Clinical Policy: Stereotactic Body Radiation Therapy

Reference Number: LA.CP.MP.22
Date of Last Revision: ~~02~~10/24

Coding Implications
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 Louisiana Healthcare Connections that up to five sessions of stereotactic body radiation therapy (SBRT) are **medically necessary** for any of the following indications:
- A. Early stage non-small cell lung cancer (i.e., stage I through II, T1 through T3,N0,M0) 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;
- E. Hepatocellular carcinoma, as an alternative to ablation/embolization techniques or when these therapies have failed or are contraindicated;
- F. Recurrent malignant disease requiring palliation and/or as palliative treatment for liver-related symptoms;
- G. Low to intermediate risk localized prostate cancer;
- H. High risk prostate cancer when combined with androgen deprivation therapy, when delivering longer courses of external beam radiation therapy would present a documented hardship;
- I. ~~Inoperable spinal~~Spinal tumors ~~causing compression or intractable pain~~;
- J. Pancreatic adenocarcinoma, one of the following:
  1. Locally advanced disease, without distant metastases;
  2. Combination therapy not feasible;
  3. Isolated local recurrence, respecting normal organ tolerance.
- K. Extracranial oligometastatic disease, all of the following:
  1. One to three metastatic lesions involving the lungs, liver or bone;
  2. Primary tumor is breast, colorectal, melanoma, non-small cell lung, prostate, renal cell, or sarcoma;
  3. Primary tumor is controlled;
  4. No prior history of metastatic disease.

II. It is the policy of Louisiana Healthcare Connections that up to five sessions of stereotactic radiosurgery (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 if other positive clinical indications exist, such as stable systemic disease, Karnofsky Performance Status 40 or greater (and expected to return to 70 or greater with treatment), and reasonable survival expectations, or Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (and expected to return to 2 or less with treatment);

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~~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~~.~~;

J. Other cranial non-neoplastic conditions, such as~~ trigeminal neuralgia and~~ select cases of medically refractory epilepsy, movement disorders such as Parkinson's disease and essential tremor, and hypothalamic hamartomas.

III. It is the policy of health plans affiliated with Louisiana Healthcare Connections that there is insufficient evidence to support more than five sessions of 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.[2]

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.[2]

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 (linear accelerator), CyberKnife® and proton beam or heavy-charged-particle radiosurgery. ~~In order to~~To enhance precision, various devices may incorporate robotics and real time imaging.[3]

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.[15]

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.[3,10,15]

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.[3,9]

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.[15] 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.[29]

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 to 2.0 Gy).[11] Results from a study comparing the efficacy of SBRT plus androgen deprivation therapy (ADT) to fractionated radiotherapy plus ADT in higher risk prostate cancer support recent NCCN guideline updates, which include SBRT as a non-preferred option for higher risk biological males. Findings demonstrated no difference in survival between SBRT + ADT and standard of care external beam radiation therapy + ADT for high-risk prostate cancer.[39]

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.[20]

A revision to the metastatic spine guideline notes that in selected cases or recurrences after previous radiation, SBRT is appropriate.[20]

Definitive radiation therapy, particularly SBRT, is recommended for individuals with early-stage non-small cell lung cancer (i.e., stage I through II, NO) who are medically inoperable or those who refuse surgery.[21]

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.[22] 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 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.[22]

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 (one to five fractions) is often used for patients with one to three 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).[23]

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.[31]

A systematic review and meta-analysis of 32 retrospective studies published between 1999 and 2019 demonstrated that the effectiveness and safety of stereotactic radiosurgery (SRS) for brainstem metastases (BSM) was comparable to SRS for ~~nonbrainstem~~non-brainstem brain metastases. Death related to BSM progression following treatment with SRS was rare and patients often experienced symptomatic improvement. Based upon the apparent effectiveness and safety of SRS for BSM in the context of acute morbidity or death from BSM growth, consideration of SRS on emerging trials of targeted therapy for ~~nonbrainstem~~non-brainstem brain metastases should be considered.[37]

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.[24] 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."[28]

Gamma knife stereotactic radiosurgery can offer a less invasive approach for resection of medial temporal structures in mesial temporal sclerosis (MTS) by allowing increased preservation of tissue. SRS may be an excellent option for patients unwilling to undergo invasive open surgical treatment of MTS. Further randomized trials are ongoing to assess the continued efficacy and outcomes of SRS as a treatment option in patients with MTS.[38] 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."[34]

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."[30] 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.[30]

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 2023, 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 and may not support medical necessity. 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

CPT® Codes	Description
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)
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 (List separately in addition to code for primary procedure)
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 (List separately in addition to code for primary procedure)
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 1 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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	02/1/2021	
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	2/22	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
to "Date of Last Revision" and "Date" in revision log to "Revision Date". Added “and may not support medical necessity” in coding implications. Reviewed by specialist.		
Annual review completed. Added I.F. “Recurrent malignant disease requiring palliation and/or as palliative treatment for liver-related symptoms”. “Inoperable spinal tumors” added as criteria I.I. Added I.K. “Extracranial oligometastatic disease: 1. One to three metastatic lesions involving the lungs, liver or bone; 2. Primary tumor is breast, colorectal, melanoma, non-small cell lung, prostate, renal cell, or sarcoma; 3. Primary tumor is controlled; 4. No prior history of metastatic disease”. Background updated and minor rewording with no clinical significance. ICD-10 Code table removed. References reviewed and updated. Reviewed by external specialist.	4/23	5/26/23
Annual review. Updated cancer staging in Criteria I.A. to align with National Comprehensive Cancer Network (NCCN) guidelines. Criteria II.C. updated to include details regarding positive clinical indications regarding stable systemic disease, Karnofsky Performance Score, survival expectations, and Eastern Cooperative Oncology Group (ECOG) Performance Status to align with ASTRO 2022 Model Policy for SRS. Added “one of the following” to I.J. Criteria II.J. added to include trigeminal neuralgia and select cases of medically refractory epilepsy, movement disorders such as Parkinson’s disease and essential tremor, and hypothalamic hamartomas to align with 2022 ASTRO Model Policy for SRS. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	02/24	4/26/24
Annual review. Updated I.I. and II.H. from “inoperable spinal tumors causing compression or intractable pain” to “spinal tumors”. Removed example of trigeminal neuralgia from criteria II.J. as already stated in II.E. Background updated with no clinical significance. References reviewed and updated.	12/24	

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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.

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.