JOHNS HOPKINS HEALTHCARE

Policy Number

Medical Policy: Proton Beam Radiotherapy
Department: Health Services
Lines of Business: EHP, USFHP, PPMCO, ADVANTAGE MD

ACTION:
☒ New Policy
☐ Revising Policy Number
☐ Superseding Policy Number
☐ Archiving Policy Number
☐ Retiring Policy Number

Effective Date: 03/02/2018

Review Dates:

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

POLICY:

For US Family Health Plan see TRICARE Policy Manual 6010.57-M, February 1, 2008, Radiology: Chapter 5, Section 3.1 Radiation Oncology and Chapter 1, Section 3.1 Rare Diseases.

For Priority Partners per Maryland Department of Health the following codes are not covered: C9728 and S8030.

For Advantage MD:
Medicare does not have a National Coverage Determination (NCD) for proton beam radiotherapy.
Local Coverage Determinations (LCDs) do not exist this time. (Accessed December 18, 2017)

I. General Considerations:
Please Note the Following Indications and Limitations for Coverage and/or Medical Necessity

Proton Beam Radiotherapy (PBRT) is considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the member. ONE of the following criteria must be met:

A. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s), OR;

B. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose “hotspot” within the treated volume to lessen the risk of excessive early or late normal tissue toxicity, OR;
C. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity, OR;

D. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

Note ~ In addition to satisfying at least ONE of the four selection criteria noted above, the following documentation requirements must be included in the member’s medical record.

II. Documentation Requirements from oncologist:
   A. Support one or more medical necessity requirement(s) as provided under the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy(listed above), AND;
   B. Include a treatment prescription that defines the goals of the treatment plan- including specific dose-volume parameters for the target and nearby critical structures- as well as pertinent details of beam delivery, such as method of beam modulation, field arrangement, and expected positional and range uncertainties, AND;
   C. Include a treatment plan, signed by a physician, which meets the prescribed dose-volume parameters for the clinical target volume (CTV) and surrounding organs at risk (OARS) in the presence of uncertainties, AND;
   D. Describe the target setup verification methodology, including patient positioning, immobilization and use of image guidance, AND;
   E. Include verification of planned dose distribution via independent dose calculation or physical measurement.

Note ~Treatment planning including MRI, CT and/or CT/PET imaging is an essential prerequisite to proton beam therapy. Treatment planning includes careful patient immobilization and determination of the radiation field (the specific anatomic regions that will be irradiated) as well as the dose and schedule for treatment.

III. When benefits are provided under the member’s contract, JHHC considers proton beam radiotherapy (PBRT) medically necessary in ANY of the following radiosensitive tumors when at least ONE of the four criteria are met in the General Considerations section and the Documentation Requirements are met from the oncologist:
   A. In children (21 years of age and younger) with primary or benign solid tumor(s) treated with curative intent, and occasional palliative intent, OR;
   B. Benign or malignant primary central nervous system tumors (e.g. medulloblastoma, astrocytoma, and glioblastoma), OR;
   C. As postoperative therapy for members who have undergone biopsy or partial resection and have a residual, localized tumor without evidence of metastasis which include the following:
1. a chordoma, OR;
2. low grade (I or II) chondrosarcoma of the basisphenoid region, OR;
3. cervical spine, OR;
4. sacral/lower spine

D. Uveal melanomas confined to the globe (i.e., not distant metastases) with ALL of the following criteria:
   1. Tumor size, diameter ≤ 24mm, AND;
   2. Tumor size, height ≤ 14mm, AND;
   3. No distant metastasis or extrascleral extension (the uvea is comprised of the iris, ciliary body, and the choroid)

IV. When benefits are provided under the member’s contract, JHHC considers proton beam radiotherapy (PBRT) medically necessary for patients with localized prostate cancer when at least ONE of the four criteria are met in the General Considerations section, the Documentation Requirements are included from the oncologist, and ALL the following criteria are met:
   A. Member ≥ 18 years of age, AND;
   B. By biopsy (diagnosis), AND;
   C. Life expectancy ≥ 5 years, AND;
   D. PSA level ≤ 20ng/ml*, AND;
   E. Gleason score ≤ 7**, AND;
   F. Stage ≤ T2c***

V. When benefits are provided under the member’s contract, JHHC considers reirradiation for unresectable recurrent tumors on a case-by-case basis.

VI. Unless specific benefits are provided under the member’s contract, JHHC considers proton beam radiotherapy for metastatic prostate cancer experimental and investigational as it does not meet Technology Evaluation Criteria (TEC) #2-5.

VII. Unless specific benefits are provided under the member’s contract, JHHC considers proton beam radiotherapy experimental and investigational for all other indications, as it does not meet Technology Evaluation Criteria (TEC) #2-5.

DEFINITIONS:

*Prostate-specific antigen, or PSA- is a protein produced by normal, as well as malignant, cells of the prostate gland. The PSA test measures the level of PSA in a man’s blood. A blood sample is sent to the laboratory for analysis. The results are usually reported as nanograms of PSA per milliliter (ng/mL) of blood. The blood level of PSA is often elevated in men with prostate cancer. Men who report prostate symptoms often undergo PSA testing (along with DRE (digital rectal exam)) to help doctors determine the nature of the problem. There is no specific normal or
abnormal level of PSA in the blood, and levels may vary over time in the same man. In the past, most doctors considered PSA levels of 4.0 ng/mL and lower as normal. Therefore, if a man had a PSA level above 4.0 ng/mL, doctors would often recommend a prostate biopsy to determine whether prostate cancer was present. However, more recent studies have shown that some men with PSA levels below 4.0 ng/mL have prostate cancer and that many men with higher levels do not have prostate cancer.25 Also, various factors can cause a man’s PSA level to fluctuate such as a man’s PSA level often rises if he has prostatitis or a urinary tract infection. Prostate biopsies and prostate surgery also increase PSA level. PSA level may also vary somewhat across testing laboratories. In general, however, the higher a man’s PSA level, the more likely it is that he has prostate cancer. Moreover, a continuous rise in a man’s PSA level over time may also be a sign of prostate cancer.25

**Gleason score (GS)** - Gleason Grade: A system of grading prostate cancer cells based on how they look under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer cells are similar to normal prostate cells and are less likely to spread; a high Gleason score means the cancer cells are very different from normal and are more likely to spread.27

**Staging** - is a way of describing where the cancer is located, if or where it has spread, and whether it is affecting other parts of the body.9

*** Stages of Prostate Cancer(9):***

**Stage T1**: Tumor is microscopic, confined to prostate, and is not detectable by digital rectal exam (DRE) or visible by transrectal ultrasound TRUS. Usually discovered by an elevated PSA or biopsy. T1a and T1b lesions are those detected incidentally in pathology specimens of resected prostate tissue. T1c lesions are those diagnosed in a prostate biopsy because of an elevated PSA or prostatic symptoms in the absence of an abnormality on a digital rectal examination.

**Stage T2**: Tumor is confined to the prostate, has not extended beyond the prostate, and can be detected by DRE. Unilateral T2 lesions are subdivided into T2a and T2b based upon the extent of involvement; if there is bilateral involvement, lesions are classified as T2c.

**Stage T3**: The tumor extends through the prostate capsule (T3a) and possibly to the seminal vesicles (T3b) but has not spread to any other organs.

**Stage T4**: The tumor has spread to lymph nodes or organs near the prostate, such as the bladder.
BACKGROUND:

One of the most common treatments for cancer is radiation. The other names for radiation treatment are radiation therapy, radiotherapy, irradiation, or x-ray therapy. Radiation therapy uses high-energy particles or waves, such as x-rays, gamma rays, electron beams, or protons, to destroy or damage cancer cells.³

Proton therapy is a type of radiation treatment that uses protons to treat cancer. It is also called proton beam therapy.¹⁰

A proton is a positively charged particle. At high energy, protons can destroy cancer cells. Physicians may use proton therapy alone or they may combine it with other treatments, such as standard radiation therapy, surgery, chemotherapy, and/or immunotherapy. Proton therapy is a type of external-beam radiation therapy. It painlessly delivers radiation through the skin from a machine outside the body.¹⁰

Proton beam radiation therapy uses proton beams instead of electrons or x-rays. Protons are parts of atoms that cause little damage to tissues they pass through but are very good at killing cells at the end of their path. This means that proton beam radiation may be able to deliver more radiation to the tumor while reducing side effects on normal tissues. Protons can only be put out by a special machine called a cyclotron or synchroton.²

A cyclotron or synchrotron speeds up the protons. The protons’ speed determines the energy level. High energy protons travel deeper in the body than low-energy ones. The protons go to the targeted place in the body. There, they deposit the specific radiation dose in the tumor. With proton therapy, radiation does not go beyond the tumor. In contrast, with photon-based external-beam radiation therapy, x-rays continue depositing radiation as they exit the body. This means that the radiation leaving the body may damage nearby healthy tissue.¹⁰

Treating with protons gives the radiation oncologist the ability to maintain target volume coverage required for efficacious therapy, while minimizing dose delivered to nearby normal tissues. A primary expected benefit of this decrease in dose to normal tissues is reduced risk of secondary malignancies as well as other radiation-induced acute and late effects.¹⁴

CODING INFORMATION:

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan
determines coverage and referral requirements. All inpatient admissions require pre-authorization.

**PRE-AUTHORIZATION REQUIRED**

*Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits*

<table>
<thead>
<tr>
<th>Employer Health Programs (EHP) <strong>See Specific Summary Plan Description (SPD)</strong></th>
<th>Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply policy criteria</th>
<th>US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria</th>
<th>Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria</th>
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<th>CPT ® CODES</th>
<th>DESCRIPTION</th>
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<tr>
<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
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<tr>
<td>77522</td>
<td>Proton treatment delivery; simple, with compensation</td>
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<tr>
<td>77523</td>
<td>Proton treatment delivery; intermediate</td>
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<td>77525</td>
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<th>HCPCS CODES</th>
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<tr>
<td>C9728</td>
<td>Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple</td>
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<td>S8030</td>
<td>Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy</td>
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**ICD10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY**

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<tr>
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<td>Malignant neoplasm of bones of skull and face</td>
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<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
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<td>C61</td>
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**REFERENCE STATEMENT:**

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

**REFERENCES:**


