Subject: Proton Beam Radiation Therapy		Original Effective Date: 3/25/15
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [5-8 44]

Proton Beam radiotherapy (PBT) 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. Proton particles deliver a smaller amount of radiation energy as they enter the body (lower entrance dose) culminating in an intensity dose peak (e.g. Bragg Peak) therefore depositing 100% of the dosage at the targeted tissue. There is no further energy deposition beyond the Bragg peak (no exit dose). 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. 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 beam therapy is typically performed on an outpatient basis. For most tumor sites, a standard course of treatment is five to seven weeks, with treatments delivered five days per week. The length of each treatment will vary depending upon the tumor type and stage. The delivery of the proton beam to the patient lasts only a few minutes, although the total time spent in the treatment room will be longer (about 15 to 20 minutes) for positioning and adjustments to the equipment settings.

RECOMMENDATION [3-30]

Medically Necessary Indications:

- ❑ Proton beam radiation therapy may be considered medically necessary and may be authorized for the following conditions when sparing the surrounding normal tissue cannot be adequately achieved with surgical excision, conventional photon beam radiation or IMRT:
  - o As primary therapy for the following ocular tumors: [3-9 10-16]
    - ➢ Melanoma of the uveal tract: includes iris, choroid, or ciliary body tumors; and [ALL]
      a. no evidence of metastasis or extrascleral extension; and
      b. tumor size diameter ≤ 24 mm; and
      c. tumor size height ≤ 14 mm
  - o As postoperative therapy for the following head and neck skull base tumors: [3-9 17-21]
    - ➢ Advanced (e.g., T4) and/or unresectable head and neck cancers
    - ➢ Chordoma at the base of the skull and: [ALL]
      a. no distal metastasis; and
      b. residual localized tumor after resection
    - ➢ Chondrosarcoma at the base of the skull and: [ALL]
      a. no distal metastases; and
      b. grade I or II chrondrosarcoma; and
      c. residual localized tumor after resection
  - o For the following OTHER clinical conditions: [3-9 22-30 37-39] [ANY]
    - ➢ Arteriovenous Malformation (AVM):
      a. intracranial AVM not amenable to surgical excision or other conventional forms of treatment; or
      b. adjacent to critical structures such as the optic nerve, brain stem or spinal cord
    - ➢ Cancers of the paranasal sinuses and other accessory sinuses
    - ➢ Central nervous system (CNS) lesions: primary or metastatic CNS malignancies, such as gliomas when both of the following are met:
      a. when adjacent to critical structures such as the optic nerve, brain stem, or spinal cord, and
      b. when other standard radiation techniques such as IMRT or standard stereotactic modalities would not sufficiently reduce the risk of radiation damage to the critical structure
    - ➢ Nonmetastatic retroperitoneal sarcomas
    - ➢ Patients with genetic syndromes making total volume of radiation minimization crucial including Neurofibromatosis (NF-1) and retinoblastoma
    - ➢ Pediatric: for children who are under the age of 21 years who have:

c. CNS tumors, or
d. primary or benign solid tumors treated with curative intent

- Repeat irradiation of previously treated fields where the dose tolerance of surrounding normal structures would be exceeded with 3D conformal radiation or IMRT [3]

Not Medically Necessary Conditions [31-36 40-44]

- Proton beam therapy (PBT) is considered not medically necessary and may not be authorized for the treatment of the following conditions because clinical outcomes of this treatment have not been shown to be superior to other approaches:
  - Abdominal tumors
  - Age-related macular degeneration (AMD)
  - Breast Cancer
  - Choroidal Hemangiomas
  - Esophageal cancer
  - Gastric cancer
  - Head and neck tumors (not listed above)
  - Hepatobiliary cancer
  - Lung cancer
  - Lymphoma (Hodgkin and non-Hodgkin)
  - Pelvic tumors including genitourinary, gynecologic, and gastrointestinal
  - Pancreatic cancer
  - Prostate Cancer: *Please reference Proton Beam Therapy for prostate Cancer MCP-153*
  - Thoracic tumors
  - Vestibular tumors

SUMMARY OF MEDICAL EVIDENCE [10-43]

Skull base tumors [17-21]

The published evidence consisting of systematic reviews, retrospective studies, and uncontrolled single arm studies is sufficient and supports that PBT is effective in the treatment of skull base tumors. A systematic review concluded that there is evidence for a benefit of proton beam therapy over photon approaches in treating chordomas. Another systematic review of seven uncontrolled single-arm studies concluded that the use of protons has shown better results in comparison to the use of conventional photon irradiation, resulting in the best long-term (10 years) outcome for skull-based chordomas with relatively few significant complications. A second systematic review by the same author reported that studies of proton beam therapy for skull-based chondrosarcoma resulted in local control ranging from 75% to 99% at 5 years. A retrospective review of 29 patients with skull base chordomas (n=18) and low-grade chondrosarcomas (CS) (n=11) assessed the clinical results of spot scanning proton beam radiation therapy (PT). Median follow-up time was 29 months (range, 6-68 months). Three year local control rates were 87.5% and 100% for chordoma and CS, respectively. According to this small study spot-scanning PT offers high tumor control rates of skull base chordoma and chondrosarcomas. A single center case series of 40 patients with chordomas of the skull base and cervical spine reviewed the

outcomes of surgery and proton radiotherapy. The median follow-up was 56.5 months. The 5-year PFS and OS rates were 70% and 83.4%, respectively. Another single center case series evaluated the clinical results of fractionated spot-scanning proton radiation therapy (PT) in 26 pediatric patients treated at Paul Scherrer Institute for chordoma (CH) or chondrosarcoma (CS) of the skull base or axial skeleton. Mean follow-up was 46 months. Actuarial 5-year local control (LC) rates were 81% for CH and 80% for CS. Actuarial 5-year overall survival (OS) was 89% for CH and 75% for CS.

Uveal Melanomas [10-16]

The published evidence consisting of a RCT, comparative studies, retrospective cohort studies, and case series is sufficient and supports that PBT is effective in the treatment of uveal melanomas. A systematic review was conducted by the American Society for Therapeutic Radiology and Oncology (ASTRO) Evaluation Subcommittee of Emerging Technologies. The review noted that the use of PBRT has been reported in thousands of cases of ocular melanoma, with combined results of leading centers in the United States and Europe showing 95% control rate and 90% eye retention rate. The technique was noted as especially useful in large and posteriorly located melanomas that are unapproachable by other techniques such as brachytherapy. This review concluded that there is evidence for a benefit of proton beam therapy over photon approaches in treating large ocular melanomas.

A report on proton beam therapy from the Institute for Clinical and Economic Review (ICER) rated the net health benefit of PBT relative to alternative treatments to be superior in ocular tumors. The RCT compared PBT alone to a combination of PBT and transpupillary thermotherapy (TTT) in 151 patients (mean age: 58 years; 52% male) treated for uveal melanoma and followed for a median of 3 years in France. Combination therapy was associated with a statistically-significantly ($p=0.02$) reduced likelihood of secondary enucleation; no other outcomes differed significantly between groups. In a separate comparison of these findings to a separate series of patients undergoing PBT with endoresection of the scar rates of secondary enucleation did not differ between groups, but rates of neovascular glaucoma were significantly lower in the PBT+endoresection group vs. the groups from the RCT (7% vs. 58% and 49% for PBT alone and PBT+TTT respectively, $p<0.0001$). Of note, however, median follow-up was less than two years in the PBT+endoresection series vs. 9 years in the RCT. Three of the cohort studies were all fair-quality and involved comparisons to surgical enucleation in patients with uveal melanoma at single centers. PBT was associated with statistically-significant improvements in overall survival rates relative to enucleation at 2-5 years in two of these studies. Rates of metastasis-related and all cancer-related death were statistically-significantly lower among PBT patients through two years of follow-up in the Seddon study, but were nonsignificant at later time points. The 5-year metastasis-free survival rate ($n=67$) was 50% higher among PBT patients in a Cox regression model controlling for baseline characteristics (59.0% vs. 39.4% for enucleation, $p=0.02$). In the third study, Kaplan-Meier curves for all-cause mortality, melanoma-related mortality and metastasis-free survival did not statistically differ for 132 patients treated with PBT and enucleation. Metastasis-free survival also did not differ in Cox regression adjusting for age, sex, and tumor thickness.

Another study assessed the impact of PBT + chemotherapy vs. PBT alone in 88 patients with uveal melanoma (aged primarily between 20-55 years; 63% male) who were followed for 5-8 years. Five-year overall survival

rates did not statistically differ between groups on either an unadjusted or Cox regression-adjusted basis. Lastly, a comparison of noncontemporaneous case series evaluated treatment with PBT + laser photocoagulation or PBT alone in 56 patients with choroidal melanoma. At one year, there were no differences in visual acuity between groups.

Other Conditions [22-30-31-43]

According to the published peer reviewed literature, proton beam therapy (PBT) may be appropriate in circumstances where intensity modulated radiation therapy (IMRT) or stereotactic would potentially damage critical structures, particularly in patients with a history of prior irradiation. PBT is also appropriate for pediatric patients because even low doses of scattered radiation in this population can affect growth and development and increase the risk of secondary malignancies later in life. Results of proton therapy have been published for AVM and CNS lesions that have concluded that generally the use of PBT for these conditions is only medically appropriate in specific circumstances where adjacent critical structures cannot be adequately spared with surgery, IMRT or SRS. [24-30]

There is limited clinical evidence that directly compares proton beam therapy (PBT) with other types of radiation therapy for other conditions. The current published evidence is of low quality and consists of small comparative studies that are not randomized or controlled, retrospective/prospective studies and individual case series. There is very limited published data in the peer reviewed literature regarding the use of PBT for breast cancer, hepatobiliary cancer, other GI cancers, lung cancer including non-small cell, lymphomas, other head and neck cancers and any other condition not listed above. Therefore, the current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat other conditions not listed in the medically necessary recommendation section above. [31-43]

Professional Society Guidelines: [3-9]

The American Society for Radiation Oncology (ASTRO) has issued an update (2017) [6] to its recommendations for the use of proton beam therapy to treat cancer. The updated model policy outlines appropriate clinical indications, or diagnoses, for proton beam therapy that include the following:

- Malignant and benign primary central nervous system (CNS) tumors
- Advanced (e.g., T4) and/or unresectable head and neck cancers
- Cancers of the paranasal sinuses and other accessory sinuses
- Nonmetastatic retroperitoneal sarcomas
- Reirradiation cases where cumulative critical structure dose would exceed tolerance dose
- Hepatocellular cancer
- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to chordoma and chondrosarcomas
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated

- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when one of the criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial, such as but not limited to NF-1 patients and retinoblastoma patients

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

HCPCS	Description
S38030	Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

RESOURCE REFERENCES

Government Agency

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2. U.S. Food and Drug Administration. 510(k) Premarket Notification Data base. Accessed at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Professional Society Guidelines

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    - Head & Neck Cancers
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    - Hodgkin lymphoma
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- Soft Tissue Sarcoma
- Thymomas and Thymic Carcinomas
- Uveal Melanoma

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REVIEW/Revision History:

3/25/15: Policy created

12/16/15, 9/15/16, 6/22/17: No changes.

7/10/18: This policy was reviewed and the clinical criteria has changed based on new evidence based literature and updated ASTRO guidelines. The following clinical conditions were added as medically necessary: AVM, cancers of the paranasal sinus, CNS tumors, nonmetastatic retroperitoneal sarcomas, genetic syndromes such as retinoblastoma and neurofibromatosis (NF-1), pediatric CNS and solid tumors and repeat irradiation of previously treated fields. The following sections were also updated: summary of medical evidence, professional society guidelines and references.