Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Populations

<table>
<thead>
<tr>
<th>Individuals:</th>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• With nonmalignant or malignant intracranial lesion(s)(^a)</td>
<td>• Stereotactic radiosurgery</td>
<td>• Other forms of radiotherapy • Surgery • Combinations of other forms of radiotherapy, surgery, or chemotherapy</td>
<td>• Overall survival • Symptoms • Treatment-related morbidity</td>
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</tr>
<tr>
<td>• With nonmalignant or malignant intra- or extracranial lesion(s)(^b)</td>
<td>• Stereotactic body radiotherapy</td>
<td>• Other forms of radiotherapy • Surgery • Combinations of other forms of radiotherapy, surgery, or chemotherapy</td>
<td>• Overall survival • Symptoms • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

\(^a\) Intracranial lesions include: arteriovenous malformations; acoustic neuromas; pituitary adenomas; nonresectable, residual, or recurrent meningiomas; craniopharyngiomas; glomus jugulare tumors; primary malignancies of the central nervous system including, but not limited to, high-grade gliomas; trigeminal neuralgia refractory to medical management; epilepsy; functional disorders other than trigeminal neuralgia; tremors; chronic pain.

\(^b\) Extracranial lesions include: spinal or vertebral body tumors (primary) in patients who received prior radiotherapy; primary and metastatic tumors of the liver, pancreas, kidney, adrenal glands, and oligometastases, except metastases to the spine; uveal melanoma.

### Description

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. Both techniques differ from conventional external beam radiotherapy (EBRT), which involves exposing large areas of tissue to relatively broad fields of radiation over multiple sessions.
Summary of Evidence

Stereotactic Radiosurgery

The evidence for SRS in patients who have a variety of benign and malignant intracranial lesions includes randomized controlled trials (RCTs), nonrandomized retrospective cohort studies, and observational studies or case series. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. General limitations of the body of evidence include, but are not limited to, a lack of trials that directly compare SRS and comparators, patient heterogeneity within and between studies, and failure to use standardized methods to collect and report outcomes (benefits and harms). There are several contextual factors to consider, such as: SRS offers a noninvasive, highly precise radiotherapy alternative to surgery (particularly important for patients unable to undergo resection due to the presence of underlying comorbidities), intracranial lesions often are difficult to access surgically (and may be associated with a high risk for devastating adverse sequelae), intracranial lesions typically are located adjacent to vital organs and structures that are highly susceptible to radiation toxicities, and the accuracy and precision of SRS in this context make this technique a viable alternative to standard, nonconformal external beam radiotherapy. Finally, given the rarity of many of the conditions under review, direct comparative trials are unlikely.

The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome of patients who have arteriovenous malformations; acoustic neuromas; pituitary adenomas; nonresectable, residual, or recurrent meningiomas; craniopharyngiomas; glomus jugulare tumors; primary malignancies of the central nervous system; or trigeminal neuralgia refractory to medical management.

The evidence is insufficient to determine the effects of the technology on health outcomes in patients who have epilepsy; functional disorders other than trigeminal neuralgia; tremors; chronic pain; or uveal melanoma.

Stereotactic Body Radiotherapy

The evidence for SBRT in patients who have a variety of solid tumors or other metastatic lesions includes a few RCTs and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. Limitations of the evidence include a lack of comparative trials, heterogeneity between patients and treatment schedules and planning techniques, and failure to use standardized methods to collect and report outcomes. SBRT has been shown to improve outcomes (reduce pain) in patients with spinal (vertebral) tumors.

The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome in patients with spinal or vertebral body tumors (primary) in patients who have received prior radiotherapy.

The evidence is insufficient to determine the effects of the technology on health outcomes in patients who have solid tumors, primary or metastatic, of the liver, pancreas, kidney, adrenal glands and oligometastases, except metastases to the spine.

Policy

Stereotactic radiosurgery using a gamma ray or linear accelerator (LINAC) unit may be considered medically necessary for the following indications:

- arteriovenous malformations;
- acoustic neuromas;
- pituitary adenomas;
- non-resectable, residual, or recurrent meningiomas;
• craniopharyngiomas;
• glomus jugulare tumors;
• primary malignancies of the central nervous system (CNS), including but not limited to high-grade gliomas (initial treatment or treatment of recurrence);
• trigeminal neuralgia refractory to medical management.

Stereotactic body radiotherapy (SBRT) may be considered medically necessary for the following indication:
• spinal or vertebral body tumors (primary) in patients who have received prior radiotherapy.

When stereotactic radiosurgery or stereotactic body radiotherapy are performed using fractionation (defined in the Policy Guidelines) for the medically necessary indications described above, it may be considered medically necessary.

Investigational applications of stereotactic radiosurgery include, but are not limited to, the treatment of seizures and functional disorders (other than trigeminal neuralgia), including chronic pain, tremor, and uveal melanoma.

Investigational body radiotherapy is investigational for primary and metastatic tumors of the liver, pancreas, kidney, and adrenal glands except as outlined in the policy statements above.

Policy Guidelines

Radiation Source

This protocol addresses the use of SRS and SRBT delivered by gamma ray or high-energy photons generated by a linear accelerator (LINAC) unit. The use of charged particle (proton or helium ion) radiotherapies is addressed in the Charged-Particle (Proton or Helium Ion) Radiotherapy Protocol.

Fractionation

Fractionated SRS refers to SRS or SBRT performed more than once on a specific site.

SBRT is commonly delivered over three to five fractions.

SRS is most often single-fraction treatment; however, multiple fractions may be necessary when lesions are near critical structures.

Medicare Advantage

Medically necessary indications for SRS/SBRT (for Cranial Lesions only):
1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions < 5 cm.
2. Primary 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.
5. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy.
6. 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).

7. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

Limitations for SRS/SBRT (for Cranial Lesions only). SRS is considered \textbf{not 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 or clinically meaningful disease stabilization, not otherwise achievable.
3. Patients with wide-spread 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 three) (see Medicare Advantage Policy Guideline)
5. Cobalt-60 pallidotomy.

\textbf{Medically necessary} indications for Stereotactic Body Radiation Therapy (SBRT):

1. SBRT is indicated for primary tumors and tumors metastatic to the 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 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, see documentation requirements below).

Limitations for Stereotactic Body Radiation Therapy (SBRT):

1. Primary treatment of lesions of bone (primary), uterus, ovary, and other internal organs not listed in the policy statements above is considered \textbf{not medically necessary}.
2. SBRT is considered \textbf{not 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 three 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).

\textbf{Medicare Advantage Policy Guidelines}

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. 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.

**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

**Background**

**Note:** This protocol does not address this treatment for cancers of the prostate, breast, lung, colon, and rectum and including metastasis to the brain/spine or bone.

SRS and SBRT are techniques that use highly focused, conformal radiation beams to treat both neoplastic and non-neoplastic conditions. Although SRS and SBRT may be completed with one session (single fraction), SRS typically refers to a single-session procedure to ablate the target lesion. However, either technique may require additional sessions (typically not more than five) over a course of days, referred to as fractionated radiotherapy.

Platforms available for SRS and SBRT are distinguished by their source of radiation; they include gamma radiation from cobalt 60 sources; high-energy photons from LINAC systems; and particle beams (e.g., protons). Particle beam therapy is not covered in this protocol.

SRS and SBRT have been used for a range of malignant and nonmalignant conditions. A comprehensive review that encompasses all potential uses is beyond the scope of this protocol. Thus, a brief discussion follows of common applications of SRS and SBRT for which published evidence has been identified in database searches.

**Stereotactic Radiosurgery**

**Non-Neoplastic Conditions Treated With SRS**

An arteriovenous malformation (AVM) comprises a tangled network of vessels in which blood passes from arteries to veins without intervening capillaries. AVMs 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 of the lesion 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, an ongoing but declining risk of hemorrhage is present. 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 to avoid future hemorrhage. However, a small subset of AVMs because of their size or location cannot be excised without serious neurologic sequelae. SRS is an important alternative in these patients.

Trigeminal neuralgia is a disorder of the fifth cranial (i.e., 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.

Seizure disorders are initially treated medically. 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. 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 lesions, and stereotactic radiofrequency thalamotomy. SRS targeting the thalamus has been considered an investigative alternative to these neurodestructive procedures.

SRS for the destruction of the thalamic nuclei (thalamotomy) has been proposed for a treatment of essential tremor and other forms of tremor (i.e., secondary to Parkinson disease, multiple sclerosis, or other neurologic conditions), as an alternative to medical therapy or surgical therapy in extreme cases.

Neoplastic Conditions Treated With SRS

PRIMARY INTRACRANIAL TUMORS

Acoustic neuromas, also called vestibular schwannomas, are benign tumors originating on the eighth cranial nerve, sometimes associated with neurofibromatosis, which can be linked to significant morbidity and even death if their growth compresses vital structures. Treatment options include complete surgical excision using microsurgical techniques; radiosurgery has also been used extensively, either as a primary treatment or as a treatment of recurrence after incomplete surgical resection.

Pituitary adenomas are benign tumors with symptoms related to hormone production (i.e., functioning adenomas) or to neurologic symptoms due to their impingement on surrounding neural structures. Treatment options include surgical excision, conventional radiotherapy, or SRS. Surgical excision is typically offered to patients with functioning adenomas, because complete removal of the adenoma leads to more rapid control of autonomous hormone production. The effects of SRS on hormone production are delayed or incomplete. In patients with nonfunctioning adenomas, the treatment goal is to control growth; complete removal of the adenoma is not necessary. Conventional radiotherapy has been used in this setting with an approximate 90% success rate with few complications.

Craniopharyngiomas are benign; however, because of proximity to the optic pathways, pituitary gland, and hypothalamus, they may cause severe and permanent damage to these critical structures and can even be life-threatening. Total surgical resection is often difficult.

Because of the rarity of glomus jugulare tumors, various treatment paradigms are currently used. No consensus exists on optimal management to control tumor burden while minimizing treatment-related morbidity.

SRS has been used for the treatment of other primary brain tumors, including gliomas, meningiomas, and primitive neuroectodermal tumors (i.e., medulloblastoma, pineoblastoma). Treatment of primary brain tumors such as gliomas is more challenging, due to their generally larger size and infiltrative borders.

Melanoma of the uvea (choroid, ciliary body, and iris) is the most common, primary, malignant, intraocular tumor in adults. Established treatment modalities include enucleation, local resection, brachytherapy, and proton beam radiotherapy. The main objectives of treating the tumor are to reduce the risk of metastatic spread and to salvage the eye with useful vision if feasible. Treatment selection depends on tumor size and location, associated ocular findings, the status of the other eye, as well as other individual factors, including age, life expectancy, quality of life issues, concurrent systemic diseases, and patient expectations.
Stereotactic Body Radiotherapy

Extracranial Primary Tumors Treated With SBRT

Surgical resection is the preferred treatment of hepatocellular carcinoma, although at the time of diagnosis, less than 20% of patients are amenable to definitive surgical management due to advanced local disease or comorbidities. These patients may be candidates for local ablative therapies, including radiofrequency ablation and chemoembolization. Radiation may be considered as an alternative to local ablative/embolization therapies or if these therapies fail.

Radiation may be part of the treatment plan for pancreatic cancer, resectable or unresectable disease, and may be used in the adjuvant or neoadjuvant setting.

Localized renal cell carcinoma is conventionally treated surgically; local ablative methods may also be an option. Preoperative and adjuvant external radiation have not improved survival. However, because renal cell cancer brain metastases—although radioresistant to conventional external radiation—have been responsive to radiosurgery, interest remains in the possibility of treating primary kidney cancer with SBRT.

Extracranial Metastatic Tumors Treated With SBRT

Oligometastases are defined as isolated sites of metastasis, with the entire burden of disease being recognized as a finite number of discrete lesions that can be potentially cured with local therapies.\(^1\)

In general, the indications for SBRT for oligometastases are the same as for metastasectomy. Recently proposed specific criteria for the use of SBRT in patients with oligometastases include: a controlled primary, favorable histology, limited metastatic disease, metachronous appearance of metastases, young age, and good performance status.\(^1\)

Management of metastatic solid tumors has historically focused on systemic treatment with palliative intent. However, surgical treatment of oligometastatic disease is now common practice in some clinical settings.\(^2\)

Although cure may be possible in some patients with oligometastatic disease, the aim of SBRT in this setting is mainly to achieve local control and delay progression, which also may postpone the need for further treatment.

Metastases from NSCLC to the adrenal gland are common, and systemic treatment is the most frequent therapeutic option. Nevertheless, in patients suffering from an isolated adrenal metastasis, a survival benefit could be achieved after surgical resection.

Spinal Primary and Metastatic Tumors Treated With SBRT

Metastatic tumors to the spine have historically been treated with conventional radiotherapy. The need for retreatment is high due to morbidity from metastatic disease (e.g., pain, myelopathy, spinal cord compression), but radiotherapy to the spine is often limited due to concern for radiation myelopathy and other adverse radiation effects. SBRT to the spine has been most widely studied in patients requiring re-irradiation, but interest has also developed in the use of SBRT for the initial treatment of spinal tumors.

Regulatory Status

Several devices that use cobalt 60 radiation (gamma ray devices) for SRS have been cleared for marketing by FDA through the 510(k) process. The most commonly used gamma ray device is the Gamma Knife® (Elekta, Stockholm; approved May 1999; product code IWB), which is a fixed device used only for intracranial lesions. Gamma ray emitting devices that use cobalt 60 degradation are also regulated through the U.S. Nuclear Regulatory Commission.

A number of LINAC movable platforms that generate high-energy photons have been cleared for marketing by FDA through the 510(k) premarket notification process. Examples include the Novalis Tx® (Novalis, Westchester,
IL); the TrueBeam STx (Varian Medical Systems, Palo Alto, CA; approved December 2012; product code IYE); and the CyberKnife® Robotic Radiosurgery System (Accuray, Sunnyvale, CA; approved December 1998; product code MUJ). LINAC-based devices may be used for intracranial and extracranial lesions.

Related Protocols

Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
Intensity-Modulated Radiotherapy: Abdomen and Pelvis
Intensity-Modulated Radiotherapy: Central Nervous System Tumors
Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


48. Raizer J. Radiosurgery and whole-brain radiation therapy for brain metastases: either or both as the optimal treatment. JAMA. Jun 7 2006; 295(21):2535-2536. PMID 16757726


