Coverage Indications, Limitations, and/or Medical Necessity

This policy discusses coverage of cranial stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT). Stereotactic radiosurgery combines anatomic accuracy and precision using stereotactic measures with high doses of highly precise, externally generated, ionizing radiation, thereby maximizing the ablative effect of the target(s) while minimizing collateral damage to the adjacent tissues.

The difference between stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) is that in SRS, high dose radiation is delivered in one fraction, to a small area, while in SRT; radiation is delivered in multiple fractions (2-5) at a somewhat lower dose than SRS to a larger area.

I. Methodology

Five main methods of this technology exist: gamma-ray radiosurgery (gamma knife), linear-accelerator radiosurgery (LINAC and Cyberknife®), proton-beam radiosurgery, helium-ion radiosurgery, and neutron-beam radiosurgery. The latter three energy sources are collectively referred to as particles.

The gamma knife and linear accelerator systems (including the Cyberknife®) are similar in concept: both use multiple photon radiation arcs that intersect at a stereotactically determined target, thus permitting higher doses of radiation delivery with sparing of surrounding normal tissues.

Personnel: A team consisting of a combination of highly skilled professionals is required to:
  a. establish a database,
  b. establish a treatment plan, and
  c. perform the interactive procedure.

The team can include specialists from neurosurgery, neuroradiology, radiation oncology, neurology, oncology, radiation physicists, computer scientists and others.

The radiosurgical procedure is preceded by a process of localizing the target, which
can be performed with one or more of the following techniques: cerebral angiography, computerized tomography, magnetic resonance imaging, PET and other tests including tissue biopsies can be performed.

Regardless of the number of sessions, both SRT and SRS 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, 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

SRS is typically performed in one session, usually as an outpatient or requiring no more than an overnight hospital stay.

Performance status is frequently used in oncology practice as a variable in determining prognosis and management strategies. Either the Karnofsky Performance Status (KPS) or the Eastern Cooperative Oncology Group (ECOG) Performance Status scoring systems may be used. This information, combined with other criteria, such as results of the Karnofsky Performance scale (simply defined as an ADL scale), and other tests, assist the team in determining which patients would benefit from this procedure.

<table>
<thead>
<tr>
<th>Karnofsky Performance Status Scale:</th>
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<tbody>
<tr>
<td>100</td>
<td>Normal, no complaints, no evidence of disease</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease</td>
</tr>
<tr>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or do active work</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance; able to care for most personal needs</td>
</tr>
<tr>
<td>50</td>
<td></td>
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</tbody>
</table>
Eastern Cooperative Oncology Group (ECOG)/Zubrod Performance Status:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Fully active, able to carry on all pre-disease performance without restriction.</td>
</tr>
<tr>
<td>1</td>
<td>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.</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.</td>
</tr>
<tr>
<td>3</td>
<td>Capable of limited self-care, confined to bed or chair more than 50% of waking hours.</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.</td>
</tr>
<tr>
<td>5</td>
<td>Dead</td>
</tr>
</tbody>
</table>

II. Stereotactic Radiosurgery (SRS)

Stereotactic radiosurgery (SRS) is a method of delivering high doses of ionizing radiation to small intracranial targets. The technique differs from conventional radiotherapy, which involves exposing large areas of intracranial tissue to relatively broad fields of radiation over a number of sessions. SRS entails delivering highly focused convergent beams in a single session so that only the desired target is radiated, sparing adjacent structures. SRS is strictly defined as radiation therapy delivered via stereotactic guidance with ~1 mm targeting accuracy to a cranial lesion in a single fraction. SRS is typically performed in one session, usually as an outpatient or requiring no more than an overnight hospital stay.

Stereotactic radiosurgery works the same as all other forms of radiation treatment. It does not remove the tumor or lesion, but it distorts the DNA of the tumor cells. The cells then lose their ability to reproduce and retain fluids. The tumor reduction occurs at the rate of the normal growth rate of the specific tumor cell. In lesions such as AVMs (a group of abnormal blood vessels in the brain), radiosurgery causes the blood vessels to thicken and close off. The shrinking of a tumor or closing off of a vessel occurs over a period of time. For benign tumors and vessels, this will usually be 18 months to two years. For malignant tumors and metastatic tumors, results may be seen as soon as a couple of months as these cells are very fast-growing.

In certain cases whole-brain radiation is administered prior to and/or following this procedure. Stereotactic radiation amounts may be reduced or the procedure may be contraindicated if the lesion is within 5 mm of the brainstem or optic chiasm.

A. Indications for SRS

Intracranial lesions would be considered medically reasonable and necessary for the following conditions:

1. 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 (e.g. grade II and IV gliomas, oligodendrogliomas, sarcomas, chondrosarcomas, chordomas, and nasopharyngeal of paranasal sinus malignancies).

2. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures.

3. Benign brain and spinal tumors such as cranial meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineal cyтомas, craniopharyngiomas, glomus tumors, and hemangioblastomas.


5. Trigeminal neuralgia not responsive to medical management.

6. Metastatic brain lesions, generally limited in number, with stable systemic disease, Karnofsky Performance Status of 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 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. Essential tremor: coverage is limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery. Coverage is further limited to unilateral thalamotomy. Gamma Knife pallidotomy remains non-covered and will be denied.

B. Limitations for SRS

SRS is not considered medically necessary under the following circumstances:

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 of clinically meaningful disease stabilization, not otherwise achievable.

3. In patients, with more than three (3) primary or metastases lesions SRS is inappropriate and consideration should be given to whole brain irradiation.

4. Patients with wide spread cerebral or extra cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.

5. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3).
III. **Stereotactic Radiotherapy (SRT)**

Stereotactic radiotherapy (SRT) refers to stereotactically guided radiation therapy applied over a period of days or weeks. This fractionated form of radiation therapy is made possible by the recent availability of noninvasive repositioning devices (removable masks and frames) that can be used in lieu of a head frame. Stereotactic radiotherapy is based on the basic radiobiologic principle that fractionation decreases the short and long-term side effects of radiation therapy. In some settings, this permits higher total dosage to be given. This is a newer technology and therefore the indications supported by literature are less than for SRS.

A. **Indications for SRT**

For many of the indications listed, surgery is the first choice of treatment. Where this is not possible due to size or location of lesion SRT may be a first line choice. It can also be an adjunct post surgery to treat areas that were non-resectable. Fractionated stereotactic radiosurgery is frequently used for brain tumors that are close to the optic chiasm (e.g., pituitary tumors) or for tumors that have normal nerves passing through their centers (e.g., acoustic neuromas and meningiomas of the cavernous sinus or skull base).

Fractionated cranial stereotactic radiotherapy is considered medically necessary for treatment of intracranial tumors in hard-to-reach locations, tumors with very unusual shapes, or for tumors located in such close proximity to a vital structure (e.g., optic nerve or hypothalamus) that even a very accurate high-dose single fraction of stereotactic radiosurgery could not be tolerated.

1. Current indications for SRT include:
   a. **Benign Lesions**
      1. Arteriovenous Malformations (AVM)
      2. Pituitary Adenoma
      3. Vestibular Schwannoma
      4. Meningioma

   b. **Benign neoplasms that were previously treated with conventional radiotherapy**
      1. Craniopharyngiomas
      2. Pineocytomas
      3. Low grade astrocytic and ganglioneuronal tumors
      4. Hemangioblastomas
      5. Nonacoustic Schwannomas

   c. **Malignant Lesions**
      1. Lesions within 5 mm of the optic nerves or chiasms
      2. Recurrent malignant Gliomas
      3. Brain metastasis
      4. Base of skull
5. Certain types of recurring malignancies - head and neck cancers, such as cancer of the tonsil, larynx, tongue, sinus, and mouth

**Non-Covered Conditions for SRT**
All other uses of stereotactic radiosurgery are considered **investigational/not medically necessary** including, but not limited to, treatment of chronic pain, psychoneurosis, Parkinson’s and epilepsy. Arteriovenous malformations (AVM) may cause seizures. In this case, coding for the AVM would be appropriate. There are coverage restrictions on other movement disorders.

**Diseases Definitions:**
Acoustic Neuromas: a non-life-threatening tumor that may develop on the nerves near the inner ear controlling hearing and balance.

Arteriovenous Malformations (AVM): an abnormal vascular structure where an artery is directly connected to a vein without the normally intervening smaller arterioles, capillaries, and veins.

Chordoma: rare type of cancer that occurs in the bones of the skull and spine. It is part of a family of cancers called sarcoma. Slow growing but are relentless and tend to recur after treatment. Located close to critical structures such as the spinal cord, brainstem, nerves, and arteries.

Craniopharyngioma: brain tumor derived from the pituitary gland embryonic tissue, rare, slow growing.

Gliomas: a brain tumor that begins in a glial, or supportive cell, in the brain or spinal cord.

Glomus Jugulare Tumors: rare, slow growing, hypervascular tumors that arise within the jugular foramen of the temporal bone.

Hemangioblastoma: a type of benign, highly vascular tumor that can occur in the brain (usually the cerebellum) and spine. As it grows, it will press on the brain and cause neurologic symptoms.

Meningiomas: a common type of slow growing, usually non-life-threatening brain tumor that arises from the membranes covering the brain or spinal cord.

Non acoustic (non-vestibular) Schwannoma: very rare tumor of the intracranial nerves. About 10% of intracranial Schwannomas are non-acoustic.

Oligodendroglioma: slow growing brain tumor within the frontal, temporal, or parietal lobes and causes seizures in a relatively high percentage of patients. Many contain little specks of calcium (bone) and can easily bleed. Usually occurs in young adults.
Pilocytic Astrocytoma: benign, slow growing tumor of the brain or spinal cord. Usually diagnosed in children and young adults. Can become a very large tumor.

Pineocytoma: rare, benign, slow growing tumor of the pineal gland.

Pituitary Adenoma: a type of benign glandular tumor that usually remains confined to the pituitary gland; serious health problems may arise from this type of tumor if it becomes too large and compresses or causes damage to nearby parts of the brain, invades or presses on other portions of the pituitary gland causing a deficiency of pituitary hormones, or produces and releases too much of one or more pituitary hormones.

Sacromas: two types of sarcomas, bone and soft tissues. There are about 50 different types of soft tissue sarcomas. They can be benign or malignant.

Trigeminal Neuralgia (tic douloureux): a nerve disorder that stimulates the fifth cranial (trigeminal) nerve in the face and causes episodes of intense, stabbing, electric shock-like pain where the branches of the nerve are distributed to the lips, eyes, nose, scalp, forehead, upper jaw, or lower jaw.

Vestibular (acoustic) Schwannoma: most common tumor of cranial nerves. Usually benign and originating from the nerve sheath. About 90% arise from the eighth facial nerve.

Methods
Radiosurgery: a form of radiation therapy, which involves various technologies, to create highly focused beams of radiation to increase the accuracy of treatment.

Stereotactic: refers to the precise positioning of tumors and other lesions in three-dimensional space which allows for increased accuracy of treatment; for example, stereotactically, as a number of precisely aimed beams of ionizing radiation are aimed from several directions to converge on a tumor.

Technology:
Particle or Proton Beam: The particle form of SRS (i.e., proton beam or cyclotron) is in limited use in the United States. At present, fewer than 10 institutions in the U.S. have proton accelerators and stereotactic targeting equipment.

Linear Accelerator (LINAC): LINAC-based systems use x-ray beams generated from a linear accelerator. As a result, these devices do not require or generate any radioactive material. They deliver high-energy x-ray photons or electrons in curving paths around the patient's head. The primary advantages for LINAC are: LINAC is more available, can be used to deliver fractionated treatment and is able to use a larger x-ray beam, which enables it to treat larger tumors more uniformly and with less repositioning. Common brand names for modified LINACS include:
X-Knife® (Radionics, Burlington, MA), Peacock® (NOMOS Corp., Pittsburgh, PA), Clinac® and Trilogy™ (Varian Medical Systems, Palo Alto, CA) and CyberKnife® (Accuray Inc., Sunnyvale, CA), among others.

The CyberKnife System is a LINAC SRS system using a miniature linear accelerator mounted on a flexible robotic arm and several x-ray cameras that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment, and use this information to target the radiation beam emitted by the linear accelerator. No immobilization device is required. However, there is need for placement of very small markers via a needle for the treatment of targets outside of the head.

The CyberKnife System for Stereotactic Radiosurgery/Radiotherapy was approved by the FDA in 1999 for use in the head and neck above the cervico-thoracic junction. In 2001, CyberKnife with Dynamic Tracking Software (DTS) was approved to provide radiosurgery for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.

The Trilogy™ Radiotherapy Delivery System is a radiation therapy accelerator intended to deliver megavoltage x-ray treatments for conventional radiotherapy (i.e., three dimensional conformal radiotherapy and intensity modulated radiotherapy) and stereotactic radiosurgery and radiotherapy. Stereotactic treatments are intended for therapy of lesions (e.g., arteriovenous malformations, primary tumors and metastases). Stereotactic treatments may be intracranial or extracranial and consist of single-session or fractionated delivery.

Intensity modulated radiation therapy (IMRT) is a LINAC-based technology using computer-controlled "beam-shaping" (for additional information, refer to Policy RAD 014).

Cobalt60-based (photon)/Gamma Knife®: Gamma rays from radioactive cobalt-60 sources are focused on the tumor using 201 multiple small beams. Because of its high accuracy, it is usually used on small- to medium-sized lesions, whereas LINAC is usually used for larger lesions. Multiple targets in the brain can be treated during a single treatment session. It cannot be used for fractionated radiosurgery (FRS). It is designed to treat intracranial targets only.

**CPT/HCPCS Codes**

**Group 1 Paragraph:** *Note: Uses of 77373 and 77435 are addressed in both this LCD and in the Stereotactic Body Radiation Therapy LCD.*

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>77373</td>
<td>STEREOTACTIC BODY RADIATION THERAPY, TREATMENT DELIVERY, PER FRACTION TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5</td>
</tr>
</tbody>
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GROUP 2 PARAGRAPH: Uses of G0339 and G0340 are addressed in both this LCD and in the Stereotactic Body Radiation Therapy LCD.

**Stereotactic Radiosurgery (SRS)**

Effective for services furnished on or after January 1, 2014, hospitals must report SRS planning and delivery services using only the CPT codes that accurately describe the service furnished.

**GROUP 2 CODES:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61796</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): 1 SIMPLE CRANIAL LESION</td>
</tr>
<tr>
<td>61797</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): EACH ADDITIONAL CRANIAL LESION, SIMPLE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
<tr>
<td>61798</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): 1 COMPLEX CRANIAL LESION</td>
</tr>
<tr>
<td>61799</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): EACH ADDITIONAL CRANIAL LESION, COMPLEX (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
<tr>
<td>61800</td>
<td>APPLICATION OF STEREOTACTIC HEADFRAME FOR STEREOTACTIC RADIOSURGERY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
<tr>
<td>63620</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): 1 SPINAL LESION</td>
</tr>
<tr>
<td>63621</td>
<td>STEREOTACTIC RADIOSURGERY (PARTICLE BEAM, GAMMA RAY, OR LINEAR ACCELERATOR): EACH ADDITIONAL SPINAL LESION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)</td>
</tr>
</tbody>
</table>
PROCEDURE)
RADIATION TREATMENT DELIVERY, STEREOTACTIC
RADIOSURGERY (SRS), COMPLETE COURSE OF TREATMENT OF
CRANIAL LESION(S) CONSISTING OF 1 SESSION; MULTI-SOURCE
COBALT 60 BASED
RADIATION TREATMENT DELIVERY, STEREOTACTIC
RADIOSURGERY (SRS), COMPLETE COURSE OF TREATMENT OF
CRANIAL LESION(S) CONSISTING OF 1 SESSION; LINEAR
ACCELERATOR BASED
STEREOTACTIC RADIATION TREATMENT MANAGEMENT OF
CRANIAL LESION(S) (COMPLETE COURSE OF TREATMENT
CONSISTING OF 1 SESSION)

Group 3 Paragraph: Stereotactic Radiotherapy (SRT)

Group 3 Codes:
STEREOTACTIC BODY RADIATION THERAPY, TREATMENT
DELIVERY, PER FRACTION TO 1 OR MORE LESIONS, INCLUDING
IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5
FRACTIONS
STEREOTACTIC BODY RADIATION THERAPY, TREATMENT
MANAGEMENT, PER TREATMENT COURSE, 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 ECOG scale). See Karnofsky Performance Status or ECOG scale listed under Coverage Indications, Limitations and/or Medical Necessity above. Clinical treatment planning includes interpretation of special testing, tumor localization, treatment volume determinations, treatment time/dosage determinations, choice of treatment modality(ies), selection of appropriate treatment devices, verification process, and other procedures such as concurrent or sequential chemotherapy or surgery.

Documentation should include the date of service and the current treatment dose. A radiation oncologist must evaluate the clinical and technical aspects of the treatment, and document this evaluation as well as the resulting management decisions. All the documentation must support the complexity.

All documentation must be available upon request of the Medicare contractor. Documentation will be requested when the place of service (POS) is a free standing facility or Office.

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)(1) of the Social Security Act.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

Utilization Guidelines

1. Radiation oncologists and neurosurgeons have separate CPT billing codes for SRS. The comprehensive CPT codes 61796, 61797, 61798, 61799, 63620, 63621 may be billed by the neurosurgeon, as one member of the team, when and only when this physician is (a) present, (b) medically necessary and (c) fully participating, during the complete course of the procedure. It is not appropriate to bill for this code for any other circumstance. The medical record must clearly indicate the critical nature of the anatomy or other circumstances necessitating the services encompassed by this code.

2. A radiation oncologist may bill the SRS management code 77432 for single fraction SRS (and only once per treatment course) when and only when fully participating in the management of the procedure. In addition, a radiation oncologist may bill other appropriate
radiation oncology (77xxx) codes as indicated by the pattern of care and other Medicare policies.

3. CPT 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 will be paid only once per course of therapy regardless of the number of sessions, lesions or days of treatment.

4. CPT 77432 will be paid only once per course of treatment regardless of the number of cranial (and spinal) lesions. This code covers a “complete course of treatment consisting of one session.” CPT 77432 and CPT 77435 cannot both be billed for the same course of therapy.

5. As the services are collegial in nature with different specialties providing individual components of the treatment, surgical assistants will not be reimbursed.

Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer