Medical Coverage Policy | Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

EFFECTIVE DATE: 01|01|2016
POLICY LAST UPDATED: 11|17|2015

OVERVIEW

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.

MEDICAL CRITERIA

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
  spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, sarcoma).

PRIOR AUTHORIZATION

Prior authorization is required for stereotactic body radiation therapy 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 for BlueCHiP for Medicare and for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Stereotactic radiosurgery is covered.

Stereotactic body radiation therapy is covered when the medical criteria are met.

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.

COVERAGE

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

BACKGROUND

Stereotactic radiosurgery and stereotactic body radiotherapy 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 1 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 >5) over a course of days, referred to as fractionated radiotherapy.

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 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, 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.

Intracranial Metastatic Disease
Intracranial metastases are 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. Whole brain radiotherapy (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.

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; solitary or multiple brain metastases in patients having good performance status and no active systemic disease; 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
Extracranial Primary Tumors Treated With SBRT
SBRT has been studied for the treatment of lung cancers, specifically non-small-cell lung cancer (NSCLC), with the greatest focus on inoperable stage 1 NSCLC.

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.

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.

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 and 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 reirradiation, but interest has also developed in the use of SBRT for the initial treatment of spinal tumors.

The evidence for stereotactic body radiotherapy (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. Survival rates may be similar for SBRT compared with surgical resection for patients with stage T1 and T2a non-small-cell lung cancer (NSCLC) who are not candidates for surgical resection because of comorbid conditions. 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 stage T1 or T2a NSCLC (not >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 radiotherapy; and spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, sarcoma).

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

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 the U.S. Food and Drug Administration (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.

CODING

BlueCHiP for Medicare and Commercial Products
The following codes are covered:
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

One to Five (1-5) Fractions:
Spinal SBRT Stereotactic body therapy
32701 77373 77435

The following related codes are covered when performed in conjunction with a covered indication.
77263 77295 77300 77301 77307
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, January 2016
Provider Update, January 2015
Provider Update, November 2013
Provider Update, February 2011

Policy Update, July 2008

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