Clinical Policy: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

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Date of Last Revision: 10/24

Coding Implications
Revision Log

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

Description

This policy outlines the medical necessity criteria for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). The policy criteria is sourced from the following Local Coverage Determination (LCD), Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076) and is supported by American Society for Radiation Oncology (ASTRO) and National Comprehensive Cancer Network (NCCN).

Benefits of Stereotactic Radiation Therapy (SRS) and Stereotactic Body Radiation Therapy (SBRT) include the ability to target tumors while limiting the radiation exposure to nearby organs and tissues. It also allows healthcare providers to remove tumors with near-surgical precision but without surgery. Risks of using SRS and SBRT include rare instances of long-term effects if the radiation damages healthy tissue including cancer development though the chance of this is extremely rare.[6] Since the following criteria is supported by ASTRO and NCCN, organizations that advocate for safe and clinically appropriate radiology and cancer treatment, respectively, the benefits of the following criteria for SRS and SBRT outweigh the risks.

Note: For criteria applicable to non-Medicare plans, please see CP.MP.22 Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT).

Policy/Criteria

I. It is the policy of Medicare health plans affiliated with Centene Corporation® that *stereotactic radiation therapy* (*SRS) for cranial and spinal lesions* is **medically necessary** for any of the following:

A. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions < 5 cm;
B. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures;
C. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas;
D. Cranial arteriovenous malformations, cavernous malformations, or hemangiomas;
E. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy;

F. As a boost treatment for larger cranial or spinal lesions that have been treated initially with external beam radiation therapy or surgery (e.g. sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or paranasal sinus malignancies);
G. Metastatic brain or spine lesions and one of the following:
   1. Stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment, see Table 1),* and otherwise reasonable survival expectations;
   2. An Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment, see Table 2);*
H. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation;
I. Choroidal and other ocular melanomas.[1]

II. It is the policy of Medicare health plans affiliated with Centene Corporation that *stereotactic radiation therapy* (*SRS) for cranial or spinal lesions* is **not medically necessary** for any of the following:
A. Treatment for anything other than a severe symptom or serious threat to life or critical functions;
B. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable;
C. Members/enrollees with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life;
D. Members/enrollees with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3, see Tables 1 and 2);*
E. Cobalt-60 pallidotomy.[1]

III. It is the policy of Medicare health plans affiliated with Centene Corporation® that *stereotactic body radiation therapy (SBRT)* is **medically necessary** for any of the following:
A. Primary tumors and tumors metastatic to the lung, liver, kidney, adrenal gland, or pancreas;
B. Treatment of pelvic and head and neck tumors that have recurred after primary irradiation;
C. Members/enrollees with clinically localized, low- to intermediate-risk prostate cancer;
D. Treatment of recurrence in or near previously irradiated regions of any body site or internal organ and both of the following:
   1. A high level of precision and accuracy or a high dose per fraction is indicated to minimize the risk of injury to surrounding normal tissues;
   2. Treatment with conventional methods is not appropriate or safe for the particular member/enrollee (medical records must describe the specific circumstances).[1]
E. Extracranial oligometastatic disease, any of the following:[3]
   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.
F. Acoustic neuroma;[4]

G. Spinal tumors.[5]

IV. It is the policy of Medicare health plans affiliated with Centene Corporation® that *stereotactic body radiation therapy (SBRT)* is **not medically necessary** for any of the following:

A. As the Primary treatment of lesions of bone, breast, uterus, ovary, and all other internal organs not specified above;
B. Treatment is unlikely to result in clinical cancer control and/or functional improvement;
C. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures;
D. Member/enrollee has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse- see Tables 1 and 2);*
E. Recurrent (other than pelvic and head and neck tumors) or metastatic disease that could be treated by conventional methods (record must describe why other radiation therapy measures are not appropriate or safe for the particular member/enrollee);
F. Any course of radiation treatment extending beyond five fractions (sessions). (This is not considered SBRT, since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame. SBRT is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment).[1]

*Note: The higher a Karnofsky Performance Status is, the better a member/enrollee is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a member/enrollee is doing.

Table 1: Karnofsky Performance Status Scale

Rating %	Performance Status
100	Normal; no complaints, no evidence of disease
90	Able to carry on normal activity; minor signs or symptoms of disease
80	Normal activity with effort; some signs or symptoms of disease
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospitalization is indicated although death not imminent
20	Very sick; hospitalization necessary; active supportive treatment is necessary
10	Moribund, fatal processes progressing rapidly
0	Dead

Table 2: Eastern Cooperative Oncology Group (ECOG) Performance Status Scale	
Grade	**Performance Status**
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work.
2	Ambulatory and capable of all self-care but unable to carry out and work activities. Up and about more than 50% of waking hours.
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5	Dead

Background

Centers for Medicare and Medicaid (CMS)[1]

Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) are methods of delivering ionizing radiation using highly focused convergent beams to target a lesion while limiting exposure to adjacent structures.

"Stereotactic" describes target lesion localization relative to a known three-dimensional reference system that allows for a high degree of anatomic accuracy and precision. Devices used for stereotactic guidance may include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV) x-rays, and CT-imaging-based systems used to confirm the location of a tumor immediately prior to treatment.

SBRT is used to treat extra-cranial sites as opposed to stereotactic radiosurgery (SRS) which is used to treat intra-cranial and spinal targets. Treatment of extra-cranial sites excluding the spinal cord and related spinal structures requires accounting for internal organ motion as well as for patient motion. Thus, reliable immobilization or repositioning systems must often be combined with devices capable of decreasing organ motion or accounting for organ motion (e.g. respiratory gating). Additionally, all SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization prior to delivery of each fraction.

SBRT is only indicated as primary treatment for tumor types or locations where the available published literature supports an outcome advantage over other conventional radiation modalities. It may be delivered in one to five sessions (fractions). Each fraction requires an identical degree of precision, localization and image guidance. SRS is typically performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system.

SRS/SBRT procedures include the following components:

- Planning

- Position stabilization (attachment of a frame or frameless)
- Imaging for localization (CT, MRI, angiography, PET, etc.)
- Computer assisted tumor localization (i.e. "Image Guidance")
- Treatment planning – number of isocenters, number, placement and length of arcs or angles, number of beams, beam size and weight, etc.
- Isodose distributions, dosage prescription and calculation
- Setup and accuracy verification testing
- Simulation of prescribed arcs or fixed portals
- Radiation treatment delivery

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. 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 (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

CPT® Codes	Description
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

HCPCS Codes	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
Original approval date.	08/23	08/23
Annual review. Added risk/benefit statement. Added criteria III.E.1-III.E.4. Extracranial oligometastatic disease, any of the following: One to three metastatic lesions involving the lungs, liver or bone; Primary tumor is breast, colorectal, melanoma, non-small cell lung, prostate, renal cell or sarcoma; Primary tumor is controlled; No prior history of metastatic disease. III.F. Acoustic neuroma; III.G. spinal tumors. Minor edits to background with no clinical significance. Added CPT codes 61796, 61797, 61798, 61799, 61800, 63620, 63621, 77371, 77372, and 77432 to policy. References reviewed and updated. Reviewed by external specialist.	10/24	10/24

References

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5. National Comprehensive Cancer Network®. NCCN Clinical Practice Guidelines in Oncology Version 3.2024. Central Nervous System Cancers. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Published September 30, 2024. Accessed October 16, 2024.
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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.

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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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/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 members/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.