

Draft LCD for Proton Beam Therapy (DL31617)

Draft

Please note: This is a Draft policy.

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Contractor Information

Draft Draft Draft

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402

Contractor Type

Carrier - MAC - FI

LCD Information

Draft Draft Draft

LCD ID Number

DL31617

LCD Title

Proton Beam Therapy

Contractor's Determination Number

RAD-040

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CMS National Coverage Policy

Primary Geographic Jurisdiction

Oversight Region

Projected Determination Effective Date

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Protons are positively charged atomic particles that have similar biological effects as conventional x-ray beams. However, unlike x-rays, proton particles deposit their radiation energy as they slow down, culminating in an intensity dose peak, also called the Bragg Peak. Proton beam therapy (PBT) delivers a focused dose of radiation energy to the targeted area while surrounding normal tissue receives minimal radiation. PBT releases its highest percentage of energy at the end of its path (i.e., Bragg peak), depositing 100% of the dosage at the targeted tissue. 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. In contrast, conventional external beam radiation therapy (EBRT) delivers radiation to all involved tissue, diseased and normal, and targeted tissue receives 60–70% of the intended dose.

Proton therapy is of particular value in those tumors located close to serially organized tissues where a small local overdose can cause fatal complication such as most 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, 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. Due to the reduction in integral dose with protons, the most important benefits can be expected for pediatric patients

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. 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. Benign or malignant conditions of the base of the skull or axial skeleton including but not limited to chordomas and chondrosarcomas
5. Malignant lesions of the head and neck
6. Lung cancers, especially NSCLC.
7. Unresectable retroperitoneal sarcoma and extremity sarcoma
8. Solid tumors in children up to age 18

In addition, Proton Beam Therapy is indicated when:

- The Dose Volume Histogram (DVH) illustrates at least three (3) 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 (> 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

- 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.

Proton beam treatment of the following conditions may be considered medically reasonable and necessary only if the above criteria are met under the auspices of a clinical trial.

Group 2

- a. Malignant lesions of the Para nasal sinus, and other accessory sinuses
- b. Malignant advanced stage, non-metastatic tumors of the bladder
- c. Advanced pelvic tumors including malignant lesions of the cervix

- d. Left breast tumors
- e. Pancreatic and adrenal tumors
- f. Skin cancer with perineural/cranial nerve invasion
- g. Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
- h. Malignant lesions of the liver, biliary tract, anal canal and rectum
- i. 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 advanced prostate cancer (i.e., Stages C or D1 [without distant metastases], also classified as T3 or T4) (the tumor has spread through the capsule on one or both sides but has not invaded seminal vesicles or other structures) and any N disease (either no spread to lymph nodes or there has been spread to the regional lymph nodes Note: Spread beyond local 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);
- b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and
- c. Documentation of the specific reasons why Proton Beam was the treatment of choice for the specific patient. Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication.

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.

Coding Information



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:

MALIGNANT NEOPLASM OF EYEBALL EXCEPT
CONJUNCTIVA CORNEA RETINA AND CHOROID -
MALIGNANT NEOPLASM OF EYE PART
UNSPECIFIED

191.0 - 191.9

MALIGNANT NEOPLASM OF CEREBRUM EXCEPT
LOBES AND VENTRICLES - MALIGNANT
NEOPLASM OF BRAIN UNSPECIFIED SITE

192.0 - 192.9

MALIGNANT NEOPLASM OF CRANIAL NERVES -
MALIGNANT NEOPLASM OF NERVOUS SYSTEM
PART UNSPECIFIED

194.0 - 194.9

MALIGNANT NEOPLASM OF ADRENAL GLAND -
MALIGNANT NEOPLASM OF ENDOCRINE GLAND
SITE UNSPECIFIED

195.0 - 195.8

MALIGNANT NEOPLASM OF HEAD FACE AND
NECK - MALIGNANT NEOPLASM OF OTHER
SPECIFIED SITES

198.3

SECONDARY MALIGNANT NEOPLASM OF BRAIN
AND SPINAL CORD

200.00 - 202.98

RETICULOSARCOMA UNSPECIFIED SITE - OTHER
AND UNSPECIFIED MALIGNANT NEOPLASMS OF
LYMPHOID AND HISTIOCYTIC TISSUE
INVOLVING LYMPH NODES OF MULTIPLE SITES

213.0 - 213.9

BENIGN NEOPLASM OF BONES OF SKULL AND
FACE - BENIGN NEOPLASM OF BONE AND
ARTICULAR CARTILAGE SITE UNSPECIFIED

225.0 - 225.9

BENIGN NEOPLASM OF BRAIN - BENIGN
NEOPLASM OF NERVOUS SYSTEM PART
UNSPECIFIED

227.3

BENIGN NEOPLASM OF PITUITARY GLAND AND
CRANIOPHARYNGEAL DUCT

227.4

BENIGN NEOPLASM OF PINEAL GLAND

237.0

NEOPLASM OF UNCERTAIN BEHAVIOR OF
PITUITARY GLAND AND CRANIOPHARYNGEAL
DUCT

237.1

NEOPLASM OF UNCERTAIN BEHAVIOR OF
PINEAL GLAND

237.2

NEOPLASM OF UNCERTAIN BEHAVIOR OF
ADRENAL GLAND

237.5

NEOPLASM OF UNCERTAIN BEHAVIOR OF BRAIN
AND SPINAL CORD

237.6

NEOPLASM OF UNCERTAIN BEHAVIOR OF
MENINGES

336.9

UNSPECIFIED DISEASE OF SPINAL CORD

747.81

CONGENITAL ANOMALIES OF
CEREBROVASCULAR SYSTEM

V21.9

UNSPECIFIED CONSTITUTIONAL STATE IN
DEVELOPMENT

Group 2

140.0 - 140.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF LIP UNSPECIFIED VERMILION BORDER
141.0 - 141.9	MALIGNANT NEOPLASM OF BASE OF TONGUE - MALIGNANT NEOPLASM OF TONGUE UNSPECIFIED
142.0 - 142.9	MALIGNANT NEOPLASM OF PAROTID GLAND - MALIGNANT NEOPLASM OF SALIVARY GLAND UNSPECIFIED
143.0 - 143.9	MALIGNANT NEOPLASM OF UPPER GUM - MALIGNANT NEOPLASM OF GUM UNSPECIFIED
144.0 - 144.9	MALIGNANT NEOPLASM OF ANTERIOR PORTION OF FLOOR OF MOUTH - MALIGNANT NEOPLASM OF FLOOR OF MOUTH PART UNSPECIFIED
145.0 - 145.9	MALIGNANT NEOPLASM OF CHEEK MUCOSA - MALIGNANT NEOPLASM OF MOUTH UNSPECIFIED
146.0 - 146.9	MALIGNANT NEOPLASM OF TONSIL - MALIGNANT NEOPLASM OF OROPHARYNX UNSPECIFIED SITE
147.0 - 147.9	MALIGNANT NEOPLASM OF SUPERIOR WALL OF NASOPHARYNX - MALIGNANT NEOPLASM OF NASOPHARYNX UNSPECIFIED SITE
148.0 - 148.9	MALIGNANT NEOPLASM OF POSTCRICOID REGION OF HYPOPHARYNX - MALIGNANT NEOPLASM OF HYPOPHARYNX UNSPECIFIED SITE
149.0 - 149.9	MALIGNANT NEOPLASM OF PHARYNX UNSPECIFIED - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 150.9	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ESOPHAGUS UNSPECIFIED SITE
151.0 - 151.9	MALIGNANT NEOPLASM OF CARDIA - MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
152.1 - 152.9	MALIGNANT NEOPLASM OF JEJUNUM - MALIGNANT NEOPLASM OF SMALL INTESTINE UNSPECIFIED SITE
153.0 - 153.9	

	MALIGNANT NEOPLASM OF HEPATIC FLEXURE - MALIGNANT NEOPLASM OF COLON UNSPECIFIED SITE
154.0 - 154.8	MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION - MALIGNANT NEOPLASM OF OTHER SITES OF RECTUM RECTOSIGMOID JUNCTION AND ANUS
155.0 - 155.2	MALIGNANT NEOPLASM OF LIVER PRIMARY - MALIGNANT NEOPLASM OF LIVER NOT SPECIFIED AS PRIMARY OR SECONDARY
156.0 - 156.9	MALIGNANT NEOPLASM OF GALLBLADDER - MALIGNANT NEOPLASM OF BILIARY TRACT PART UNSPECIFIED SITE
157.0 - 157.9	MALIGNANT NEOPLASM OF HEAD OF PANCREAS - MALIGNANT NEOPLASM OF PANCREAS PART UNSPECIFIED
159.0 - 159.9	MALIGNANT NEOPLASM OF INTESTINAL TRACT PART UNSPECIFIED - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM
160.0 - 160.9	MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ACCESSORY SINUS UNSPECIFIED
161.0 - 161.9	MALIGNANT NEOPLASM OF GLOTTIS - MALIGNANT NEOPLASM OF LARYNX UNSPECIFIED
162.0 - 162.9	MALIGNANT NEOPLASM OF TRACHEA - MALIGNANT NEOPLASM OF BRONCHUS AND LUNG UNSPECIFIED
163.0 - 163.9	MALIGNANT NEOPLASM OF PARIETAL PLEURA - MALIGNANT NEOPLASM OF PLEURA UNSPECIFIED
164.0 - 164.9	MALIGNANT NEOPLASM OF THYMUS - MALIGNANT NEOPLASM OF MEDIASTINUM PART UNSPECIFIED
173.0 - 173.9	OTHER MALIGNANT NEOPLASM OF SKIN OF LIP - OTHER MALIGNANT NEOPLASM OF SKIN SITE UNSPECIFIED
174.0 - 174.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0 - 175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
179 - 184.9	MALIGNANT NEOPLASM OF UTERUS-PART UNS - MALIGNANT NEOPLASM OF FEMALE GENITAL ORGAN SITE UNSPECIFIED

185	MALIGNANT NEOPLASM OF PROSTATE
186.0 - 186.9	MALIGNANT NEOPLASM OF UNDESCENDED TESTIS - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED TESTIS
187.1 - 187.9	MALIGNANT NEOPLASM OF PREPUCE - MALIGNANT NEOPLASM OF MALE GENITAL ORGAN SITE UNSPECIFIED
188.0 - 188.9	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
189.1 - 189.9	MALIGNANT NEOPLASM OF RENAL PELVIS - MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED
193	MALIGNANT NEOPLASM OF THYROID GLAND
197.7	MALIGNANT NEOPLASM OF LIVER SECONDARY

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Any diagnosis not listed above.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information



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-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. Each claim must be submitted with ICD-9-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9-CM codes will be returned.
5. Documentation in the patient medical record must support:
The reasonable and necessary requirements are outlined under the coverage and limitations sections of this LCD and must be available to the contractor for review upon request.
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

Appendices

Utilization Guidelines

Sources of Information and Basis for Decision

Other Contractor Policies: High mark, First Coast

Agency for Healthcare Research and Quality; AHRQ; **Particle Beam Radiation Therapies for Cancer**
Publication No. 09-EHC019-EF; Revised November 2009, www.ahrq.gov

Agency for Healthcare Research and Quality; **Comparative effectiveness of therapies for clinically localized prostate cancer**; Feb 2008, www.ahrq.gov

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Chen JCT, Girvigian, MR.; **Stereotactic radiosurgery; instrumentation and theoretical aspects-part 1**;
Perm Jour; 2005 Fall 9(4) 23-26.

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Kirsch DG, Tarbell NJ.; **New technologies in radiation therapy for pediatric brain tumors: the rationale for proton radiation therapy**. Pediatric Blood Cancer, (2004) 42(5): 461-4.

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Noel G, et al.; **Combination of Photon and Proton Rad Therapy for Chordomas and Chondrosarcomas of the Skull Base**; *Int J Radiation Onc, Bio, Physics* 2001; 51(2):392-398.

Merchant TE, Hua CH, Shukla H, et al. **Proton versus photon radiotherapy for common pediatric brain tumors: comparison of models of dose characteristics and their relationship to cognitive function.** *Pediatr Blood Cancer.* 2008; 51(1):110-117.

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Nguyen, Paul I. et al; **Proton-Beam vs Intensity-Modulated Radiation Therapy Which Is Best for Treating Prostate Cancer?**; *ONCOLOGY.* Vol. 22 No. 7; 06/01/2008

Olsen D.R. *et al.*; **Proton therapy - a systematic review of clinical effectiveness;** *Radiother Oncol* 2007; 83:123-132.

Paganetti, Harald and Bortfeld, Thomas; **Proton Beam Radiotherapy - The State of the Art;** Massachusetts General Hospital, Boston, MA, USA

Petit, Joshua H. et al; **Proton Stereotactic Radiotherapy for Persistent Adrenocorticotropin-Producing Adenomas;** *J Clin Endocrinol Metab,* February 2008, 93(2):393–399 jcem.endojournals.org

Slater, Jerry; **Clinical Applications of Proton Irradiation Treatment at Loma Linda University: Review of a Fifteen Year Experience;** *Technology in Cancer Research and Treatment* ISSN 1533-0346. Vol. 5 No. 2 April 2006

Smith RP; **Modern radiation treatment planning and delivery from Röntgen to real time;** *Hematol Oncol Clin North Am.;* 2006 Feb;20; (1):45-62.

U.S. Food and Drug Administration (FDA) 510(k) summary; Hitachi's PROBEAT k053280; Mar 9, 2006; www.fda.gov

U.S. Food and Drug Administration (FDA) 510(k) summary; Optivus proton beam therapy system k992414; July 21,2000; www.fda.gov.

Advisory Committee Meeting Notes

Meeting Date:

Wisconsin 01/28/2011

Illinois 01/26/2011

Michigan 02/02/2011

Minnesota 01/20/2011

J5 - Iowa, Kansas,

Missouri, Nebraska 02/10/2011

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the MAC contractor this policy was developed in cooperation with advisory groups which include representatives from various specialties, and adapted for the purpose of converting to MAC jurisdiction.

Start Date of Comment Period

02/10/2011

End Date of Comment Period

03/27/2011

Start Date of Notice Period

Revision History Number

Revision History Explanation

Reason for Change

Last Reviewed On Date

12/01/2010

Related Documents

This LCD has no Related Documents.

LCD Attachments

[Billing and Coding Guidelines Version 1](#) (PDF - 10,141 bytes)

Draft Contact

Kenneth Bussan - policycomments@wpsic.com
WPS Medicare
1717 W. Broadway
Madison, WI 53701-1787

All Versions



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