EFFECTIVE DATE:12/01/2014
POLICY LAST UPDATED: 11/04/2014

OVERVIEW

This policy documents the coverage guidelines for Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy. Stereotactic radiosurgery (SRS) is a method of delivering high doses of precisely targeted ionizing radiation to intracranial lesions. SRS, when used extracranially, is called stereotactic body radiation therapy (SBRT). The technique differs from conventional radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over a longer duration of sessions. SRS and SBRT entail delivering highly focused convergent beams sparing adjacent structures. It may offer a non-invasive alternative to invasive surgery, particularly for patients unable to undergo surgery or for lesions that are difficult to access surgically or are adjacent to vital organs.

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial

Prior authorization is required for Stereotactic body radiation therapy (SBRT) for BlueCHiP for Medicare and recommended for Commercial products and is obtained via the online tool for participating providers. See Related Policies section.

Prior authorization is not required for the covered stereotactic radiosurgery (SRS) for BlueCHiP for Medicare and for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Stereotactic radiosurgery (SRS) is covered.

Stereotactic body radiation therapy (SBRT) is covered for any of the conditions listed in the medical criteria below.

SBRT is considered not medically necessary for all other indications not listed in the medical criteria as there is insufficient clinical evidence to support its efficacy.

MEDICAL CRITERIA

BlueCHiP for Medicare:

Stereotactic body radiation therapy (SBRT) is considered medically necessary for the following indications:

- Retroperitoneal metastases;
- Hepatic and Pancreatic tumors;
- Pulmonary tumors;
- Mediastinal tumors;
- Prostate neoplasm;
- Spinal tumors;
- Intracranial lesions

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial Products:
Stereotactic body radiation therapy (SBRT) is considered medically necessary for any the following indications:

- Patients with stage T1 or T2a non-small cell lung cancer (not larger than 5 cm) showing no nodal or distant disease and who are not candidates for surgical resection;
- Spinal or vertebral body tumors (metastatic or primary) in patients who have received prior radiation therapy.
- Intracranial lesions

BACKGROUND

SRS and SBRT are techniques that use highly focused radiation beams to treat both neoplastic and non-neoplastic conditions, in contrast to traditional external radiation beam therapy (EBRT), which involves the use of relatively broad fields of radiation over a number of sessions that may occur over weeks to months. SRS and SBRT rely on 3-dimensional imaging to localize the therapy target. Because they are more targeted than traditional EBRT, SRS and SRBT are often used for treatment at sites that are difficult to reach via surgery, located close to other vital structures, or subject to movement within the body.

Both SRS and SBRT may be completed with 1 session (single-fraction) or less may require additional sessions (typically no more than 5) over a course of days, referred to as fractionated stereotactic radiotherapy. The fractionation used for SRS and SBRT is less than that used for conventional EBRT, thus, "hypofractionated." Fractionation of stereotactic radiotherapy aims to optimize the therapeutic ratio; that is the ratio between tumor control and late effects on normal tissues. The main advantage of fractionation is that it allows higher total doses to be delivered to the tumor because of increased tolerance of the surrounding healthy tissues to each individual, fractionated dose. In addition, some lesions such as large arteriovenous malformations may require more than 1 procedure to complete the obliteration process.

The most commonly used gamma ray device is the Gamma Knife® (Elekta Inc., Stockholm), which is a fixed device used for intracranial lesions, typically for smaller lesions. Several brands of LINAC devices are available, including the Novalis Tx® (Novalis, Westchester, IL), the TrueBeamSTx (Varian Medical Systems, Palo Alto, CA), and the CyberKnife® system (Accuray, Sunnyvale, CA).

Applications of SRS and SBRT

SRS

The most common applications of SRS include treatment of intracranial malignancies, including primary and metastatic tumors, and benign intracranial tumors such as meningiomas, pituitary adenomas, and acoustic neuromas (vestibular schwannomas). SRS has been used for trigeminal neuralgia that is resistant to other therapies. It is also an established treatment for arteriovenous malformations (AVMs). More recently, SRS has been investigated as a treatment of functional disorders, which are defined as conditions having no detectable organic cause.

Arteriovenous malformations 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 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, 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 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 (ie, 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 (DREZ) 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 (ie, secondary to Parkinson disease, multiple sclerosis, or other neurologic conditions), as an alternative to medical therapy or surgical therapy in extreme cases.

SRS is used for primary intracranial tumors and tumors that have metastasized to the CNS.

Acoustic neuromas, also called vestibular schwannomas, are benign tumors originating on the eighth cranial nerve, sometimes seen in association with neurofibromatosis, which can be associated with significant morbidity and even death if their growth compresses vital structures. Treatment options include complete surgical excision using microsurgical techniques, but 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 that are related to hormone production (ie, functioning adenomas) or to neurologic symptoms due to their impingement on surrounding neural structures. Treatment options for pituitary adenomas 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, may cause severe and permanent damage to such critical structures and can even be life-threatening. Total surgical resection is often difficult. Because of the rarity of glomus jugulare tumors, a variety of treatment paradigms are currently used. There is no consensus regarding the 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 (ie, medulloblastoma, pineoblastoma). The treatment of primary brain tumors such as gliomas is more challenging, due to their generally larger size and infiltrative borders.

Intracranial metastases have been considered ideal targets for radiosurgery due to their small spherical size and noninfiltrative borders. Brain metastases are a frequent occurrence, seen in 25% to 30% of all patients with cancer, particularly in those with lung, breast, or colon cancer or melanoma. WBRT is considered the standard of care in the treatment of brain metastases, and the addition of SRS to WBRT has been shown to improve survival and local tumor control in selected patients. SRS offers the additional ability to treat tumors with relative sparing of normal brain tissue in a single fraction. Ongoing research addresses whether using SRS alone to avoid the adverse effects of WBRT on normal tissues.

SBRT

Studies are being conducted to evaluate SBRT for a number of extracranial sites. This approach is being studied to better target lesions (sparing surrounding normal structures) and to shorten the length of time needed to complete the treatments.

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 a 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, there is interest in the possibility of treating primary kidney cancer with SBRT.

Metastases from non-small cell lung cancer (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.

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. 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.

The 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.

Metastatic tumors to the spine have historically been treated with conventional radiotherapy. The need for retreatment is high due to morbidity from metastatic disease (eg, 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 reirradiation, but interest has also developed in the use of SBRT for the initial treatment of spinal tumors.

SRS is an established safe and effective treatment modality for many benign and malignant intracranial tumors/conditions. The evidence, largely consisting of nonrandomized cohort studies, combined with clinical input, supports the use of SRS for the following conditions: intracranial arteriovenous malformations; acoustic neuromas (vestibular schwannomas); pituitary adenomas; nonresectable, residual, or recurrent meningiomas; craniopharyngiomas; glomus jugulare tumors; and primary malignancies of the central nervous system (CNS); and trigeminal neuralgia that is refractory to medical management. Evidence from several randomized controlled trials (RCTs) demonstrate the benefit of SRS for small numbers of brain metastases from a variety of tumor types. Evidence from nonrandomized studies suggests that outcomes from SRS for intracranial metastatic disease is not worse for larger numbers of metastases; therefore, SRS may be considered medically necessary for solitary or multiple brain metastases in patients who have otherwise good performance status.

For the treatment of uveal melanoma, no studies that directly compare patients treated with SRS with other radiotherapies were identified. Existing cohort studies generally report high rates of local control (LC), but some have limited reporting about distant metastases and overall survival (OS). Therefore, the evidence is insufficient to conclude that SRS for uveal melanoma is associated with improved outcomes.

For the treatment of tremor, noncomparative studies in heterogeneous patient populations generally report improvements in tremor scores from pre- to post-SRS. However, studies with longer-term follow-up are needed to determine the risk/benefit ratio. The evidence related to the use of SRS for the management of other intracranial conditions, including epilepsy and chronic pain, is limited. Therefore, SRS is considered not medically necessary due to lack of efficacy in peer-reviewed literature.

For the use of SBRT, improved outcomes following SBRT have been demonstrated in patients with early stage non-small-cell lung cancer (NSCLC) who are not considered to be candidates for resection. The literature and input from clinical vetting support its use in spinal tumors that have been previously irradiated and in radioresistant metastases to the spine. Therefore, SBRT may be considered medically necessary for the treatment of early stage NSCLC and metastases to the spine, in patients who meet appropriate criteria.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable radiation therapy benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial

Single Fraction:

SRS-Stereotactic Radiosurgery authorization not required.

61796	**61797**	**61798**	**61799**
63620	**63621**	**61800**	**77371**
77372	**77432**		

The following codes are covered when the medical criteria are met

Two to Five (2-5) Fractions:

Cranial SBRT-Stereotactic body radiation therapy

Note: This code is used for cranial although the code description is not specific to cranial

77435

32701	**77373**	**77435**	
The following related codes are covered when performed in conjunction with a covered indication.			
77263	**77295**	**77300**	**77301**
77315	**77332**	**77334**	**77370**
The following HCPCS codes are covered but **not separately reimbursed** as providers should file with the appropriate CPT code:			
G0339	**G0340**		

RELATED POLICIES

Preauthorization via Web-Based tool for Procedures

PUBLISHED

Provider Update	Jan 2015
Provider Update	Nov 2013
Provider Update	Jul 2008
Provider Update	Nov 2007

REFERENCES

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