

Clinical Policy: Proton and Neutron Beam Therapy

Reference Number: CP.MP.70

Last Review Date: 02/18

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Proton beam therapy (PBT) is a form of external beam radiation therapy (EBRT) that utilizes protons (positively charged subatomic particles) to precisely target a specific tissue mass. Proton beams can penetrate deep into tissues to reach tumors, while delivering less radiation to surrounding tissues. This may make PBT more effective for inoperable tumors, or for those areas in which damage to healthy tissue would pose an unacceptable risk.

Neutron beam therapy (NBT) is a less widely available form of EBRT which utilizes neutrons. Its clinical use is very limited due to difficulties in the delivery of this treatment modality.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that proton and neutron beam therapy is **medically necessary** for the following indications:
 - A. Ocular tumors with no distant metastasis. Fiducial markers (tantalum clips) are permitted to allow eye and tumor position verification; or
 - B. 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; or
 - C. Tumors that approach or are located at the base of the skull, including but not limited to: chordoma or chondrosarcoma; or
 - D. Primary hepatocellular cancer treated in a hypofractionated regimen; or
 - E. Primary or benign solid tumors in members ≤ 18 years old; or
 - F. Members with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma.
- II. It is the policy of health plans affiliated with Centene Corporation that NBT is **medically necessary** in the treatment of salivary gland tumors considered surgically unresectable or for a patient who is medically inoperable
- III. All other indications for PBT and NBT are considered **not medically necessary** as insufficient evidence exists to recommend proton beam therapy as superior to other treatments available.

Background

PBT is an important method of treatment used in managing malignant disease with a well-defined target. Unlike x-rays, protons cause little damage to the tissues they pass through to reach their destination. Their energy is released after traveling a specified distance, thus delivering more radiation to the tumor and doing less damage to the nearby normal tissue.

CLINICAL POLICY

Proton and Neutron Beam Therapy

Because of this, PBT may be more useful for tumors with distinct edges rather than those whose edges are mixed with normal tissue.

The American Society of Radiation Oncology (ASTRO) evaluated the evidence of use of PBT up until November 2009. The use of PBT was evaluated for CNS tumors, gastrointestinal malignancies, lung, head and neck, prostate, and pediatric tumors. Data evaluated did not provide sufficient evidence to support PBT for lung cancer, head and neck cancer, GI malignancies, and pediatric non-CNS malignancies. For hepatocellular carcinoma and prostate cancers, evidence supports the efficacy of PBT, but there is no support that it is a superior treatment to other external beam radiation therapy approaches. For pediatric CNS malignancies, PBT appears to be superior to other EBRT approaches, but more data is needed to determine the most appropriate approach. For large ocular melanomas and chordomas, evidence supports there to be a benefit of PBT over other EBRT approaches. Current evidence is limited for PBT indications and more robust clinical trials are needed to determine the appropriate clinical setting for its use.

National Comprehensive Cancer Network

Guidelines from NCCN regarding PBT in the treatment of head and neck cancer state, “Achieving high conformal dose distributions is especially important for patients whose primary tumors are periocular in location and/or invade the orbit, skull base, and/or cavernous sinus; extend intracranially or exhibit extensive perineural invasion; and who are being treated with curative intent and/or who have long life expectancies following treatment. Non-randomized single institution clinical reports and systematic comparisons demonstrate safety and efficacy of PBT in the above mentioned specific clinical scenarios.”¹²

NBT utilizes neutrons, rather than photons, to destroy tumor cells. Neutrons are much heavier than photons and appear to be more effective at causing damage to very dense tumors. It is however more clinically difficult to generate neutron particles, so it has not gained wide acceptance for treatment. It has most commonly been studied in salivary gland tumors which are either unable to be removed completely or for recurrent disease.

National Comprehensive Cancer Network

Guidelines from NCCN regarding NBT in the treatment of unresectable salivary gland tumors note that data supports the use of neutron therapy, although there are few published studies.

Per NCCN guidelines on uveal melanoma, “Tumor localization for PBT may be performed using indirect ophthalmoscopy, transillumination, and/or ultrasound (intraoperative and/or preoperative), MRI and or/CT. For intraocular tumors, fiducial markers (tantalum clips) are encouraged to permit eye and tumor position verification for image-guided radiotherapy delivery.”²¹

A practice parameter on PBT from the American College of Radiology/ASTRO also notes that in the most common systems, the ophthalmologist will guide patient selection with tumor/target definition through techniques such as fundoscopic examination, fluorescein angiogram, ultrasound, and direct tumor measurements intraoperatively. Most commonly but not imperatively, radio-opaque fiducial markers are sutured to the sclera and used as references for

CLINICAL POLICY

Proton and Neutron Beam Therapy

tumor definition. Treatment planning for ocular tumors has been most frequently performed with a treatment planning algorithm and software system developed specifically for treatment of ocular tumors. This requires multiple measurements that are obtained by the ophthalmologist, both from clinical examination and from surgical evaluation at the time of fiducial clip placement.²⁰

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2017, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Codes for proton beam therapy considered medically necessary for indications listed in this policy

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

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

ICD-10-CM diagnosis codes that support coverage criteria for proton beam therapy

+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
C22.0 – C22.8	Malignant neoplasm of liver and intrahepatic ducts
C41.0	Malignant neoplasm of bones of skull and face
C41.2	Malignant neoplasm of vertebral column
C69.00 – C69.92	Malignant neoplasm of eye and adnexa
C70.0 – C70.9	Malignant neoplasm of meninges
C71.0 – C71.9	Malignant neoplasm of cerebrum, except lobes and ventricles
C72.0 – C72.9+	Malignant neoplasm of spinal cord
C75.1 – C75.3	Malignant neoplasm of pituitary, craniopharyngeal duct, and pineal gland
C79.31	Secondary malignant neoplasm of brain
C79.4 – C79.49+	Secondary malignant neoplasm of other and unspecified parts of nervous system
D32.0 – D32.9	Benign neoplasm of meninges

CLINICAL POLICY

Proton and Neutron Beam Therapy

ICD-10-CM Code	Description
D33.0 – D33.9	Benign neoplasm of brain and other parts of central nervous system
D35.2	Benign neoplasm of pituitary gland
D44.3	Neoplasm of uncertain behavior of pituitary gland
D44.4	Neoplasm of uncertain behavior of craniopharyngeal duct

CPT Codes for neutron beam therapy considered medically necessary for indications listed in this policy

CPT Codes	Description
77422	High energy neutron radiation treatment delivery; single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking.
77423	High energy neutron radiation treatment delivery; 1 or more isocenter(s) with coplanar or non-coplanar geometry with blocking and/or wedge, and/or compensator(s)

ICD-10-CM codes considered medically necessary for neutron beam therapy for adults

ICD-10-CM Code	Description
C06.9	Malignant neoplasm of mouth, unspecified site (minor salivary gland, unspecified site)
C08.0 – C08.9	Malignant neoplasm of other and unspecified major salivary glands

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	03/14	03/14
Removed re-irradiation from I.A. Changed policy/criteria to Disease State only. Changed I.A.2 from list of tumors to spinal tumors language. Added tumors of the base of the skull to I.A.3 for clarification. Removed pituitary and sinus tumors. Updated background information	02/15	03/15
Added hepatocellular tumors and members with genetic syndromes to Criteria I Updated background information Updated template	03/16	03/16
Added ICD-10 CM codes	06/16	
References reviewed and updated. ICD-10 codes updated	02/17	03/17
References reviewed and updated.	02/18	02/18
Added fiducial markers (tantalum clips) as medically necessary when treating ocular tumors.	09/18	

References

1. Aihara T, Moriat N, Kamitani N, et al. Boron neutron capture therapy for advanced salivary gland carcinoma in head and neck. *Int J Clin Oncol*. 2013 June 25.
2. Allen AM, Pawlicki T, Dong L, et al. An evidence based review of proton beam therapy: The report of ASTRO's emerging technology committee. *Radiother Oncol*. 2012 Apr;103(1);8-11.

CLINICAL POLICY

Proton and Neutron Beam Therapy

3. American Cancer Society. Brain and spinal cord tumors in adults. Accessed 2/12/18
<http://www.cancer.org/cancer/braincstumorsinadults/detailedguide/brain-and-spinal-cord-tumors-in-adults-treating-radiation-therapy>.
4. American Cancer Society. Brain and spinal cord tumors in children. Accessed 2/13/18.
<http://www.cancer.org/cancer/braincstumorsinchildren/detailedguide/brain-and-spinal-cord-tumors-in-children-treating-radiation-therapy>.
5. ASTRO Model Policies. Proton beam therapy (PBT). May 20, 2014.
https://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf
6. Gewanter RM, Movsas B, Rosenzweig KE, Chang JY, Decker R, Dubey S, Kong FM, Lally BE, Langer CJ, Lee HK, Expert Panel on Radiation Oncology-Lung. ACR Appropriateness Criteria® nonsurgical treatment for non-small-cell lung cancer: good performance status/definitive intent. [online publication]. Reston (VA): American College of Radiology (ACR); 2010.
7. Kahalley LS, et al "IQ change within three years of radiation therapy in pediatric brain tumor patients treated with proton beam versus photon radiation therapy." ASCO 2013; Abstract 10009.
8. Kieran MW, Marcus KJ. Focal brainstem glioma. In: UpToDate, Loeffler JS, Wen PY, Gajjar A (Ed), UpToDate, Waltham, MA. Accessed 2/13/18.
9. Korf BR. Neurofibromatosis type 1 (NF1): Management and prognosis. In: UpToDate, Patterson MC, Firth HV (Ed), UpToDate, Waltham, MA. Accessed 2/13/18.
10. Lydiatt WM, Quivey JM. Salivary gland tumors: Treatment of locoregional disease. In: UpToDate, Brockstein BE, Brizel DM, Deschler DG, Fried MP (Ed), UpToDate, Waltham, MA. Accessed 2/13/18.
11. Mendenhall NP, Hoppe BS, Morris CG, et al. Five-year outcomes of proton therapy in localized prostate cancer on 3 prospective trials for low-, intermediate-, and high-risk prostate cancer. International Journal of Radiation Oncology *Biology* physics. Oct 2013, 87;2:S155.
12. National Comprehensive Cancer Network (NCCN). NCCN Guidelines: Head and neck cancers. 2.2013. <http://www.NCCN.org> Update 2.2017
13. Proton Therapy Guideline Working Group, Guideline Advisory Group. Proton beam radiation therapy. Edmonton (AB): Alberta Health Services, Cancer Care; 2013 Mar. 20 p. (Clinical practice guideline; no. RT-002).
14. Seattle Cancer Care Alliance. Neutron therapy: A rare and special kind of radiation. 2004 – 2017. <http://www.seattlecca.org/diseases/salivary-gland-cancer-treatment-neutron-therapy.cfm>
15. Singer RJ, Ogilvy CS, Rordorf G. Brain arteriovenous malformations. In: UpToDate, Biller J (Ed), UpToDate, Waltham. Accessed 2/13/18.
16. Stenson KM, Haraf DJ. Paranasal sinus cancer. In: UpToDate, Brockstein BE, Brizel DM, Fried MP (Ed), UpToDate, Waltham. Accessed 2/13/18.
17. Synderman C, Lin D. Chordoma and chondrosarcoma of the skull base. In: UpToDate, Loeffler JS, Wen PY, Fried MP (Ed), UpToDate, Waltham, MA. Accessed 2/13/18.
18. National Comprehensive Cancer Network (NCCN). NCCN Guidelines. Hepatobiliary Cancers. Version 4.2017
19. National Comprehensive Cancer Network. NCCN Guidelines. Central Nervous System Cancers. Version 1.2017

CLINICAL POLICY

Proton and Neutron Beam Therapy

20. National Comprehensive Cancer Network. NCCN Guidelines. Prostate Cancer. Version 2.2017
21. National Comprehensive Cancer Network. NCCN Guidelines. Uveal melanoma. Version 1.2018. March 2018
22. ACR-ASTRO Practice Parameter for the Performance of Proton Beam Radiation Therapy. Revised 2018. Accessed September 19,2018.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

CLINICAL POLICY

Proton and Neutron Beam Therapy

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.