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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** 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.*

Description

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.

Traditional external-beam radiation therapy may involve daily treatments for a duration of six weeks or longer. The emerging trend in recent years has been toward shorter, more "hypofractionated" courses, such as with SRS and SBRT. Both SRS and SBRT may be completed with one session (single-fraction) or less may require additional sessions (typically no more than five) over a course of days, referred to as fractionated stereotactic radiotherapy. Fractionation has been made possible by the ability to duplicate the treatment plan from one session to the next. 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 one procedure to complete the obliteration process.

The main methods of this technology include gamma-ray radiosurgery (Gamma Knife®), most frequently used for intracranial lesions, and linear-accelerator radiosurgery or LINAC (e.g., CyberKnife®). The radiosurgical procedure using SRS or SBRT is preceded by a process of localizing the target with three-dimensional imaging such as computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography/computed tomography (PET/CT).

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. 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. Examples of functional disorders include chronic pain.

Acoustic neuromas are benign tumors originating on the eighth cranial nerve, and they can be seen in association with neurofibromatosis. Although these tumors are benign, they are associated with significant morbidity and even death if their growth compresses vital structures. Treatment 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. Acoustic neuromas were one of the first indications for SRS, dating back to 1969.

Pituitary adenomas are benign tumors with symptoms that are 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 radiation therapy, or SRS. Surgical excision is typically offered to patients with functioning adenomas, since 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 radiation therapy 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.

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 (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 (DREZ) lesions, and stereotactic radiofrequency thalamotomy. SRS targeting the thalamus has been considered an investigative alternative to these neurodestructive procedures.

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 25–30% of all patients with cancer,

particularly in those with lung, breast, or colon cancer or melanoma. Whole-brain radiation treatment (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. Stereotactic radiosurgery (SRS) offers the additional ability to treat tumors with relative sparing of normal brain tissue in a single fraction. The idea of deferring WBRT in order to avoid its effects on normal tissues and using SRS alone continues to generate significant discussion and interest. Several trials have been conducted to address this issue.

The 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.

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. (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)

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.

Note: The use of charged particle (proton or helium ion) radiation therapies is addressed in a separate Protocol.

Policy (Formerly Corporate Medical Guideline)

Stereotactic radiosurgery using a gamma knife or 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 indications:

- spinal or vertebral body tumors (metastatic or primary) in patients who have received prior radiation therapy;
- spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, and sarcoma).

When stereotactic radiosurgery or stereotactic body radiation therapy 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 and the treatment of uveal melanoma.

Stereotactic body radiation therapy is **investigational** for primary and metastatic tumors of the liver, pancreas, kidney, and adrenal glands.

Policy Guideline*Fractionation*

Fractionated stereotactic radiotherapy refers to when SRS or SBRT is performed more than one time 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.

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.

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.

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