

EFFECTIVE DATE: 01/01/2023
POLICY LAST UPDATED: 09/21/2022

OVERVIEW

Stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) are 3-dimensional conformal radiotherapy methods that deliver highly focused, convergent radiotherapy beams on a target that is defined with 3-dimensional imaging techniques with ability to spare adjacent radiosensitive structures. SRS primarily refers to such radiotherapy applied to intracranial lesions and SBRT refers to therapy sometimes applied to intracranial as well as other areas of the body. This policy is applicable to SBRT only; SRS is a covered service.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Cranial Lesions

SBRT is medically necessary when one or more of the following are met:

1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions < 5 cm.
2. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures.
3. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.
4. Cranial arteriovenous malformations, cavernous malformations, and hemangiomas.
5. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy. 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).
6. Metastatic brain or spine lesions, with stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, OR an Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment).
7. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
8. Choroidal and other ocular melanomas

SBRT is not medically necessary for any of the following indications:

1. Treatment for anything other than a severe symptom or serious threat to life or critical functions.
2. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
3. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
4. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3)

All other lesions:

SBRT is medically necessary when one or more of the following are met:

1. SBRT is indicated for primary tumors and tumors metastatic to the lung, liver, kidney, adrenal gland, or pancreas.
2. SBRT is indicated for treatment of pelvic and head and neck tumors that have recurred after primary irradiation.
3. SBRT is indicated for patients with clinically localized, low- to intermediate-risk prostate cancer.
4. SBRT treatment, of any body site or internal organ, is indicated for treatment of recurrence in or near previously irradiated regions when 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 and treatment with conventional methods is not appropriate or safe for the particular patient (medical records must describe the specific circumstances)

SBRT is not medically necessary for any of the following indications:

1. Primary treatment of lesions of bone, breast, uterus, ovary, and other internal organs not listed as covered is not considered medically necessary.
2. SBRT is not considered medically necessary under the following circumstances for any condition:
 - a. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
 - b. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
 - c. The patient has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse).
 - d. Recurrent (other than pelvic and head and neck tumors) or metastatic disease could be treated by conventional methods (record must describe why other radiation therapy measures are not appropriate or safe for the particular patient).
3. 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, any course of radiation treatment extending beyond five fractions is not considered SBRT and is not to be billed using these codes. 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.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial products and is obtained via the online tool for participating providers. See Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Stereotactic body radiation therapy is covered when the medical criteria are met.

SBRT is considered not medically necessary for all other indications not listed in the medical criteria as there is insufficient clinical evidence to support its efficacy.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for the applicable radiation therapy benefits/coverage.

BACKGROUND

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 of 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 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.

SBRT 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.

Karnofsky Performance Status Scale

- 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

ECOG Performance Status Scale

- Grade 0: Fully active, able to carry on all pre-disease performance without restriction.
- Grade 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.
- Grade 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.
- Grade 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
- Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
- Grade 5: Dead

Note:

The higher a Karnofsky Performance Status, the better a patient is doing.

The lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing. This is the opposite of the Karnofsky Performance scores where a lower score reflects a poorer status.

SRS/SBRT procedures include the following components:

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

CODING

Medicare Advantage Plans and Commercial Products

The following codes are covered when the medical criteria are met:

Two to Five (2-5) Fractions:

Cranial SBRT-Stereotactic body radiation therapy

Note: This code is used for cranial although the code description is not specific to cranial

77435 Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions

One to Five (1-5) Fractions:

Spinal SBRT Stereotactic body therapy

32701 Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment

77373 Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

77435 Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions

RELATED POLICIES

Preauthorization via Web-Based tool for Procedures

PUBLISHED

Provider Update, November 2022

Provider Update, November 2021

Provider Update, December 2020

Provider Update, November 2019

Provider Update, February 2019

REFERENCES

1. CMS.gov Centers for Medicare and Medicaid Service Local Coverage Determination (LCD): Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076)

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