Clinical Policy: Proton and Neutron Beam Therapy

Reference Number: CP.MP.70
Last Review Date: 09/2022

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; 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.

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.

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

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
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)

ICD-10-CM Code	Description
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

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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.

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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.