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.

### 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 to
- 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:
a. Position stabilization (attachment of a frame or frameless)
b. Imaging for localization (CT, MRI, angiography, PET, etc.)
c. Computer assisted tumor localization (i.e. “Image Guidance”)
d. Treatment planning - number of isocenters, number, placement and length of arcs or angles, beam size and weight, etc.
e. Isodose distributions, dosage prescription and calculation
f. Setup and accuracy verification testing
g. Simulation of prescribed arcs or fixed portals

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.

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.

**Karnofsky Performance Status:**
100 Normal, without symptoms
50 Requires considerable assistance and frequent medical care
90 Able to carry on normal activity; minor signs or symptoms of disease
40 Disabled; requires special care and assistance
80 Normal activity with effort; some signs or symptoms of disease
30 Severely disabled; hospitalization is indicated
70 Cares for self; unable to carry on normal activity or do active work
20 Very sick; active support treatment is necessary
60 Requires occasional assistance; able to care for most personal needs
10 Moribund; fatal processes progressing rapidly

**ECOG 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 any 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.
I. 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.

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.

Indications for SRS

Intracranial lesions under the following conditions:
1. The lesion(s) has an image-distinct margin.
2. The Karnofsky Performance Scale is greater than 50% (range is 0 - 100% with 100% = maximum functional level) or the ECOG performance status should be 2 or less.
3. Specific indications will include:
   a. Neuromas of the cranial nerves including acoustic, trigeminal, etc.
   b. Intracranial unresectable meningioma and/or residual meningioma where the neurosurgeon determines the patient's medical condition precludes surgery; and where, because of the location of the tumor, surgery would result in devastating neurodeficits.
   c. Coverage for treatment of metastatic brain lesions under the following conditions:
      - Patients should have essentially otherwise stable disease.
      - The lesion(s) margins should be radiographically distinct.
      - The number of lesions treated should not exceed five.
   d. As a boost treatment for larger cranial lesions that have been treated initially with external beam radiation therapy or surgery: i.e., grade III and IV gliomas: pilocytic astrocytoma oligodendrogliomas sarcomas chordomas
e. Trigeminal neuralgia refractory to medical treatment. F
f. *Essential tremor (333.1): 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.

4. AV Malformations
5. Acoustic neuromas
6. Pituitary adenomas
7. Craniopharyngiomas
8. Globus Jugulare tumors

II. 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.

**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.

**Current indications for SRT include:**
**Benign Lesions**
1. Arteriovenous Malformations
2. Pituitary Adenoma
3. Vestibular shawnomatoma
4. Meninigioma

**Also for 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.

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
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 may cause seizures. In this case coding for the AVM would be appropriate. If and when literature supports coverage of SRS for treatment of certain lesions responsible for epilepsy we can reconsider. There are restrictions on coverage on other movement disorders.

Definitions:

Diseases:
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.

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

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

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.

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
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.

**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 Indications and Limitation of Coverage and/or Medical Necessity above.

Documentation should include the date 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 documentation must be available upon request of the Medicare carrier.

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.

When requesting a written redetermination (formerly appeal), please send all relevant documentation with the request.

Documentation will be requested when the place of service (POS) is a free standing facility or Office.

**Appendices**

**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.
### CPT/HCPCS Codes

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<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 FRACTIONS</td>
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<tr>
<td>77435</td>
<td>STEREOTACTIC BODY RADIATION THERAPY, TREATMENT MANAGEMENT, PER TREATMENT COURSE, TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS</td>
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**Uses of G0339 and G0340 are addressed in both this LCD and in the Stereotactic Body Radiation Therapy LCD.**

#### SRS

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<tr>
<td>77371</td>
<td>RADIATION TREATMENT DELIVERY, STEREOTACTIC RADIOSURGERY (SRS), COMPLETE COURSE OF TREATMENT OF CRANIAL LESION(S) CONSISTING OF 1 SESSION; MULTI-SOURCE COBALT 60 BASED</td>
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<td>77372</td>
<td>RADIATION TREATMENT DELIVERY, STEREOTACTIC RADIOSURGERY (SRS), COMPLETE COURSE OF TREATMENT OF CRANIAL LESION(S) CONSISTING OF 1 SESSION; LINEAR ACCELERATOR BASED</td>
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<td>77432</td>
<td>STEREOTACTIC RADIATION TREATMENT MANAGEMENT OF CRANIAL LESION(S) (COMPLETE COURSE OF TREATMENT CONSISTING OF 1 SESSION)</td>
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<td>G0173</td>
<td>LINEAR ACCELERATOR BASED STEREOTACTIC RADIOSURGERY, COMPLETE COURSE OF THERAPY IN ONE SESSION</td>
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#### SRT

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<td>STEREOTACTIC BODY RADIATION THERAPY, TREATMENT DELIVERY, PER FRACTION TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS</td>
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<tr>
<td>77435</td>
<td>STEREOTACTIC BODY RADIATION THERAPY, TREATMENT MANAGEMENT, PER TREATMENT COURSE, TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS</td>
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<tr>
<td>G0251</td>
<td>LINEAR ACCELERATOR BASED STEREOTACTIC RADIOSURGERY, DELIVERY INCLUDING COLLIMATOR CHANGES AND CUSTOM PLUGGING, FRACTIONATED TREATMENT, ALL LESIONS, PER SESSION, MAXIMUM FIVE SESSIONS PER COURSE OF TREATMENT</td>
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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
ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.

Note: The primary malignancy should be listed in addition to codes 198.3 or 198.4.

All ICD-9 codes associated with this policy are limited to lesions above the neck or on the spine.

SRS: 61796, 61797, 61798, 61799, 63620, 63621, 77371, 77372, 77432
SRT: G0251, G0339, G0340, *77435, *77373

**146.0 - 146.9**
MALIGNANT NEOPLASM OF TONSIL - MALIGNANT NEOPLASM OF OROPHARYNX

**147.0 - 147.9**
MALIGNANT NEOPLASM OF SUPERIOR WALL OF NASOPHARYNX - MALIGNANT NEOPLASM OF NASOPHARYNX UNSPECIFIED SITE

**160.0 - 160.9**
MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ACCESSORY SINUS UNSPECIFIED

**170.2**
MALIGNANT NEOPLASM OF VERTEBRAL COLUMN EXCLUDING SACRUM AND COCCYX

**190.0 - 190.9**
MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID - MALIGNANT NEOPLASM OF EYE PART UNSPECIFIED

**191.0 - 191.9**
MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES - MALIGNANT NEOPLASM OF BRAIN UNSPECIFIED SITE

**192.0**
MALIGNANT NEOPLASM OF CRANIAL NERVES

**192.1**
MALIGNANT NEOPLASM OF CEREBRAL MENINGES

**192.2**
MALIGNANT NEOPLASM OF SPINAL CORD

**192.3**
MALIGNANT NEOPLASM OF SPINAL MENINGES

**194.3**
MALIGNANT NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT

**194.4**
MALIGNANT NEOPLASM OF PINEAL GLAND

**198.0**
SECONDARY MALIGNANT NEOPLASM OF BRAIN AND SPINAL CORD

**198.4**
SECONDARY MALIGNANT NEOPLASM OF OTHER PARTS OF NERVOUS SYSTEM

**198.5**
SECONDARY MALIGNANT NEOPLASM OF BONE AND BONE MARROW

**198.89**
SECONDARY MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES

**225.0 - 225.2**
BENIGN NEOPLASM OF BRAIN - BENIGN NEOPLASM OF CEREBRAL MENINGES

**227.3**
BENIGN NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
227.4    BENIGN NEOPLASM OF PINEAL GLAND
227.6*   BENIGN NEOPLASM OF AORTIC BODY AND OTHER PARAGANGLIA
228.02   HEMANGIOMA OF INTRACRANIAL STRUCTURES
234.8*   CARCINOMA IN SITU OF OTHER SPECIFIED SITES
237.0    NEOPLASM OF UNCERTAIN BEHAVIOR OF PITUITARY GLAND AND
237.6    CRANIOPHARYNGEAL DUCT - NEOPLASM OF UNCERTAIN BEHAVIOR OF MENINGES
239.6    NEOPLASM OF UNSPECIFIED NATURE OF BRAIN
239.7    NEOPLASM OF UNSPECIFIED NATURE OF ENDOCRINE GLANDS AND OTHER PARTS
          OF NERVOUS SYSTEM
333.1*   ESSENTIAL AND OTHER SPECIFIED FORMS OF TREMOR
350.1    TRIGEMINAL NEURALGIA
350.8    OTHER SPECIFIED TRIGEMINAL NERVE DISORDERS
350.9    TRIGEMINAL NERVE DISORDER UNSPECIFIED
351.0 - 351.9    BELL'S PALSY - FACIAL NERVE DISORDER UNSPECIFIED
352.0 - 352.9    DISORDERS OF OLFATORY (1ST) NERVE - UNSPECIFIED DISORDER OF CRANIAL
                 NERVES
747.81    CONGENITAL ANOMALIES OF CEREBROVASCULAR SYSTEM
990*     EFFECTS OF RADIATION UNSPECIFIED

* ICD-9-CM codes 198.4, 198.5, 198.89, 234.8, 237.5, 237.6, 239.6, 239.7, 333.1, 352.0, 352.1,
          352.2, 352.3, 352.4, 352.5, 352.6, 352.9 and 747.81 are all limited to use for lesions occurring
          either above the neck or in the spine.

* ICD-9-CM 333.1 code 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

* ICD-9-CM 990 may only be used where prior radiation therapy to the site is the governing
          factor necessitating SRS in lieu of other radiotherapy. An ICD-9-CM code for the anatomic
          diagnosis must also be used.