplasm of pituitary gland and craniopharyngeal duct (pouch)
233.4	Carcinoma in situ of prostate
237.0	Neoplasm of uncertain behavior of pituitary gland and craniopharyngeal duct
237.5	Neoplasm of uncertain behavior of brain and spinal cord
239.2	Neoplasm of Bone, Soft Tissue and Skin
747.81	Arteriovenous Malformation of brain (AVM)

***Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©**

REFERENCES

Peer Reviewed

1. Hayes Directory. (2004, July 16). Proton beam therapy for ocular tumors, hemangiomas, and macular degeneration [archived August 16, 2009]. Retrieved from http://www.hayesinc.com
2. Hayes Directory. (2006, October 28). Proton beam therapy for prostate cancer [archived November 28, 2011]. Retrieved from http://www.hayesinc.com
3. Hayes Directory. (2006, October 24). Proton beam therapy for thoracic and abdominal organs [archived November 24. 2011]. Retrieved from http://www.hayesinc.com
4. Wilt, T.J., Shamliyan, T., Taylor, B., & et al. (2008). Comparative effectiveness of therapies for clinically localized prostate cancer. *Agency for Healthcare Research and Quality,* Review No. 13.

Government Agencies, Professional and Medical Organizations

1. American Academy of Orthopedic Surgeons (AAOS). Chordoma. October 2007. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00084
2. American Urological Association (AUA). Prostate cancer. Guidelines for the management of clinically localized prostate cancer: 2007 Update.
3. Centers for Medicare and Medicaid Services. Local Coverage Determination for Proton Beam Radiotherapy (L29263). First Coast Services Options. February 2, 2009.
4. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp?button=I+Agree#site

HISTORY AND REVISIONS

Date	Action
4/5/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
8/12/2011	• Approved by MPC. No changes.