BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 6.01.10 Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

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Related Policies:

8.01.46 - Intensity-Modulated Radiotherapy of the Lung
8.01.49 - Intensity-Modulated Radiotherapy: Abdomen, Pelvis and Chest
8.01.59 - Intensity-Modulated Radiotherapy: Central Nervous System Tumors

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Description

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 the ability to spare adjacent radiosensitive structures. SRS primarily refers to such radiotherapy applied to intracranial lesions. SBRT refers to therapy generally applied to other areas of the body. Both techniques differ from conventional external-beam radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over multiple sessions.

OBJECTIVE

The objective of this evidence review is to determine whether the use of stereotactic radiosurgery to treat benign or malignant intracranial lesions and the use of stereotactic body radiotherapy to treat primary and metastatic extracranial tumors improve the net health outcome.

POLICY STATEMENT

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

- arteriovenous malformations;
- trigeminal neuralgia refractory to medical management;
- mesial temporal lobe epilepsy refractory to medical management when standard alternative surgery is not an option;
- acoustic neuromas;
- pituitary adenomas;
- nonresectable, residual, or recurrent meningiomas;
- craniopharyngiomas;
- glomus jugulare tumors;
- malignant neoplastic intracranial lesion(s) (eg, gliomas, astrocytomas);
- solitary or multiple brain metastases in individuals having good performance status and no active systemic disease (defined as extracranial disease that is stable or in remission) (see Policy Guidelines section);
- uveal melanoma

Stereotactic body radiotherapy may be considered **medically necessary** for the following indications:

- primary or metastatic spinal or vertebral body tumors in individuals who have received prior spinal radiotherapy;
- spinal or vertebral metastases that are radioresistant (eg, renal cell carcinoma, melanoma, sarcoma);
- individuals with stage T1 or T2a non-small cell lung cancer (not >5 cm) showing no nodal or distant disease and who are not candidates for surgical resection;
- primary or metastatic tumors of the liver as an alternative locoregional treatment for individuals with inoperable primary or metastatic lesions;
- primary renal cell carcinoma in individuals who are not good surgical candidates or who have metastatic renal cell carcinoma;
- oligometastases involving the lung, adrenal glands, and bone (other than spine or vertebral body).

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

Stereotactic radiosurgery is **investigational** for other applications including, but not limited to, the treatment of functional disorders (other than trigeminal neuralgia), and including chronic pain, tremor.

Stereotactic body radiotherapy is **investigational** for prostate cancer, pancreatic adenocarcinoma, kidney, adrenal glands and other conditions except as outlined in the policy statements above.

POLICY GUIDELINES

Radiation Source

This evidence review addresses the use of stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) 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 not addressed.

Number of Lesions

A TEC Assessment (1995) on SRS for multiple brain metastases found that evidence was sufficient to show that radiosurgery improved health outcomes for up to 3 metastases in the presence of good performance status and no active systemic disease. While evidence continues to demonstrate the importance of good performance status and absence of active systemic disease, it appears that the number of metastases may not be as predictive of outcome. Thus, individuals with more than 3 metastases who otherwise have good performance status and no evidence of active systemic disease may still benefit from SRS.

Many individuals with brain metastases can either receive whole-brain radiotherapy (WBRT) along with SRS, or WBRT may be delayed for use as salvage therapy for recurrent intracranial disease.

Fractionation

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

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

SBRT is commonly delivered over 3 to 5 fractions.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Several devices that use cobalt 60 radiation (gamma-ray devices) for SRS have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The most commonly used gamma-ray device, approved in 1999, is the Gamma Knife (Elekta; 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 FDA through the 510(k) process. Examples include the Novalis Tx (Novalis); the TrueBeam STx (Varian Medical Systems; approved 2012; FDA product code IYE); and the CyberKnife Robotic Radiosurgery System (Accuray; approved 1998; FDA product code MUJ). LINAC-based devices may be used for intracranial and extracranial lesions.

RATIONALE

Summary of Evidence

Stereotactic Radiosurgery

For individuals with non-neoplastic intracranial conditions (eg, arteriovenous malformations [AVMs]), the evidence includes noncomparative cohort studies, systematic reviews, and a single randomized controlled trial (RCT). Relevant outcomes are symptoms, treatment-related morbidity, and overall survival (OS). Observational studies have reported relatively high rates (40% to 70%) of complete obliteration of AVM after stereotactic radiosurgery (SRS). An RCT that compared medical therapy with various interventions in the treatment for AVM showed no significant improvement in outcomes; however, given that the interventional studies included a variety of therapies, it is difficult to assess whether a particular component of the intervention has or lacks benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with non-neoplastic intracranial conditions (eg, trigeminal neuralgia refractory to medical management), the evidence includes systematic reviews and case series. Relevant outcomes are symptoms, treatment-related morbidity, and overall survival (OS). A case series identified improvements in pain related to trigeminal neuralgia after treatment with SRS. Comparative studies that evaluated the use of SRS compared with alternative treatments for trigeminal neuralgia were reviewed in a systematic review without meta-analysis and were judged to be of poor quality. Only 1 study specifically addressed the use of radiosurgery, and it was stopped before accrual was completed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with epilepsy refractory to medical management, the evidence on the use of SRS as a treatment for epilepsy includes a case series in primary epileptic disorders and for tumor-related epilepsy. Relevant outcomes are symptoms, treatment-related morbidity, and quality of life (QOL). The available evidence from patients with epileptic lesions of various sizes and locations is insufficient to show what factors are associated with a favorable outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with mesial temporal lobe epilepsy, the evidence includes a systematic review of data from 13 studies, a single RCT comparing SRS to anterior temporal lobectomy (ATL), and case series.a Relevant outcomes include symptoms, treatment-related morbidity, and QOL. In the RCT, remission rates were reported for a total of 58 patients (31 in SRS arm and 27 in ATL arm). Seizure remission rates suggest that ATL (78%) has an advantage over SRS (52%) in terms of proportion with seizure remission. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with tremor and movement disorder, the evidence related to the use of SRS includes a systematic review and nonrandomized observational studies, many of which reported outcomes from the treatment of tremors of varying etiologies. Relevant outcomes include symptoms, treatment-related morbidity, and QOL. Most studies report improvements in standardized tremor scores, although few studies used a blinded evaluation of tremor score, allowing for bias in assessment. No studies comparing SRS with alternative methods of treatment or a control group were identified. Limited long-term follow-up is available, making the long-term risk-benefit ratio of an invasive therapy uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic pain syndromes refractory to standard medical and psychological treatments, the evidence includes a systematic review of noncomparative studies. Relevant outcomes include OS, symptoms, and treatment-related morbidity. Although clinical success was reported in varying percentages of patients dependent upon the radiation target and pain etiology, the data are primarily from a period of time before the common use of other treatments for patients with chronic pain syndromes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals in the subgroup of uncommon benign neoplastic intracranial lesions (acoustic neuroma [ie, vestibular schwannoma] and pituitary adenoma,) the published evidence for the use of SRS remains limited to systematic reviews of nonrandomized observational studies, other nonrandomized observational studies, and case series. Relevant outcomes include OS, symptoms, and treatment-related morbidity. These reports would suggest that long-term outcomes of fractionated radiosurgery for these benign neoplasms are associated with good local control and acceptable treatment-related side effects. One systematic review found that SRS and microsurgery are comparable treatments for primary management of small to medium (<3 cm) vestibular schwannomas with regard to hearing preservation at 65 months; microsurgery was favored over SRS for tumor control at 70 months (98% vs 92%), while SRS was favored over microsurgery for reducing the proportion of patients with facial nerve dysfunction at 12 months (2% vs 10%). The likelihood of high-quality systematically acquired evidence is low due to the rarity of the conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals in the subgroup of uncommon benign neoplastic intracranial lesions (craniopharyngioma and glomus jugulare tumors) the published evidence for the use of SRS remains limited to systematic reviews of nonrandomized observational studies, other nonrandomized observational studies, and case series. Relevant outcomes include OS, symptoms, and treatment-related morbidity. These reports would suggest that long-term outcomes of fractionated radiosurgery for these benign neoplasms are associated with good local control and, acceptable treatment-related side effects. The likelihood of high-quality systematically acquired evidence is low due to the rarity of the conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with malignant neoplastic intracranial conditions (eg, gliomas, astrocytomas), the evidence on the use of SRS as a treatment for epilepsy includes a single systematic review and meta-analysis of case series with ≥5 patients and heterogeneous observational studies. Relevant outcomes are symptoms, treatment-related morbidity, and OS. Observational studies have demonstrated local control using SRS in combination with chemotherapy to treat gliomas in the primary and recurrent setting. These tumors are very aggressive and there are limited treatment options. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with malignant neoplastic intracranial conditions (eg, brain metastases), the evidence includes systematic reviews, RCTs, and nonrandomized observational studies. Relevant outcomes are symptoms, treatment-related morbidity, and OS. The existing evidence body indicates that SRS improves outcomes in the treatment of brain metastases. Stereotactic radiosurgery appears to be feasible for treatment of larger numbers (eg, >10) of brain metastases, and outcomes after SRS treatment do not appear to be worse for patients with larger numbers of metastases, at least for patients with ≤10 metastases. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with uveal melanoma, evidence for use of SRS is limited to a meta-analysis of case series and individual case series. Relevant outcomes include OS, symptoms, and treatment-related morbidity. The published literature is insufficient to demonstrate improved outcomes with SRS over other accepted radiation modalities in the treatment of uveal melanoma. The condition is rare with poor clinical outcomes and treatment options. There are currently no active clinical trials to evaluate SRS to treat uveal melanoma and, therefore, there are limited prospects for accumulating additional high-quality data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Stereotactic Body Radiotherapy

For individuals with primary and metastatic spinal or vertebral body tumors who have received prior radiotherapy who are treated with stereotactic body radiotherapy (SBRT), the evidence includes an RCT that compared SBRT to external beam radiotherapy (EBRT) in patients with painful spinal metastasis and observational literature that primarily addresses metastases that recur after prior radiotherapy. Relevant outcomes are OS, progression-free survival (PFS), disease-free survival (DFS), symptoms, and treatment-related morbidity. In the RCT, SBRT was superior to EBRT for the achievement of a complete response from pain 3 months after radiotherapy. Repeat administration of conventional radiation therapy increases the risk of treatment-related myelopathies. Nonrandomized study results are sufficient to determine that SBRT improves outcomes (reduces pain) in patients with spinal (vertebral) tumors. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with stage T1 or T2A non-small cell lung cancer (NSCLC) there is no direct comparative evidence for the use of SBRT compared to surgical resection in patients with stage T1 and T2A cancer without nodal or distant disease. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Although no direct comparative evidence is available, evidence suggests that survival rates may be similar for SBRT and surgical resection for patients with stage T1 and T2A NSCLC tumor (not >5 cm in diameter) who show no nodal or distant disease and who are not candidates for surgical resection because of comorbid conditions. Additionally, SBRT was associated with improved survival and a reduced risk of adverse events as compared to conventional radiotherapy and radiofrequency ablation (RFA) in inoperable NSCLC. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with primary hepatocellular carcinoma (HCC), there are no RCTs reported on the use of SBRT for HCC treatment. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Studies have used heterogeneous treatment schedules, treatment planning techniques, patient populations, and outcome measures. The optimal dose and fractionation scheme are unknown. Although promising local control rates of 71% to 100% at 1 year have been reported, there are only retrospective studies reporting on the use of SBRT in conjunction with or as an alternative to established treatment modalities, including systemic therapy, RFA, and transarterial chemoembolization. Similar short-term lesion-control rates have been reported for metastatic liver disease. Palliative treatment, including for larger lesions (>3 cm), has also been reported. The use of SBRT, either alone or in conjunction with other liver-directed therapies, is emerging as a bridge to transplant. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with primary prostate carcinoma, the evidence on the use of SBRT consists of systematic reviews of prospective and retrospective studies, a phase 2, randomized study, single-arm assessments of acute and late toxicity, and early prostate-specific antigen (PSA) outcome data retrospectively compared with historical controls. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Studies have shown promising initial results on the use of SBRT in prostate cancer with seemingly low toxicity rates. One comparative study of intensity-modulated radiotherapy and SBRT suggested higher gastrointestinal (GI) and genitourinary (GU) complication rates after SBRT; while this study had a large number of patients and attempted to control for bias using matching on observed variables, it was subject to limitations deriving outcome measures from claims data. In the randomized ORIOLE study, SBRT was associated with a significant improvement in disease progression and median PFS as compared to observation in men with recurrent hormone-sensitive prostate cancer and 1 to 3 metastases with a similar toxicity profile. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with pancreatic adenocarcinoma, the evidence for the use of SBRT consists of systematic reviews, retrospective comparative studies, and noncomparative studies. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Combined chemoradiotherapy plays a significant role in the treatment of locally advanced pancreatic cancer whereas re-resection demonstrates improved median OS outcomes for isolated local recurrence. Noncomparative observational studies of SBRT have reported increased patient survival compared with historical data. Acute, grade 3 toxicities have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with renal cell carcinoma (RCC), the evidence for the use of SBRT consists of small case series, a systematic review of case series, and other observational studies. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Generally, high rates of local control have been reported for primary RCC. Adverse effects include nephron loss and kidney shrinkage, however, avoidance of nephrectomy in patients with hypertension or solitary kidney may be desirable. RCC is considered to be relatively radioresistant. Case series have reported good local control in patients with spinal metastases. There are no RCTs that have evaluated SBRT for primary RCC or metastatic lesions to the brain or spine that permit comparisons between SBRT and currently established treatment modalities for RCC. Two observational studies demonstrated that SBRT extends the duration of ongoing systemic therapy by approximately 1 year in patients with metastatic RCC with fewer than 3 to 5 sites of progression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with oligometastatic disease, the evidence for the use of SBRT for the management of oligometastases at multiple sites, including the lungs, adrenal glands, and bones (other than spine or vertebral body) primarily consists of relatively small, noncomparative studies that confirm clinically important rates of local control and 1 RCT. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. In the randomized SABR-COMET trial that compared SBRT versus standard of care palliative treatment in patients with oligometastatic cancers, results revealed a significantly improved median OS in the SBRT group with grade 2 or worse adverse events occurring more frequently, including 3 treatment-related deaths versus 0 in the control group. In a subsequent publication of long-term results of the SABR-COMET trial, the 5-year OS rate was significantly improved with SBRT with no new grade 2 to 5 adverse events reported. Systemic therapy is most frequently the preferred therapy for patients with metastatic disease of these selected tumor types. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association Scientific Statement

In 2017, the American Heart Association and American Stroke Association published a scientific statement on the management of brain arteriovenous malformations (AVMs).[206,] The statement concludes that the available literature supports the use of SRS for small- to moderate-volume brain AVMs that are generally 12 cm^3 or less in volume or located in deep or eloquent regions of the brain.

American Society of Clinical Oncology

In 2021, the American Society of Clinical Oncology (ASCO), Society for NeuroOncology (SNO), and the American Society for Radiation Oncology (ASTRO) published a guideline that addresses the role of surgery, radiation therapy, and systemic therapy in the treatment of patients with brain metastases secondary to nonhematologic solid tumors.[207,] The following recommendations regarding the use of SRS in this population were made in this guideline:

- "SRS alone (as opposed to WBRT [whole brain radiotherapy] or combination of WBRT and SRS) should be offered to patients with one to four unresected brain metastases, excluding small-cell carcinoma."
    - "Qualifying Statement: The inclusion criteria of the randomized trials that underly this recommendation were generally tumors of less than 3 or 4 cm in diameter and did not include radioprotectant strategies of memantine or hippocampal avoidance"
- "SRS alone should be offered to patients with one to two resected brain metastases if the surgical cavity can be safely treated and considering the extent of remaining intracranial disease."
    - "Qualifying Statement: The randomized trials upon which this recommendation is based were of single-fraction SRS and conventional WBRT (without radioprotectant strategies of memantine or hippocampal avoidance)"
- "SRS, WBRT, and the combination of SRS plus WBRT are all reasonable options for patients with more than four unresected or more than two resected brain metastases and better performance status (eg, [Karnofsky Performance Status] KPS ≥70). SRS may be preferred for patients with better prognosis or where systemic therapy that is known to be active in the CNS [central nervous system] is available."

American Society for Radiation Oncology

In 2017, the ASTRO published an evidence-based guideline on SBRT in patients with early-stage NSCLC.[208,] The guideline concluded that "SBRT has an important role to play in treating early-stage NSCLC, particularly for medically inoperable patients with limited other treatment options." Additionally, the document noted that "lower quality evidence led to conditional recommendations on use of SBRT for tumors >5 cm, patients with prior pneumonectomy, T3 tumors with chest wall invasion, synchronous multiple primary lung cancer, and as a salvage therapy after prior radiation therapy." Of note, the ASCO reviewed the ASTRO guideline in 2018 and determined that "the recommendations from the ASTRO guideline...are clear, thorough, and based on the most relevant scientific evidence."[209,]

In 2022, ASTRO published an evidence-based guideline on indications and techniques for external beam radiation therapy (EBRT) in patients with primary liver cancers.[210,] SBRT (also referred to as ultrahypofractionation delivered in ≤5 fractions) was among the EBRT techniques discussed for patients with confirmed HCC and intrahepatic cholangiocarcinoma (IHC). The choice of regimen is based on tumor location, underlying liver function, and available technology.

Congress of Neurological Surgeons

In 2019, the Congress of Neurological Surgeons published evidence-based guidelines on the use of SRS in the treatment of adults with metastatic brain tumors.[211,] The Congress recommended the following regarding specific clinical questions:

1. Should patients with newly diagnosed metastatic brain tumors undergo SRS compared with other treatment modalities?

- SRS is recommended as an alternative to surgical resection in solitary metastases when surgical resection is likely to induce new neurological deficits and tumor volume and location are not likely to be associated with radiation-induced injury to surrounding structures
- SRS should be considered as a valid adjunctive therapy to supportive palliative care for some patients with brain metastases when it might be reasonably expected to relieve focal symptoms and improve quality of life in the short term if this is consistent with the overall goals of the patient.

2. What is the role of SRS after open surgical resection of brain metastases?

- After open surgical resection of a solitary brain metastasis, SRS should be used to decrease local recurrence rates.

3. What is the role of SRS alone in the management of patients with 1 to 4 brain metastases?

- For patients with solitary brain metastasis, SRS should be given to decrease the risk of local progression.
- For patients with 2 to 4 brain metastases, SRS is recommended for local tumor control, instead of whole brain irradiation therapy, when their cumulative volume is <7 mL.

4. What is the role of SRS alone in the management of patients with more than 4 brain metastases?

- The use of SRS alone is recommended to improve median overall survival for patients with >4 metastases having a cumulative volume <7 mL.

All of these recommendations are Level 3 - based on randomized studies with significant design flaws hampering interpretation and application to all patients, single institution case series, and comparative studies based on historical controls.

International Stereotactic Radiosurgery Society

The International Stereotactic Radiosurgery Society (ISRS) has published a variety of relevant clinical practice guidelines and practice opinions related to SRS. For select guidelines, recommendations are based on a ranking of evidence quality with a corresponding strength of recommendation rating scheme (Table 1).

Table 1. International Stereotactic Radiosurgery Society Guidelines: Rating Schemes for the Strength of the Evidence and Recommendations.

Strength of Evidence	Strength of Recommendation
Class I: • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review of Class I RCTs (and study results were homogenous)	Level I: High degree of clinical certainty (Class I evidence or overwhelming Class II evidence)
Class II: • Lesser quality (eg, <80% follow-up, no blinding, or improper randomization • Prospective comparative study • Systematic review of Class II studies or Class I studies with inconsistent results • Case control study • Retrospective comparative study	Level II: Clinical certainty (Class II evidence or a strong consensus of Class III evidence)
Class III: • Case series • Expert Opinion	Level III: Clinical uncertainty (Inconclusive or conflicting evidence or opinion)

RCT: randomized controlled trial.

Recommendations and conclusions from various ISRS guidelines and practice opinions include:

Intracranial noncavernous sinus benign meningioma: Current literature supporting SRS for this condition "lacks level I and II evidence. However, when summarizing the large number of level III studies, it is clear that SRS can be recommended as an effective evidence-based treatment option (recommendation level II) for grade 1 meningioma.[212,]

Non-functioning pituitary adenomas: SRS is an effective and safe treatment for patients with non-functioning pituitary adenomas via consensus opinion.[213,] The position paper states that "encouraging short-term data support hypofractionated stereotactic radiotherapy for select patients, and mature outcomes are needed before definitive recommendations can be made."

Benign (World Health Organization Grade I) cavernous sinus meningiomas: Current literature is "limited to level III evidence with respect to outcomes of SRS in patients with cavernous sinus meningiomas. Based on the observed results, SRS offers a favorable benefit to risk profile for patients with cavernous sinus meningioma."[214,]

Arteriovenous malformations: Current literature cautiously suggests that "SRS appears to be a safe, effective treatment for grade I to II arteriovenous malformation and may be considered a front-line treatment, particularly for lesions in deep or eloquent locations." However, the literature is "low quality, limiting interpretation."[215,]

Arteriovenous Fistulas: SRS is recommended for patients with "complex dural arteriovenous fistula who are planned for embolization and are at high risk for not achieving complete obliteration with embolization alone; dural arteriovenous fistula who have received previous embolization without complete obliteration and have refractory symptoms; high-risk noncavernous sinus dural arteriovenous fistula or symptomatic cavernous sinus dural arteriovenous fistula who are not candidates for or have refused both embolization or microsurgery."[216,]

Epilepsy: Current literature states that "radiosurgery is an efficacious treatment to control seizures in mesial temporal lobe epilepsy, possibly resulting in superior neuropsychological outcomes and quality of life metrics in selected subjects compared to microsurgery."[217,]

Tremor: For medically refractory tremor, "SRS to the unilateral thalamic ventral intermediate nucleus, with a dose of 130 to 150 Gy, is a well-tolerated and effective treatment....and 1 that is recommended by the International Stereotactic Radiosurgery Society."[218,]

Trigeminal neuralgia: Current literature is "limited in its level of evidence, with only 1 comparative randomized trial reported to date. At present, 1 can conclude that stereotactic radiosurgery is a safe and effective therapy for drug-resistant trigeminal neuralgia."[219,]

Reirradiation for spinal metastases: Current literature suggests that "SBRT to previously irradiated spinal metastases is safe and effective with respect to both local control and pain relief. Although the evidence is limited to low-quality data, SBRT can be a recommended treatment option for reirradiation."[220,]

Postoperative spine malignancy: "Postoperative spine SBRT delivers a high 1-year local control with acceptably low toxicity. Patients who may benefit from this include those with oligometastatic disease, radioresistant histology, paraspinal masses, or those with a history of prior irradiation to the affected spinal segment...the ISRT recommends a minimum interval of 8 to 14 days after invasive surgery before simulation for SBRT, with initiation of radiation therapy within 4 weeks of surgery."[221,]

Postoperative brain metastases resection cavities: "After surgery for a brain metastasis, postoperative SRS is preferred over observation due to superior local control (recommendation level I)." "For patients with 1 resected brain metastasis, ECOG performance status of 0 to 2, and a resection cavity measuring <5 cm, postoperative SRS to the resection cavity is recommended to minimize cognitive toxicity compared with WBRT (recommendation level I)."[222,]

Secretory pituitary adenomas: "SRS is an effective option to control growth of GH-, ACTH-, & PRL-secreting residual or recurrent pituitary adenomas after prior surgical resection but offers lower rate of endocrine improvement or remission." "SRS could also be used as primary therapy for GH- and ACTH-secreting pituitary adenomas in patients deemed medically unfit for surgical resection, or as an alternative to surgical resection for PRL-secreting pituitary adenomas unresponsive to dopaminergic agonists." "Withdrawal of antisecretory medications is preferred, typically for 4 to 12 weeks prior to radiosurgery, if safely possible considering endocrinologic status of patient."[223,]

Vestibular schwannoma: Single-fraction radiosurgery and fractionated stereotactic radiation therapy is recommended for small newly diagnosed vestibular schwannoma without significant mass effect (Koos Grades I to III) and for growing vestibular schwannoma that is small to moderate in size without significant mass effect. [224,]

National Comprehensive Cancer Network Guidelines

The National Comprehensive Cancer Network provides guidelines for cancer treatment by site that include the use of SRS and SBRT for certain cancers (Table 2).

Table 2. National Comprehensive Cancer Network Recommendations for Stereotactic Radiosurgery and Stereotactic Body Radiotherapy[i,ii] [225,]

Cancer Site	**Tumor Type**	**Recommendation**	**Version**
Bone	• Chondrosarcoma • Chordoma • Ewing sarcoma family of tumors • Giant cell tumor of the bone • Osteosarcoma	• Consider SRS to allow high-dose therapy while maximizing normal tissue sparing (category 2A) • Consider use of SRS, especially for oligometastases	2.2022
CNS	• Adult low-grade glioma/pilocytic and infiltrative supratentorial astrocytoma/oligodendroglioma • Anaplastic gliomas/glioblastomas • Adult intracranial ependymoma • Adult medulloblastoma • Primary CNS lymphoma • Primary spinal cord tumors • Meningiomas • Limited brain metastases • Extensive brain metastases • Leptomeningeal metastases • Metastatic spine tumors	• Principles of RT including consideration of SRS or SBRT are applied to each of the listed tumors (category 2A)	1.2022

Colon	• Oligometastases to liver or lung	• Resection is preferred over locally ablative treatment. However, IGRT and SBRT may be considered in patients with a limited number of liver or lung metastases in highly selected cases or in the setting of a clinical trial. RT should not be used in place of surgical resection. • IMRT is preferred for unique clinical situations such as reirradiation of previously treated patients with recurrent disease or unique anatomical situations where IMRT facilitates the delivery of recommended target volume doses while respecting accepted normal tissue dose-volume constraints.	1.2022
Head and neck		• The panel acknowledged that SBRT might be beneficial in the setting of re-irradiation, palliation, or older adults.	2.2022
Hepatobiliary	• Hepatocellular carcinoma • Biliary tract cancers	• Principles of locoregional therapy includes recommendations for SBRT • SBRT can be considered as an alternative to ablation/embolization techniques for HCC or when these therapies have failed or are contraindicated. SBRT (3 to 5 fractions) is often used for patients with 1 to 3 tumors. SBRT could be considered for larger lesions or more extensive disease, if there is sufficient uninvolved liver and liver radiation tolerance can be respected. There should be no extrahepatic disease or it should be minimal and addressed in a comprehensive management plan.	1.2022

Lung	• NSCLC	• SBRT (also known as SABR) has achieved good primary tumor control rates and overall survival, higher than conventionally fractionated radiotherapy. Although SABR is not proven equivalent to lobectomy, some prospective series have demonstrated similar overall and cancer-specific survival (Stage 1, selected node-negative Stage IIA). • Close follow-up and salvage therapy for isolated local and/or locoregional recurrence after SABR have been shown to improve overall survival. • SABR is an appropriate option for patients with high surgical risk (eg, age ≥75 years, poor lung function) • SABR is most commonly used for tumors up to 5 cm in size, though selected larger isolated tumors can be treated safely if normal tissue constraints are respected. • Definitive RT to limited oligometastases, particularly SABR, is an appropriate option when it can be delivered safely to the involved sites (Stage IV, advanced/metastatic)	3.2022

Pancreas	• Pancreatic adenocarcinoma	Locally advanced disease
		• SBRT should be avoided if direct invasion of the bowel or stomach is identified on CT, MRI, and/or endoscopy
		• Data are limited to support specific RT recommendations for locally advanced disease. Options may include:
		  ○ chemoradiation, SBRT, or hypofractionated RT in selected patients who are not candidates for combination chemotherapy
		  ○ induction chemotherapy followed by chemoradiation or SBRT in select patients (locally advanced without systemic metastases)
		• SBRT should be delivered at an experienced, high-volume center with technology that allows for image-guided RT or in a clinical trial
		
		Recurrent pancreatic cancer
		• Data are limited to support specific RT recommendations for locally recurrent disease. Options for patients with recurrent, unresectable disease may include:
		  ○ Induction chemotherapy followed by chemoradiation or SBRT (if not previously performed)
		  ○ Chemoradiation or SBRT in selected patients who are not candidates for induction chemotherapy
		• SBRT should be delivered at an experienced, high-volume center with technology that allows for image-guided RT or in a clinical trial
			1.2022

Prostate	• Prostate cancer	• Principles of RT identifies SBRT as acceptable in practices with appropriate technology, physics, and clinical expertise. SBRT for metastases can be considered in the following circumstances:
		  ○ In patients with limited metastatic disease to the vertebra or paravertebral region when ablation is the goal
		  ○ In symptomatic patients where the lesion occurs in or immediately adjacent to a previously irradiated treatment field
		  ○ In patients with oligometastatic progression where progression-free survival is the goal.
		• SBRT combined with ADT can be considered when delivering longer courses of EBRT would present medical or social hardship for patients with:
		  ○ Unfavorable intermediate risk
		  ○ High and very high risk
			4.2022

Kidney cancer	• Non-clear cell and clear cell renal carcinoma	• SBRT may be considered for medically inoperable patients with stage 1 kidney cancer (category 2B) or stage II/III kidney cancer (both category 3) • Relapse or Stage IV: Metastasectomy or SBRT or ablative techniques for oligometastatic disease	4. 2022
Cutaneous Melanoma	• Intact extracranial metastases	• Principles of RT include recommendations for use of SBRT • SBRT may be considered for selected patients with oligometastasis	3.2022
Uveal melanoma	• Primary and recurrent intraocular tumors	• SRS is the least often used form of definitive RT	2.2022
Soft tissue sarcoma	• Extremity/superficial trunk/head and neck • Retroperitoneal/intra-abdominal	• If disseminated metastases: SBRT as a palliative option (category 2A) • For Stage IV with single organ and limited tumor bulk that are amenable to local therapy: SBRT with or without chemotherapy as an option • For metastatic disease with isolated regional disease or nodes: SBRT as an option	2.2022

Thyroid	• Iodine-refractory unresectable locoregional recurrent/persistent disease • Iodine-refractory soft tissue metastases • Iodine-refractory bone metastases	• Consider resection of distant metastases and/or EBRT/SBRT/IMRT/other local therapies when available for progressive and/or symptomatic metastatic lesions • Most recurrent tumors respond well to iodine therapy; or EBRT, SBRT, or IMRT • Consider surgical palliation and/or EBRT/SBRT/other local therapies when available if symptomatic, or asymptomatic in weight-bearing sites	2.2022

ADT: androgen-deprivation therapy; CNS: central nervous system; CT: computed tomography; EBRT: external-beam radiotherapy; HCC: hepatocellular carcinoma; IGRT: image-guided radiotherapy; IMRT: intensity-modulated radiotherapy; MRI: magnetic resonance imaging; NCCN: National Comprehensive Cancer Network; NSCLC: non-small cell lung cancer; RT: radiotherapy; SABR: stereotactic ablative radiotherapy; SBRT: stereotactic body radiotherapy; SRS: stereotactic radiosurgery.

[i] Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 1, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org.

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U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New Policy	
December 2013	Replace policy	Policy updated with literature review, several references added. Policy statement updated to reference uveal melanoma.
December 2014	Replace policy	Policy updated with literature review and extensively revised. References 3-8, 16-23, 31-33, 43-47, 50-51, 59-60, 64-67, 70, 80-84, 83, 92-95, 100, 107, 113-114, 116, and 118 added. Tremor added to the list of investigational indications for SBRT. Policy statement otherwise unchanged
December 2015		Policy updated with literature review through July 9, 2015; references 34-38 added. Policy statements unchanged.
March 2018	Archived	Policy updated with literature review through September 15, 2017. References 5, 19-20, 23, 25, 29-30, 36-38, 52, 54, 72, 81-82, 90, 95-96, 98, 110-111, 113-116, 126-129, 144, 149-151, and 177-179 were added. Policy statement unchanged.
March 2023	Reactivated policy	Policy updated with literature review through June 1, 2022; references added. Clinical input reviewed. Additional indications for SRS and SBRT added to the first 2 medically necessary policy statements, and revisions made to the investigational statements.