

**Policy terminated because coverage is provided under the combined
Medicaid and Health Choice policy 1K-6, Radiation Oncology.**

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1.0 Description of the Procedure, Product, or Service

Stereotactic radiosurgery (SRS) is a method of delivering high doses of ionizing radiation to a small target within the cranium (skull). 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 and adjacent structures are spared.

1.1 Methods

The two main methods of this technology are gamma-ray radiosurgery (Gamma Knife®) and linear-accelerator radiosurgery (LINAC). The differences in the various sources are summarized in the following table:

Device	Energy Source	Characteristics of Energy Emitted
Gamma Knife®	201 separate cobalt-60 sources arranged in a steel shell; beams intersect on target	gamma rays, consisting of two photons with an average energy of 1.25 MeV.
Linear accelerator (LINAC) adapted for stereotactic use	single beam of x-rays, rotated to produce multiple intersecting beams	x-rays consisting of photons with an average energy of 2MeV

The above table shows that the gamma knife® and linear accelerator systems are similar in concept. Both use multiple photon radiation arcs that intersect at a stereotactically determined target. This permits higher doses of radiation to be delivered while sparing surrounding normal tissues. The difference between the two relate to how the energy is produced (through decaying cobalt or from x-rays) and the number of energy sources used (multiple energy sources in the gamma knife® versus one in the linear accelerator system).

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, and magnetic resonance imaging. SRS is typically performed in one session, usually requiring no more than an overnight hospital stay.

Stereotactic body radiation therapy (SBRT) refers to stereotactically guided radiation therapy that is given over several days. The ability to deliver fractionated radiation therapy is due to the recent design of noninvasive repositioning devices that can be used such as relocatable head frames. Stereotactic body radiation therapy gives the ability to deliver fractionated radiation which is thought to decrease the short and long term side effects of radiation therapy. In some situations it also permits higher total radiation dosage to be given.

Cyberknife® is a relatively new technology of delivering radiotherapy or radiosurgery using real-time image guidance. This technology uses a lightweight linear accelerator (LINAC) device utilizing a robotic manipulator to permit a wide range of beam orientations. Other examples of this technology include Brain-Lab Novalis and Tomotherapy and LINACS with computerized tomography (CT).

1.2 Stereostatic Radiosurgery (SRS)

SRS is a multistep procedure involving the following:

- a. localization of the target (responsibility of the radiation oncologist)
- b. radiation dose planning (responsibility of the radiation oncologist)
- c. attachment of the stereotactic head frame to the recipient (responsibility of the neurosurgeon)
- d. actual radiosurgery (may be done by either the radiation oncologist or the neurosurgeon)
- e. removal of the head frame (responsibility of the neurosurgeon)

1.3 The Most Common Applications of SRS

- a. The most common applications of SRS include treatment of intracranial metastases, arteriovenous malformations (AVMs), acoustic neuromas, and other benign intracranial tumors such as meningiomas or pituitary adenomas.

1. Intracranial Metastases.

Intracranial metastases have been considered ideal targets for radiosurgery due to their small spherical size, non-infiltrative borders, and location in non-eloquent areas of the brain. Brain metastases are a frequent occurrence, seen in 25 to 30% of all recipients with cancer, particularly in those with lung, breast, colon cancer or melanoma. The treatment of primary brain tumors such as gliomas is more challenging due to their generally larger size and infiltrative borders.

2. Acoustic Neuromas.

Acoustic neuromas are benign tumors originating on the eight cranial nerves, and they can be seen in association with neurofibromatosis. Although these tumors are benign, they are associated with significant morbidity and even death if their growth compresses vital structures. Treatment involves complete surgical excision using microsurgical techniques, but radiosurgery has also been investigated, either as a primary treatment or as a treatment of recurrence after incomplete surgical resection. In fact, acoustic neuromas were one of the first indications for gamma knife® radiosurgery, dating back to 1969.

3. Pituitary Adenomas.

Pituitary adenomas are benign tumors with symptoms that are related to hormone production (functioning adenomas) or to neurologic symptoms due to their impingement on surrounding neural structures. Treatment options for pituitary adenomas include surgical excision, conventional radiation therapy,

or SRS. Surgical excision is typically offered to recipients with functioning adenomas, since complete removal of the adenoma is required to control the autonomous hormone production and the effects of radiation therapy may be delayed or incomplete. In recipients with non-functioning adenomas, treatment goals are to control growth; complete removal of the adenomas is not necessary. Conventional radiation therapy has been used in this setting with an approximate 90% success rate with rare complications.

4. Arteriovenous malformations.

AVMs consist of a tangled network of vessels in which blood passes from arteries to veins without intervening capillaries. They range in size from small, barely detectable lesions to huge lesions that can occupy an entire hemisphere. SRS incites an inflammatory response in the vessels, which results in ongoing fibrosis with eventual complete obliteration over a course of months to years. This latency period is variable, depending on the size of the AVM and the dose distribution of the radiosurgery. During this latency period, there is an ongoing but declining risk of hemorrhage. In contrast, surgical excision provides an immediate effect on the risk of hemorrhage. Total surgical extirpation of the lesion, if possible, is the desired form of therapy in order to avoid future hemorrhage. However, there is a small subset of AVMs that because of their size or location cannot be excised without serious neurological sequelae. SRS is an important alternative in these recipients.

1.4 SRS as a Treatment of Functional Disorders.

More recently, SRS has been investigated as a treatment of functional disorders, which are defined as conditions having no detectable organic cause. Examples of functional disorders include trigeminal neuralgia, epileptic seizures, and chronic pain.

a. Trigeminal neuralgia.

Trigeminal neuralgia is a disorder of the fifth cranial (trigeminal) nerve that causes episodes of intense, stabbing pain in the face. Although trigeminal neuralgia is initially treated medically, in a substantial number of cases, drug treatment is either ineffective or the adverse effects become intolerable. Neurosurgical options include microvascular decompression, balloon compression, and rhizotomy. SRS has been investigated as an alternative to these neurosurgical treatments.

b. Seizure disorders.

Seizure disorders are initially treated medically, and due to its potential morbidity, surgical treatment is only considered in those rare instances when the seizures have proven refractory to all attempts at aggressive medical management, when the seizures are so frequent and severe as to significantly diminish quality of life, and when the seizure focus can be localized to a focal lesion in a region of the brain that is amenable to resection. SRS has been investigated as an alternative to neurosurgical resection.

c. Chronic pain.

For chronic pain that is refractory to a variety of medical and psychological treatments, there are a variety of surgical alternatives. Neurodestructive procedures

include cordotomy, myelotomy, dorsal root entry zone (DREZ) lesions, and stereotactic radiofrequency thalamotomy. SRS targeting the thalamus has been considered as an alternative to these neurodestructive procedures.

1.5 Stereotactic body radiation therapy (SBRT)

Stereotactic body radiation therapy (SBRT) is being studied for treatment of extracranial sites including lung tumors, liver tumors, and spinal lesions. This approach is being researched to better target the tumor (sparing surrounding tissue) and reduce the length of time to complete the treatment.

1.6 Medical Term Definitions

- a. Chronic: long-term, not acute or sudden.
- b. Fractionated: in radiology, to split up the dose of radiation into small doses given at intervals.
- c. Intracranial: within the cranium (skull). Refractory: not responding to treatment.
- d. Tomography: a technique of using x-rays or ultrasound waves to produce an image of structures at a particular depth within the body, bringing them into sharp focus. The visual record is called the Tomogram.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Stereotactic radiosurgery is covered under the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria are met.

- a. Stereotactic radiosurgery using a Gamma knife®, Cyberknife®, or linear accelerator (LINAC) unit may be considered medically necessary for the following indications:
 1. Arteriovenous malformations;
 2. Acoustic neuromas;
 3. Pituitary adenomas;
 4. Non-resectable, residual, or recurrent meningiomas;
 5. Solitary or multiple brain metastases [up to three (3)] in recipients having good performance status and no active systemic disease (defined as extracranial disease that is stable or in remission);
 6. Primary malignancies of the CNS, including but not limited to high-grade gliomas (initial treatment or treatment of recurrence);
 7. Trigeminal neuralgia refractory to medical management or in cases where the recipient is unable to tolerate the side effects of medications.
- b. Stereotactic Body Radiotherapy (SBRT) with Gamma knife®, Cyberknife®, or linear accelerator (LINAC) may be considered medically necessary for the following indications:
 1. Recipients with stage one (1) non-small cell lung cancer showing no nodal or distant disease and who are not candidates for surgical resection;
 2. Spinal or vertebral body tumors (metastatic or primary) in recipients who have received prior radiation therapy.

3.3 Policy Guidelines

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

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

- a. Stereotactic radiosurgery (SRS) is not covered in the following situations:
 1. SRS is considered investigational for any indications other than those listed in **Subsection 3.2**.
 2. SRS is considered investigational for the following applications including, the treatment of seizures and functional disorders (other than trigeminal neuralgia), including pain.
- b. Stereotactic body radiosurgery therapy (SBRT) is considered investigational for the treatment of extracranial sites, except for the cases of spinal tumors after prior radiation therapy and stage 1 non-small cell lung cancer as noted in **Subsection 3.2.b**.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for SRS.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
4/30/12	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes				
20660	61795	61796	61797	61798
61799	61800	63620	63621	77331
77332	77333	77334	77370	77371
77372	77373	77402	77403	77404
77406	77407	77408	77409	77411
77412	77413	77414	77416	77432
77435				

HCPCS Codes			
G0173	G0251	G0339	G0340

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.