Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Proton Beam Therapy (PBT). Also Known As: Proton beam radiation therapy, Proton radiotherapy

PRIOR AUTHORIZATION: Required.

POLICY:
SWHP may consider proton beam radiation therapy medically necessary for the following:
1. Melanoma of the uveal tract (includes the iris, ciliary body and choroid) when BOTH of the following conditions are met:
   • There is no evidence of extra-scleral extension, AND
   • When there is contraindication to other established treatment options which preserve the eye, (e.g., local surgical excision, transpupillary thermal therapy, laser photocoagulation therapy, brachytherapy, stereotactic radiosurgery)
2. As postoperative therapy for individuals who have undergone biopsy or partial resection of a chordoma or lowgrade (I or II) chondrosarcoma of the basisphenoid region (e.g. skull-base chordoma or chondrosarcoma) or cervical spine and have residual, localized tumor without evidence of metastasis;
3. Pituitary adenoma when conventional stereotactic radiation is not an available option;
4. Central nervous system (CNS) lesions including but not limited to, primary or metastatic CNS malignancies or arterio-venous malformations, adjacent to critical structures such as the optic nerve, brain stem or spinal cord, and not amenable to conventional surgical, conventional radiotherapeutic, or endovascular techniques.
5. Malignancies in children - 21 years of age and younger.

SWHP considers PBT NOT medically necessary in the treatment of prostate cancer because PBT has not been shown to offer any clinical advantage of other treatment modalities.

SWHP considers PBT NOT medically necessary for the treatment of locally advanced breast cancer because there is a lack of quality studies in the published literature that demonstrate definitive clinical benefit to PBT over other treatment modalities.

SWHP considers proton beam radiation therapy unproven for all other conditions.

OVERVIEW:
Proton beam radiation therapy (PBRT) is a type of radiation therapy which uses protons to deliver ionizing radiation which causes cellular damage to a specific target. In order for protons to penetrate the body and reach the intended target they must be accelerated to 60% of the speed of light.
light using a cyclotron. Since PBRT is still experimental for many types of cancer and the cost associated with building a cyclotron are enormous very few centers in the United States offer this service.

With standard radiation therapy the greatest energy release is at the surface of the tissue and decreases exponentially with the distance travelled. In contrast to standard radiation therapy, the greatest energy of a proton beam is released at the end of its path (more commonly called the target area). This region is called the Bragg peak. Since the energy release of the proton beam is confined to the Bragg peak, the collateral damage to surrounding healthy tissues is reduced and an increased dose of radiation can be delivered to the target area. It is these physical properties of PBRT which have led to the theory that PBRT may be especially useful for targets located in body tissues which are highly sensitive to radiation or where damage to the healthy tissue would be an unacceptable risk. In addition, PBRT may also benefit patients with tumors which are not amendable to surgery.

Though there is encouraging data that proton therapy may be able to deliver a dosimetric outcome that avoids a higher integral dose to normal tissue that may be seen with IMRT techniques, there is a lack of quality studies in the published literature that demonstrate definitive clinical benefit to PBT over IMRT in the treatment of locally advanced breast cancer. In addition, there is a paucity of published patient-reported outcomes for breast cancer patients treated with IMRT vs. PBT. PBT is significantly more costly than is IMRT, and without demonstrable clinical benefit.

**MANDATES:**
There are no state or federal mandates for this service.

**SUPPORTING DATA:**

**Melanoma of the Uveal tract:**
The safety and efficacy of PBRT for the treatment of melanomas of the uveal tract is supported by systematic reviews, randomized controlled trials, prospective case series and retrospective reviews. Patient populations ranged from 21–2645 and follow-up ranged from 18 months to 15 years. Outcomes varied based on the tumor characteristics. Ten- and 15-year local control rates up to 98%, 15-year overall eye retention rates up to 84%, and subsequent enucleation rates as low as 9% have been reported. The rate of development of distant metastases following PBRT ranged from 7%–24.2%. Five-year tumor specific survival rates have been reported at 79%. Five-, 10- and 15-year survival rates have been reported at 86%, 77%, and 73% respectively.

**AV Malformations:**
A Cochrane review assessed the clinical effects of various interventions to treat brain arteriovenous malformations (AVMs) in adults. Interventions include neurosurgical excision, stereotactic radiotherapy/radiosurgery, endovascular embolization and staged combinations of these interventions. The authors concluded there is no evidence from randomized trials with clear clinical outcomes comparing different interventional treatments for brain AVMs against each other or against usual medical therapy to guide the interventional treatment of brain AVMs in adults. One such trial (ARUBA) is ongoing.

**Prostate Cancer:**
The safety and efficacy of PBRT for the treatment of prostate cancer is supported by systematic reviews, randomized controlled trials, non-randomized comparative studies, case series and retrospective reviews. Studies comparing PBRT alone to conventional radiation therapy, brachytherapy or IMRT are lacking. Studies have primarily compared outcomes following conventional radiation therapy to conventional radiation therapy plus a proton boost. Overall, studies have reported that outcomes from treatment with PBRT were as good as, but not better than conventional radiation therapy. In a systematic review, Brada et al. (2009) stated “there
is currently no objective evidence of benefit in any of the important outcome measures for protons compared with conventional radiation therapy”.

**Chordomas and Chondrosarcomas:**
Due to the location of chordomas and chondrosarcomas, complete surgical excision can rarely be achieved. Radiotherapy including PBRT has become an established treatment option for these types of tumors. Overall, case series and retrospective reviews with small patient populations support PBRT for the treatment of chondrosarcoma and chordoma. Results varied based on tumor type and reported an overall survival rate of up to 94.3%, a five-year survival rate of 95%–100% (n=3–11), and progression-free survival rates of 81% for chondrosarcomas and 77% for chordomas. However, there is insufficient evidence to support that PBRT results in better outcomes than conventional radiotherapy. Studies comparing PBRT alone to conventional radiotherapy alone are lacking. Therefore, while PBRT has been shown to be clinically neutral as compared to conventional radiotherapy, it is not known whether the use of PBRT for these tumors is clinically superior in terms of meaningful patient health outcomes.

**CMS:**
There is no NCD or LCD for Proton Beam Radiation Therapy.

**CODES:**

*Important note:*
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

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**CPT Not Covered:**

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<td>ICD10 codes:</td>
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<td>Q28.2, Q28.3 - AVM brain</td>
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**POLICY HISTORY:**

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MEDICAL COVERAGE POLICY

SERVICE: Proton Beam Radiation Therapy

Policy Number: 203
Effective Date: 09/01/2019
Last Review: 06/27/2019
Next Review Date: 06/27/2020

Updated 01/30/2018 Clarified covered indications and non-covered indications
Updated 03/20/2018 Added additional language to policy point #4
Reviewed 06/26/2019 No changes

REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


MEDICAL COVERAGE POLICY

SERVICE: Proton Beam Radiation Therapy

Policy Number: 203

Effective Date: 09/01/2019

Last Review: 06/27/2019

Next Review Date: 06/27/2020


### MEDICAL COVERAGE POLICY

**SERVICE:** Proton Beam Radiation Therapy

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