Policy Title: Stereotactic radiosurgery and stereotactic body radiotherapy

Coverage policy

Select Health of South Carolina considers the use of stereotactic radiosurgery (SRS) to be clinically proven and, therefore, medically necessary for persons age 18 years or older for any of the following conditions:

1. Primary central nervous system malignancies, generally under 5 cm.
2. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent boney structures.
3. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, pituitary adenomas, and pineal cytomas.
5. 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.
6. As a boost treatment for larger cranial 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 malignances).
7. Metastatic brain or spine lesions, generally limited in number, with stable systemic disease, Karnofsky Performance Status 70 (out of 100) or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations.

8. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation (CMS, L34223).

Select Health of South Carolina considers the use of stereotactic body radiotherapy (SBRT) to be clinically proven and, therefore, medically necessary for persons age 18 years or older for any of the following:

1. Treatment of pelvic and head and neck tumors that have recurred after primary irradiation.
2. Treatment of patients with clinically localized, low- to intermediate-risk prostate cancer.
3. Treatment of any site or internal organ for 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 (CMS, L35076).

Limitations:

Select Health of South Carolina considers SRS to not be clinically proven, and thus investigational/experimental, for any of the following:

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. Patients with wide-spread cerebral or extra-cranial metastases.
4. Patients with poor performance status (Karnofsky Performance Status less than 40 of 100).
5. Stereotactic cingulotomy as a means of psychotherapy.
6. For ICD-10-CM code G25.0, essential tremor, only for patients who cannot be controlled with medication, have major systemic disease or coagulopathy, and who are unwilling or unsuited for open surgery.
7. Unilateral thalamotomy.
8. Gamma Knife pallidotomy (CMS, 34233).

Select Health of South Carolina considers SBRT to not be clinically proven, and thus investigational/experimental, for any of the following:

1. Primary treatment of lesions of bone, breast, uterus, and ovary.
2. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
3. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
4. The patient has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group Status of 3 or worse).

5. Recurrent (other than pelvic and head and neck tumors) or metastatic disease that could be treated by conventional methods.

6. Any course of radiation treatment extending beyond five fractions is not considered SBR, which is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment (CMS, L35076).

Alternative covered services:

- Medical therapy.
- Surgery.
- Chemotherapy.
- Other forms of radiation therapy (e.g., external beam radiation therapy, intensity-modulated radiation therapy).
- Deep brain stimulation.
- Endovascular embolization.

Background

SRS is a form of radiation therapy that delivers multiple-intersecting, precisely targeted external beam radiation therapy at much higher doses than traditional radiation therapy. Despite its name, there is no surgical incision or resection involved but rather selective ablation. SRS employs three-dimensional imaging and localization techniques that permit maximum dose delivery within the targeted lesion while minimizing the radiation dose to the surrounding healthy tissue (RSNA, 2015).

SRS may be delivered in a single, large dose or a few (usually two to five) fractionated treatments at lower dosage than SRS but still higher than that of traditional external beam radiation therapy. Multiple treatments are important for lesions larger than one inch in diameter, as the volume of normal surrounding tissue also treated increases proportionally to the lesion size. Fractionating radiation treatment in a few sessions as opposed to one can improve safety and allow the normal tissue to heal in between treatments (RSNA, 2015).

SRS systems use either photon-based or proton-based radiation sources. The two photon SRS systems are Cobalt-60 based gamma-emitting radiation and linear accelerator generated X-rays; proton SRS employs heavy charged particle beams from a cyclotron (Amichetti, 2012; RSNA, 2015):

- Cobalt-60 gamma radiation-emitting sources were introduced in clinical practice at the end of the 1960s. The Gamma Knife® (Elekta Instruments AB, Stockholm, Sweden) uses 192 or 201 beams of highly focused gamma rays all aiming at the target region. It is the most commonly used SRS system for intracranial radiosurgery, particularly for treating small- to medium-sized intracranial lesions and irregularly shaped targets.
• Linear accelerator machines are prevalent throughout the world and can perform SRS on larger tumors in a single session or during multiple sessions. Multiple manufacturers make this type of machine (e.g., CyberKnife®, Accuray, Sunnyvale, CA). Radiation delivered by linear accelerator-based SRS is more homogeneous in dose than that delivered by Gamma Knife, an advantage when treating larger tumors that include radiation-sensitive brain structures.

• Protons release most of their energy within the tumor region and, unlike photons, deliver only a minimal dose beyond the tumor boundaries, thus helping to spare normal tissue from radiation better than photons do. Proton beam SRS is in limited use in North America, although the number of centers offering proton therapy has increased in recent years. (This policy addresses clinical indications using photon-based systems only. For proton-based systems, see Clinical Policy #05.02.01 Proton beam therapy.

SRS was initially developed to treat small tumors and functional abnormalities of the brain. The principles of cranial SRS are now applied to treating body tumors. This is stereotactic body radiotherapy (SBRT), or stereotactic ablative radiotherapy (SABR) (Amichetti, 2012). SBRT is typically performed using linear accelerator-based systems. SBRT may use a body frame designed to immobilize patients. For such treatment, frameless systems that rely on skeletal landmarks or implanted fiducial markers locate and guide the therapy beam. SBRT’s reported theoretical advantages compared to other forms of EBRT include the use of high-dose radiation; the delivery of one to five fractions within fewer days (e.g., two to three days), thereby decreasing the overall length of treatment; and an improved treatment response. Limitations of SBRT include difficult administration because of body movements, a higher potential for radiation injury because of a higher radiation fraction dose than external beam radiation therapy, and required strict quality control of the tumor images and the regular verification of the image sets.

SRS and SBRT are proposed as alternatives to invasive surgery (RSNA, 2015):
• When surgery is not feasible.
• For tumors and abnormalities that are hard to reach, located close to vital organs/anatomic regions, or subject to movement within the body.
• For macroscopic residual after surgical intervention.
• As an alternative, definitive treatment.

Searches

Select Health of South Carolina searched PubMed and the databases of:
• UK National Health Services Centre for Reviews and Dissemination.
• Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
• The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on April 6, 2018. Search terms were “radiosurgery,” “radiotherapy,” “stereotactic,” and “gamma knife.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Select Health of South Carolina identified many systematic reviews and evidence-based guidelines for this policy. The majority of studies were case series of adults with intracranial indications treated with Gamma Knife, reflecting the preponderance of clinical experience with Gamma Knife in these areas. Evidence from randomized controlled trials is available for the following indications:

- SRS as an adjunct to whole-brain radiation therapy in persons with a single brain metastasis or with four or fewer metastases.
- A comparison of SRS added to external beam radiation therapy and carmustine versus external beam radiation therapy and carmustine only in persons with newly diagnosed malignant glioma.
- A comparison of SRS to other approaches for treating disease recurrence/progression of brain metastases.
- A comparison of medical management to medical management plus interventional therapy in adults with small arteriovenous malformations less than 3 cm in size (the Unruptured Brain Arteriovenous Malformations Trial [ARUBA trial], ClinicalTrials.gov identifier NCT00389181).

For treatment of solid malignant tumors outside the brain, head, and neck, most studies focused on SBRT of thoracic tumors in adults using modified linear accelerator and CyberKnife systems, as Gamma Knife is not used for therapy outside these regions. The evidence consists of prospective or retrospective, uncontrolled case series limited by a lack of uniform reporting of treatment populations and outcomes.

The evidence is insufficient to support the superiority of one SRS system over another, including **robotically assisted SRS**. Evidence from randomized controlled trials directly comparing one SRS system to another is lacking. Indirect comparisons from low-quality cohort studies suggest at least comparable safety and efficacy of robotically assisted SRS and nonrobotic photon-based SRS treatment for
intracranial indications. Evidence-based guidelines make no recommendations for one SRS system over another (CADTH, 2014; Hayes, 2011; Boudreau, 2009).

The evidence is sufficient to support the use of SRS for intracranial tumors that are likely to benefit from radiation therapy, are not suitable for surgical treatment due to lesion location or poor patient health, or are not suitable for less sophisticated forms of radiation therapy such as whole brain radiation therapy or conformal radiation therapy.

**Brain metastases from an extracranial source:** There is high-quality evidence from randomized controlled trials supporting the use of SRS for treatment of three or fewer brain metastases in patients who have good performance status (a score between 80 and 100 on the Karnofsky Performance Scale; i.e., at a minimum, able to perform normal activity with effort) and no active systemic disease (defined as extracranial disease that is stable or in remission). Single-dose SRS along with whole brain radiation therapy led to significantly longer patient survival compared with WBRT alone for patients with a single brain metastasis who have a Karnofsky Performance Scale ≥70. The National Comprehensive Cancer Network regards surgical resection or SRS followed by whole brain radiation therapy as the standard of care for solitary brain metastases, but SRS alone or SRS following resection may be considered (NCCN, 2015). The American College of Radiology recommends surgery for tumors greater than 4 cm in greatest diameter or causing significant mass effects in persons with single brain metastasis, but the College stated no clear treatment preference for a smaller metastasis, as no randomized controlled trial comparing surgery to SRS has been done in this population (Vassil, 2012).

A systematic review of 14 articles (n=1024) assessed the ability of SBRT to improve previously untreated spinal metastases. A 90 percent one-year local control rate was reported; and a 54 percent complete pain response rate was observed in the three studies that reported this measure. The most common adverse event was new/progressing vertebral compression fracture (Husain, 2017).

The efficacy of SRS and SBRT is pronounced in cancers with a rising incidence over time that can metastasize to the brain, spine, and nervous system. One such malignancy is renal cell cancer. A systematic review of nine studies comparing SBRT with conventional external beam radiotherapy showed an improvement in pain in 41 to 95 percent of patients. Local control rates after SBRT ranged 71.2 - 85.7 percent after one year, a significant improvement over conventional therapy (Smith, 2018).

For patients with two to three metastases, SRS plus whole brain radiation therapy improved performance status and local control, and possibly contributed to longer patient survival, than whole brain radiation therapy alone. The American College of Radiology and National Comprehensive Cancer Network recommend SRS alone or with whole brain radiation therapy in persons with two to three metastases, regardless of resectability status (NCCN, 2015; Videtic, 2014). However, since the effectiveness of SRS for patients with multiple metastases may be primarily a function of proper patient selection, it may not replace the benefits of whole brain radiation therapy for the majority of patients with multiple brain metastases. The National Comprehensive Cancer Network also considers whole brain radiation therapy or SRS as primary therapy in patients with more than three metastatic lesions,
good performance status, and low overall tumor volume; this rationale is based on using overall tumor volume rather than the number of metastases to determine appropriate therapy (NCCN, 2015).

A meta-analysis of five studies (n = 763) compared patients with brain metastases who underwent whole brain radiation therapy versus SBRT, or both. No significant survival benefits were noted for any of the three approaches, but local control was significantly greater when whole brain radiotherapy was combined with SRS. No difference in adverse events was observed between groups (Khan, 2017). However, a Cochrane review (meta-analysis) of two studies (n=358) documented no difference in overall survival between patients given whole brain radiation therapy with or without SRS, despite less local failure, better performance scores, and less steroid use in patients with both procedures (Khan, 2017).

**Primary malignant or benign brain tumors:** Multiple case series and evidence-based guidance suggest a role for SRS as a primary- or second-line treatment for some primary malignant or benign brain tumors (excluding low-grade gliomas) that are small to medium in size (generally less than 3 cm in greatest diameter), not completely resectable, have failed conventional therapy, or are not amenable to alternative treatment (NCCN, 2015). SRS may offer comparable local control and improved short-term preservation of neurological function and quality of life versus microsurgery, but there is a clear need for well-designed clinical trials of treatment alternatives in specific diseases.

**Recurrent/progressive brain metastases:** There is insufficient evidence to make definitive treatment recommendations in this population. The American College of Radiology considers SRS alone or in combination with other modalities valid approaches to managing patients with brain recurrences even after prior therapies (including WBRT) and especially if limited new foci are present (Patel, 2011). For local recurrences, SRS may be considered in patients who were previously treated with surgery only or in patients previously treated with SRS with a durable response for more than six months (NCCN, 2015). Ultimately, the decision to proceed with SRS should be individualized based on a patient's functional status, extent of disease, volume/number of metastases, recurrence or progression at original versus non-original site, previous treatment, and type of primary cancer; enrollment in clinical trials is encouraged.

The evidence is **sufficient** to support the use of SRS for treatment of small arteriovenous malformations of the brain with maximum volume of 10 cm$^3$ or maximum diameter of 3 cm in persons with high surgical risk. Treatment goals for AVMs are typically the prevention of hemorrhage, seizure control, or stabilization of progressive neurological deficits. Factors increasing the risk of subsequent hemorrhage are an arteriovenous malformation presenting with hemorrhage, its vascular anatomy, and deep location (Ogilvy, 2001). Results of a large number of cohort studies suggest SRS is effective for AVMs smaller than 3.5 cm, but complete obliteration requires approximately one to three years after treatment and cure is not always obtained. Delayed complications such as hemorrhage in the latency period and radiation edema or necrosis can occur.

Evidence-based guidance recommends selecting candidates for SRS on the basis of AVM volume and location, patient age, and relative risk analysis compared with surgical and endovascular therapies as
predicted by the Spetzler-Martin Grade scale (IRSA, 2009; Ogilvy, 2001). Surgery is recommended as the primary treatment for arteriovenous malformations of Spetzler-Martin Grade I or II in persons with low surgical risk, although observation may be a viable alternative in this population with a low hemorrhage risk based on interim results of the multicenter randomized controlled trial Unruptured Brain Arteriovenous Malformations Trial (ARUBA, ClinicalTrials.gov identifier NCT00389181).

SRS may be considered primary treatment for persons with small arteriovenous malformations of Spetzler-Martin Grade I or II who are at high surgical risk based on location and vascular anatomy. SRS may be indicated for small brain arteriovenous malformations of higher Spetzler-Martin Grade as part of a multimodal approach in persons who are at high surgical risk (IRSA, 2009; Ogilvy, 2001). The American Association of Neurological Surgeons also recommends SRS to reduce the size of large arteriovenous malformations otherwise associated with significant surgical morbidity by single-dose SRS, fractionated SRS, or splitting the volume of the nidus (AANS, 2015). However, evidence for this recommendation is lacking.

The evidence is sufficient to support the use of SRS for treatment of classic trigeminal neuralgia in patients refractory to medical therapy who continue to have pain. Uncontrolled studies suggest 55 to 89 percent of patients improved pain relative to pretreatment status that could not be adequately controlled with medication at two to four years after SRS. Studies comparing the efficacy of SRS to other treatments are lacking, and uncertainty exists regarding the efficacy of most neurosurgical procedures for trigeminal neuralgia because of poor trial quality. According to the American Academy of Neurology and the European Federation of Neurological Societies, anticonvulsants (e.g., carbamazepine and oxcarbazepine) are first-line therapy for trigeminal neuralgia; lamotrigine or baclofen may also be added (Gronseth, 2008). For patients with classic trigeminal neuralgia who have failed medical therapy and continue to have pain, microvascular decompression via craniotomy, percutaneous ablation and SRS targeting the trigeminal root in the posterior fossa may be considered. SRS may also have a role in treating persons who refuse other treatments or with medical comorbidities.

There is sufficient evidence to support the use of SBRT for treatment of persons with stage 1 non-small cell lung cancer who are medically inoperable or who refuse surgical resection. The majority of clinical studies of SBRT addressed persons with medically inoperable early-stage non-small cell lung cancer (Tipton, 2011). No comparative studies have been published to date, but evidence from multiple case series suggests high rates of local control (85 to 98.5 percent) and low toxicity (four percent) associated with SBRT in this population, with survival rates comparable to surgery. Both the American College of Chest Physicians and the American College of Radiology regard surgical resection as the standard of care for medically operable stage 1 non-small cell lung cancer; SBRT may be considered for patients with clinical stage 1 lung cancer deemed unable to tolerate a lobectomy or segmentectomy or who refuse surgery (Howington, 2013; Videtic, 2013).

More recently, a meta-analysis of six studies (n=864) showed overall survival at one and three years after treatment was significantly lower for non-small cell lung cancer patients given SBRT than those undergoing surgery (Zhang, 2014). This finding was duplicated in a systematic review of 81 studies that
showed significantly greater survival for particle beam therapy than for SBRT in non-small cell lung cancer patients (Chi, 2017).

Ongoing studies are defining the role of SBRT in this population. For example, two phase III studies comparing SRS or hypofractionated SRS to conventional radiation therapy are slated for completion in 2018 (clinicaltrials.gov identifiers NCT01014130 and NCT01968941), and one phase III study is evaluating the value of stereotactic ablative radiotherapy added to standard chemotherapy in patients with oligometastatic non-small cell lung cancer (clinicaltrials.gov identifier NCT02417662). A number of phase II studies are evaluating SBRT for high-risk or fully operable early-stage non-small cell lung cancer and the optimal SBRT dose and fractionation in different clinical situations, e.g., central lesions (Vidatic, 2013).

There is insufficient evidence of safety and efficacy to support the use of either SRS or SBRT for all other indications. There is no consensus among guidelines regarding the use of SRS for other intracranial uses. For SBRT, no comparative studies have been completed to confirm the theoretical advantages of SBRT over other radiotherapies in the clinical setting. An Agency for Healthcare Research and Quality report acknowledged its wide dissemination for treatment of a variety of cancer types, and most studies addressed treatment for lung/thoracic tumors (Tipton, 2011). Subsequent systematic reviews of SBRT have identified limited small case series for a range of solid tumors.

A literature review concluded that SBRT, which had low rates of short- and long-term toxicity, had similar incidence of regional recurrence, as did surgery for lung cancer (Wink, 2017). A meta-analysis of 12 articles (n=1716) found that SRS alone had a greater rate of complete obliteration of brain arteriovenous malformations, compared to SRS with prior embolization (62.7 versus 48.4 percent), but the adverse effect rate in the SRS-only group was higher (11.1 versus 6.6 percent) (Russell, 2017). Another systematic review found that macrovascular decompression produced a significantly greater quality of life than SRS, seven years after treatment (Berger, 2017).

Policy updates:

A total of three guidelines/other and four peer-reviewed references were added to, and three guidelines/other and three peer-reviewed references removed from, this policy in April 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Husain (2017)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Stereotactic body radiotherapy for previously untreated spinal metastases</td>
<td>• Systematic review of 14 articles (n=1024) of previously untreated spinal metastases.</td>
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<tr>
<td></td>
<td>• Median follow-up ranged from 9 to 49 months.</td>
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<td></td>
<td>• A 90 percent one-year local control rate after SBRT was reported.</td>
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<td></td>
<td>• In-field local tumor control assessment showed 85% of 407 lesions remained controlled.</td>
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<tr>
<td></td>
<td>• A 54 percent complete pain response rate was observed in three studies.</td>
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</tbody>
</table>
The most common adverse event was new/progressing vertebral compression fracture, reported in 9.4% of cases.

### CADTH (2014)
Hayes (2011)
Boudreau (2009)
Comparison of different SRS systems

**Key points:**
- Low-quality evidence suggests robotically assisted SRS is at least as safe and effective as nonrobotic SRS. Most studies used Gamma Knife or CyberKnife systems for intracranial indications.
- Direct comparisons from RCTs are lacking.
- Insufficient evidence to reliably estimate the comparative clinical effectiveness (benefit and harm), cost effectiveness and impact on quality of life of TomoTherapy®, Gamma Knife and CyberKnife.
- No guidelines identified specific to a particular SRS system or evidence-based recommendations on which SRS system to use in any particular clinical situation.

### Ratko (2013) for AHRQ
Zheng (2014)
Non-small cell lung cancer (NSCLC)

**Key points:**
- No comparative studies of SBRT versus other RT interventions for either medically inoperable patients with stage I NSCLC or medically operable patients with stage I NSCLC.
- Meta-analysis of 10 prospective studies, 30 retrospective SBRT case series studies (n = 4850) and 23 retrospective surgical case studies (n = 7071) published between 2000 and 2012 found no significant differences in overall survival or local control among patients undergoing SBRT, lobectomy, and limited resection, adjusting for age and operability status. Low toxicity. (High risk of bias and significant heterogeneity.)
- Safety and efficacy of surgical resection has been demonstrated in RCTs and remains the current standard for patients with medically operable lesions; SBRT may be offered to patients with medically inoperable limited lesions or those who refuse surgical resection.

### Zhang (2014)
Early-stage non-small cell lung cancer

**Key points:**
- Efficacy of SBRT vs. surgery for early-stage NSCLC.
- Meta-analysis, 6 studies, 864 patients.
- Overall survival (OS) for 1- and 3-year post-operative follow-up higher for surgery group.
- No difference between groups in 1) cancer-specific survival, 2) disease-free survival, 3) local control, 4) distant control.

### References

**Professional society guidelines/other:**


ACR Appropriateness Criteria® retreatment of recurrent head and neck cancer after prior definitive radiation. Reston (VA): American College of Radiology (ACR); 2014. 12 p. [67 references].


Radiological Society of North America, Inc. (RSNA). Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT). 2015. Available at:


Peer-reviewed references:


Soon YY, Tham IW, Lim KH, Koh WY, Lu JJ. Surgery or radiosurgery plus whole brain radiotherapy versus surgery or radiosurgery alone for brain metastases. *Cochrane Database of Systematic Reviews.* 2014(3);CD009454. Doi: 10.1002/14651858.CD009454.pub2.


van Beijnum J, van der Worp HB, Buis DR, et al. Treatment of brain arteriovenous malformations: a


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

L34224 Stereotactic Body Radiation Therapy. Effective date October 1, 2015. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=34224&ver=9&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=34224&ver=9&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&).

Accessed April 6, 2018.

L35076 Stereotactic Radiation Therapy. Stereotactic Radiation Surgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). Effective date October 1, 2015. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=35076&ver=35&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&.](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=35076&ver=35&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&).

Accessed April 6, 2018.

L34151 Stereotactic Radiation Therapy. Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). Effective date October 1, 2015. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=34151&ver=20&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&.](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDid=34151&ver=20&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAA&).

Accessed April 6, 2018.

L33410  Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). Effective date October 1, 2015. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33410&ver=13&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=stereotactic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed April 6, 2018.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>77387</td>
<td>Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed</td>
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<tr>
<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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<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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<table>
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<th>ICD-10 Code</th>
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<tr>
<td>C75.3</td>
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Appendix

CMS Documentation Requirements and Utilization Guidelines

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). 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 five 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.