Coverage Indications, Limitations, and/or Medical Necessity

Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) are noninvasive means of administering high-dose radiotherapy to discreet tumor foci in cranial or extracranial locations respectively. The two forms of treatment share certain overarching principles, namely, the use of image guidance and related treatment delivery technology for escalating the radiation dose to the tumor with as little radiation dose to the surrounding tissue as possible. Both methods are achieved with a “stereotactic” technique, implying that fiducial reference markers serve to align the treatment machine so that an internal lesion is targeted accurately; however, notable differences in clinical applications emerge given the vastly different anatomic and clinical consideration between cranial and extracranial target lesions.

This LCD recognizes these two distinct treatment approaches and is specific to treatment delivery:

1. **Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT):** cranial lesions are distinct disciplines that utilize externally generated high dose ionizing radiation in certain cases to inactivate or eradicate (a) defined target (s) in the head without the need to make an incision. The target is defined by high-resolution stereotactic imaging. The process of care involves the radiation oncologist and/or neurosurgeon and physicist. For a subset of tumors involving the skull base, the multidisciplinary team may also include a head and neck surgeon with training in stereotactic radiosurgery. SRS/SBRT are typically performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system, but can be performed in a limited number of sessions, up to a maximum of five.

Technologies that are used to perform SRS/SBRT include linear accelerators, particle beam accelerators, and multi-source Cobalt 60 units. In order to enhance precision, various devices may incorporate robotics and real time imaging.

To qualify for SRS/SBRT a high dose should be delivered in a single fraction or in 2-5
fractions. 500 cGy (5 Gray) in a single dose is considered the minimum dose as a ‘high dose’ for SRS. A more typical dose would be 1400-2500 cGy (14-25 Gray) if given in one fraction.

In general, SRS/SBRT is not indicated for cancers that are widely disseminated, unless evidence can be provided to justify the expectation of a meaningful clinical benefit, as well as evidence of a dosimetric advantage for SRS/SBRT over other forms of radiation therapy.

**Indications**

**SRS/SBRT: cranial lesions** will be considered medically reasonable and necessary for the following indications:

- Primary central nervous system malignancies, generally under 5 cm and as a boost treatment for larger cranial, base of skull, or spinal lesions that have been treated initially with external beam radiation therapy or surgery (i.e., grade III and IV gliomas, oligodendrogliomas, sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or paranasal sinus malignancies).
- Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent boney structures.
- Benign brain tumors and spinal tumors such as cranial meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineal cytomas, craniopharyngiomas, glomus tumors, and hemangiolaestomas.
- Cranial arteriovenous malformations and hemangiomas.
- Trigeminal neuralgia not responsive to medical management.
- Metastatic brain lesions, generally limited in number, 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).
- Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
- Other cranial non-neoplastic conditions for which it has been proven effective, e.g., movement disorders such as Parkinson’s disease, essential tremor and other disabling tremor that are refractory to conventional therapy, such as severe, sustained trigeminal neuralgia not responsive to other modalities.

2. **Stereotactic Body Radiation Therapy (SBRT)** is an emerging treatment method that utilizes externally generated high dose ionizing radiation in certain cases to inactivate or eradicate (a) defined target (s) within the body. The target is defined by high-resolution stereotactic imaging. In addition to the radiation oncologist and/or neurosurgeon and physicist, the process may involve input from other surgical specialists. SBRT performed using immobilization technology and a stereotactic image-guidance system can be performed in a limited number of sessions, up to a maximum of five.
To qualify for SBRT, a high dose should be delivered in a single fraction or in 2-5 fractions. 500 cGy (5 Gray) is considered the minimum dose as a ‘high dose’ for SBRT. A more typical dose would be 1400-2500 cGY (14-25 Gray) if given in one fraction.

**Indications**

SBRT will be considered medically reasonable and necessary for certain conditions as long as the following criteria are met:

- Either #1, #2, or #3 must be present and
- Either #4 or #5 must be present and
- #6 must always be present.

1. When dose constraints to normal tissues limit the total dose of radiation safely deliverable to the tumor with other indicated methods.

2. When there is a reason to believe that doses generally thought to be above the level otherwise attainable with other methods might improve control rates.

3. In circumstances when the higher levels of precision associated with SBRT as compared to other radiation methods are necessary, i.e., clinically relevant.

4. For the treatment of primary lesions, the intent of treatment must be curative with the exception of lesions within the pancreas or liver.

5. For the treatment of metastatic lesions, there must be:
   - the expectation of a long-term benefit (> 6 months) that could not have been attained with conventional therapy
   - the expectation of a complete eradication of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for SBRT over other forms of radiation therapy.

6. The patient’s record demonstrates why SBRT is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over conventional radiation therapy, IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

SBRT will be considered medically reasonable and necessary only if the above criteria are met as specified for the following conditions:
Spinal Lesions

- Previously untreated spinal metastases or spinal metastases that have recurred after conventional radiotherapy and clinical reasons preclude a surgical approach.

Lung Cancer

- Early stage bronchogenic carcinoma - treatment of early stage bronchogenic carcinomas in medically unresectable patients
- Pulmonary metastatic disease - patient has limited pulmonary metastatic disease and no active disease elsewhere in the body,
- Patients that might otherwise be candidates for resection, but precluded by co-existing medical condition(s) or technically difficult lesion location.
- Recurrent disease - very selected cases for long-term palliative use

Liver Cancer

- Primary hepatocellular carcinoma - Patients who are not surgical candidates.
- Secondary metastases to the liver, not amenable to surgical resection. Generally limited to less than 4 simultaneous lesions.

Pancreatic Cancer

- Palliative intent and selected cases for curative intent or unresectable.

Kidney and Adrenal Gland

- Primary and metastatic tumors

Limitations:

1. Treatment for anything other than a severe symptom or serious threat to life or critical functions, not responsive or reasonably amenable to another therapy.

2. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.

3. In general, stereotactic radiosurgery is not indicated for cancers that are widespread with cerebral or extra-cranial metastases. The intent of treatment should be curative, except in cases where radiosurgery will provide the best palliation, resulting in significant quality of life.

4. Patients with poor performance status (Karnofsky Performance Status < 40), see Karnofsky Performance Status below* or Eastern Cooperative Oncology Group (ECOG)
Performance Status > 3.

5. A claim for stereotactic cingulotomy as a means of psychotherapy, considered investigational, per Medicare National Coverage Determinations (NCD) Manual, Publication 100-03, Chapter 1, Part 2, Section 160.4.

6. Lesions of bone, breast, uterus, ovary and other internal organs not listed above are not covered for primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities.

7. Claims for primary prostate cancer will be developed (documentation requested) for medical review and payment considered on an individual case by case basis (refer to the ‘Documentation Requirements’ section of this LCD).

*Karnofsky Performance Scale* (Perez and Brady, p 225)

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

**Eastern Cooperative Oncology Group: Performance Scale and corresponding Karnofsky Rating** (Cancer Medicine 5th ed)

0 Fully active, able to carry on all pre disease activities without restriction (Karnofsky 100)

1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework/office work (Karnofsky 80-90)
2 Ambulatory and capable of all self care but unable to carry out any work activities; up and about more than 50% of waking hours (Karnofsky-70)

3 Capable of limited self-care, confined to bed or chair 50% or more of waking hours (Karnofsky 40-50)

4 Completely disabled; cannot carry on any self-care; totally confined to bed or chair (Karnofsky 30 or less)

5 Dead

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

999999 Not Applicable

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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
STEREOTACTIC BODY RADIATION THERAPY, TREATMENT DELIVERY, PER FRACTION TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS

IMAGE-GUIDED ROBOTIC LINEAR ACCELERATOR-BASED STEREOTACTIC RADIOSURGERY, COMPLETE COURSE OF THERAPY IN ONE SESSION OR FIRST SESSION OF FRACTIONATED TREATMENT
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

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements

The patient's record must support the necessity and frequency of treatment. Medical records should include not only the standard history and physical but also the patient’s functional status and a description of current performance status (Karnofsky Performance Status or Eastern Cooperative Oncology Group Performance Scale). See Karnofsky Performance Scale and Eastern Cooperative Oncology Group Performance Scale listed under the Indications and Limitations of Coverage and/or Medical Necessity section of the LCD above.

The patient's record demonstrates why SBRT is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over conventional radiation therapy, IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be included.

Documentation should include the date and the current treatment dose.

• A radiation oncologist and/or a neurosurgeon, as clinically indicated, must evaluate the clinical aspects of the treatment, and document and sign this evaluation as well as the resulting management decisions.
• A radiation oncologist and/or a neurosurgeon, and medical physicist must evaluate the technical aspects of the treatment and document and sign this evaluation as well as the resulting treatment management decisions.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862 (a) of the Social Security Act.

For prostate cancer, claims will be developed (documentation requested) for medical review and payment considered on an individual case by case basis. Documentation should include the information noted above, as well as the following information:

• Patient selection (stage and other favorable factors).

• Verification that the patient was informed of the range of therapy choices, including the risks and benefits of SBRT (especially the risk of long term toxicities).

• The rationale for SBRT as a treatment choice for the patient.

**Utilization Guidelines**

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.