Clinical Policy: Stereotactic Body Radiation Therapy

Reference Number: CP.MP.22 Coding Implications
Date of Last Revision: 01/22 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Stereotactic body radiation therapy (SBRT) and stereotactic radiosurgery (SRS) are radiation therapies delivered via stereotactic guidance to a small, precise target. Both largely spare the surrounding tissue by converging multiple non-parallel radiation beams into one sharply defined target, thereby greatly reducing the amount of radiation to which the surrounding tissue is exposed. SBRT is used to treat extra-cranial sites and can be performed in one to five sessions (fractions). SRS is used to treat intra-cranial and spinal targets. SRS is typically performed in a single session but can be performed in a limited number of sessions, up to a maximum of five. Gamma-ray photons, X-ray photons, protons, helium ions, and neutrons have all been used for SBRT and SRS.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that up to 5 sessions of SBRT are **medically necessary** for any of the following indications:
- A. Early stage non-small cell lung cancer (i.e., stage I-II, NO) as an alternative to surgery;
- B. Acoustic neuroma;
- C. Localized malignant conditions in the body where highly precise application of high-dose radiotherapy is required, including tumors of any type arising in or near previously irradiated regions;
- D. Recurrences of metastatic spine cancer after previous radiation;[23]
- E. Hepatocellular carcinoma, as an alternative to ablation/embolization techniques or when these therapies have failed or are contraindicated;
- F. Low to intermediate risk localized prostate cancer;
- G. High risk prostate cancer when combined with androgen deprivation therapy, when delivering longer courses of external beam radiation therapy would present a documented hardship;
- H. Pancreatic adenocarcinoma:
  1. Locally advanced disease, without distant metastases;
  2. Combination therapy not feasible;
  3. Isolated local recurrence, respecting normal organ tolerance.

II. It is the policy of health plans affiliated with Centene Corporation® that up to 5 sessions of SRS are **medically necessary** for any one of the following indications:
- A. Cranial indications when unresectable due to deep intracranial location or member/enrollee is unable to tolerate conventional operative intervention, one of the following:
  1. Inoperable, small (≤ 3 cm) arteriovenous (AV) malformations,
  2. Benign tumors including meningiomas, pituitary adenomas, craniopharyngiomas, hemangiomas, and neoplasms of the pineal gland;

B. Small acoustic neuromas (≤ 3 cm) or enlarging neuromas in patients who are not candidates for surgery;
C. Brain malignancies, primary and/or metastatic lesions;
D. Intracranial lesions where the patient refuses surgery;
E. Severe, sustained trigeminal neuralgia not responsive to other treatments,
F. Booster treatment for larger cranial or spinal lesions that have been treated initially with external beam radiation therapy or surgery. Avoid when in close proximity to cranial nerves II and VIII if the maximal dose delivered exceeds 10 Gy;
G. Relapse in previously irradiated cranial or spinal field where additional stereotactic precision is required to avoid unacceptable vital tissue radiation;
H. Inoperable spinal tumors causing compression or intractable pain;
I. Refractory epileptic seizures in children when the lesion is located where a conventional surgical approach is technically difficult or excessively risky.[37]

III. It is the policy of health plans affiliated with Centene Corporation® that there is insufficient evidence to support more than 5 sessions of SBRT or SRS or SBRT or SRS for indications other than those listed above.

Background

Stereotactic body radiation therapy or stereotactic ablative therapy (SBRT) and stereotactic radiosurgery (SRS) both pair a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation to inactivate or eradicate a defined target(s). The target is defined by high resolution stereotactic imaging. The procedure involves a multidisciplinary team often consisting of a surgeon, radiation oncologist, radiologist, medical radiation physicist, dosimetrist, radiation therapist, radiation therapy nurse and a specialist of the disease site such as a neurologist.

Stereotactic describes a procedure during which a target lesion is localized relative to a fixed 3-D reference system, such as a rigid head frame affixed to a patient, fixed bony landmarks, a system of implanted fiducial markers, or other similar system. This localization procedure allows physicians to perform image-guided procedures with a high degree of accuracy and precision.

The risk of developing permanent damage following SRS varies by the location of the lesion in the brain. Lesions located deep in the gray matter (thalamus, basal ganglia) or brainstem (pons, midbrain) carry the maximum risk of neurologic complications. Complications are less likely with lesions in the frontal and temporal lobes. Fractionated radiation therapy is often preferred to SRS for the treatment of lesions in the deep gray matter or the brainstem.

Technologies that are used to perform SBRT and SRS include Gamma Knife®, LINAC, CyberKnife® and proton beam or heavy-charged-particle radiosurgery. In order to enhance precision, various devices may incorporate robotics and real time imaging.[4]

Gamma Knife

Standard gamma knife uses 192 or 201 beams of highly focused gamma rays all aiming at the target region. The Gamma Knife is ideal for treating small to medium size lesions.

Linear accelerator- (LINAC)
LINAC machines deliver high-energy x-rays, also known as photons. It can provide treatment on larger tumors in a single session or during multiple sessions (fractionated SRT). The principles of LINAC are identical to GammaKnife.[4]

CyberKnife
This device combines a mobile LINAC machine with an image guided robotic system that delivers either a single large dose or fractionated radiation therapy. The overall length of time of treatment on a CyberKnife is typically longer than with other radiation therapy modalities. [4, 11]

Proton Beam
There is limited use of proton beam in North America; however the number of centers has dramatically increased in the last several years. Protons are atoms that carry a positive charge. Compared to the use of photons (x-rays), the energy from protons conforms to the tumor better and causes less damage to the surrounding tissue. This allows a greater dose of radiation to be used due to minimizing the effects to normal tissue.

The National Comprehensive Cancer Network (NCCN) states that SBRT/extremely hypofractionated image-guided intensity-modulated radiation therapy (IMRT) regimens (6.5 Gy per fraction or greater) can be considered as an alternative to conventionally fractionated regimens in the treatment of prostate cancer at clinics with appropriate technology, physics, and clinical expertise. Longer follow-up and prospective multi-institutional data are required to evaluate longer-term results, especially because late toxicity theoretically could be worse in hypofractionated regimens compared to conventional fractionation (1.8 Gy-2.0 Gy).[13]

The World Health Organization notes the following information regarding Grade I meningiomas: stereotactic or image guided therapy is recommended when using tight margins or when close to critical structures.[23]

A revision to the metastatic spine guideline notes that in selected cases or recurrences after previous radiation, SBRT is appropriate.[23]

Definitive radiation therapy, particularly SBRT, is recommended for individuals with early stage non-small cell lung cancer (i.e., stage I-II, NO) who are medically inoperable or those who refuse surgery.[24]

SBRT for the treatment of pancreatic adenocarcinoma should be delivered at an experienced high-volume center with technology that allows for image-guided radiation therapy or in a clinical trial .[25] Most recent guidelines from NCCN on the principles of radiation therapy note that data are limited to support radiation therapy recommendations for locally advanced disease. The guidelines include SBRT as an “option” in select patients with pancreatic adenocarcinoma with good performance status and locally advanced disease without systemic metastasis. Chemo radiation or SBRT may be also be an option in select patients who are not candidates for combination therapy, an option in disease progression when SBRT had not been previously given, and as an option for isolated local recurrence. SBRT should be avoided if direct invasion of the bowel or stomach is observed on imaging and/or endoscopy.[25]

SBRT can be considered in patients with hepatocellular carcinoma, as an alternative to ablation/embolization techniques or when these therapies have failed or are contraindicated. SBRT (1-5 fractions) is often used for patients with 1-3 tumors. SBRT could be considered for larger lesions or more extensive disease, if there is sufficient uninvolved liver and liver radiation tolerance can be respected. There should be no extrahepatic disease or it should be minimal and addressed in a comprehensive management plan. (Category 2B recommendation) [26]

There is currently insufficient evidence to recommend SBRT for treatment of head and neck cancers, however, it might be beneficial for palliation or for older adults. When using SBRT techniques in reirradiation, selection of patients who do not have circumferential carotid involvement is advised. The best outcomes are seen in patients with smaller tumors and no skin involvement.[34]

The American Academy of Neurology states there is insufficient evidence to make recommendations regarding the use of gamma knife thalamotomy in the treatment of essential tremor. Per UpToDate, "Gamma knife thalamotomy has not generally been adopted for essential tremor due to concerns about delayed radiation side effects, including risk of radiation necrosis and a theoretical risk of secondary tumor formation."[31]

Per UpToDate on seizures and epilepsy in children, "Stereotactic radiosurgery may be helpful for selected cases when the lesion is located where a conventional surgical approach is technically difficult or excessively risky. More information is needed on long-term outcome before wider application of this procedure."[37]

American Society for Radiation Oncology (ASTRO), the American Society of Clinical Oncology (ASCO), and the American Urological Association (AUA)
Per a recent new guideline on hypofractionated radiation therapy for localized prostate cancer from ASTRO, ASCO, and the AUA, "Based on high-quality evidence, strong consensus was reached for offering moderate hypofractionation across risk groups to patients choosing external beam radiation therapy. The task force reached a weaker consensus for ultrahypofractionated radiation therapy. Extremely hypofractionated radiation therapy, also known as ultrahypofractionation, SBRT or stereotactic ablative radiation therapy (SABR) may be offered for low and intermediate risk prostate cancer, but strongly encourages treatment of intermediate-risk patients on a clinical trial or multi-institutional registry. For high-risk disease, the panel does not suggest offering ultrahypofractionation outside of a trial or registry."[33] Recommendations for ultrahypofractionation were graded by the panel as conditional, reflecting the limited base of current evidence on this approach. The guideline recommends large-scale randomized clinical trials and stresses the importance of shared decision making between clinicians and patients.[33]

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 2020, 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	Description
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator; each additional cranial lesion, simple
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator; 1 complex cranial lesion
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator; each additional cranial lesion, complex
61800	Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

HCPS	Description
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment

ICD-10-CM Diagnosis Codes that Support Coverage Criteria (may not be all inclusive)

ICD-10-CM Code	Description
C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts
C25.0- C25.9	Malignant neoplasm of pancreas

ICD-10-CM Code	Description
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C61	Malignant neoplasm of prostate
C70.0-C70.9	Malignant neoplasm of meninges
C71.0-C71.9	Malignant neoplasm of brain
C72.0-C72.59	Malignant neoplasm of spinal cord, cranial nerves
C78.00-C78.02	Secondary malignant neoplasm of lung
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.89	Secondary malignant neoplasm of other digestive organs
C79.31-C79.32	Secondary malignant neoplasm of brain and cerebral meninges
D18.02	Hemangioma of intracranial structures
D32.0-D32.9	Benign neoplasm of meninges
D33.0	Benign neoplasm of brain, supratentorial
D33.1	Benign neoplasm of brain, infratentorial
D33.3	Benign neoplasm of cranial nerves
D35.2	Benign neoplasm of pituitary gland
D35.3	Benign neoplasm of craniopharyngeal duct
D35.4	Benign neoplasm of pineal gland
D42.0-D42.9	Neoplasm of uncertain behavior of meninges
D43.0-D43.9	Neoplasm of uncertain behavior of brain and central nervous system
D44.3	Neoplasm of uncertain behavior of pituitary gland
D44.4	Neoplasm of uncertain behavior of craniopharyngeal duct
D49.6	Neoplasm of unspecified behavior of brain
G40.011-G40.019	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable
G40.111-G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable
G40.211-G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable
G40.311-G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable
G40.A11-G40.A19	Absence epileptic syndrome, intractable
G40.B11-G40.B19	Juvenile myoclonic epilepsy, intractable
G40.411-G40.419	Other generalized epilepsy and epileptic syndromes, intractable
G40.803-G40.804	Other epilepsy, intractable
G40.813-G40.814	Lennox-Gastaut syndrome, intractable
G40.823-G40.824	Epileptic spasms, intractable,

ICD-10-CM Code	Description
G40.911-G40.919	Epilepsy, unspecified, intractable
G50.0	Trigeminal neuralgia
Q28.2	Arteriovenous malformations of cerebral vessels
Z51.0	Encounter for antineoplastic radiation therapy

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Updated codes and disclaimers for HIX products	05/13	
Clarified language in Policy/Criteria section	12/13	12/13
Removed Authorization Criteria section Added indication for patients who refuse surgery and with more tumors arising in or near previous irradiated regions Clarified differences in SBRT and SRS and split Policy/Criteria appropriately Specialist review (radiation oncology)	03/14	03/14
Bibliography reviewed and updated Procedure codes updated per 2015 code updates for deleted codes	02/15	03/15
References reviewed and updated; added acoustic neuroma as an indication for SBRT; for SRS, removed acoustic neuroma from cranial indications and added a requirement that it be small or enlarging if not a candidate for surgery.	03/16	03/16
Added stage I-II, NO as indication to define non-small cell lung cancer per NCCN; added SBRT as indication for recurrences of metastatic spine cancer after previous radiation, per NCCN; added CyberKnife to the background information; added to background from NCCN that SBRT needs longer follow-up before used on prostate cancer; added additional information from NCCN to support SBRT to background section.	02/17	03/17
Added hepatocellular cancer as an indication for SBRT per NCCN; updated background section from NCCN that SBRT for pancreatic adenocarcinoma be used preferably in a clinical trial; added to background from AAN that there is insufficient evidence to make recommendations regarding the use of gamma knife thalamotomy in the treatment of essential tremor. Codes reviewed and updated.	01/18	01/18
Added low to intermediate risk localized prostate cancer to section I.as medically necessary. Updated background. Revised coding section, combining ICD 10 codes into applicable categories. References reviewed and updated.	01/19	01/19
Revised wording in I.A from “in patients who are not surgical candidates” to “as an alternative to surgery”; Added to section I. Indications for SBRT: Pancreatic cancer and high risk prostate cancer, when specific criteria are met; Added to section II- indication for SRS:	12/19	01/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Refractory epileptic seizures in children, when criterion is met. Updated background information regarding NCCN recommendations on pancreatic cancer. Added note that ICD 10 code list may not be all inclusive. Added the following ICD-10 code/code ranges: C25.0-C25.9, C78.89, G40.011-G40.019, G40.111-G40.119, G40.211-G40.219, G40.311-G40.319, G40.A11-G40.A19, G40.B11-G40.B19, G40.411-G40.419, G40.803-G40.804, G40.813-G40.814, G40.823-G40.824, and G40.911-G40.919. Internal and external specialist review.		
Annual review of policy. References reviewed and updated. Added CPT- 61800. Replaced "member" with" member/enrollee" in all instances.	12/20	01/21
Annual Review. In II.A., clarified that "one of the following" must be met. Removed "SBRT" from the note about proximity to cranial nerves in II.F. "Experimental/investigational" verbiage replaced in criteria III. with descriptive language. Changed "Last Review Date" in the header to "Date of Last Revision" and "Date" in revision log to "Revision Date". Reviewed by specialist.	01/22	01/22

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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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees 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 member/enrollees, 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 member/enrollees, 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.