Molina Clinical Policy
Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
Policy No. 224

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Stereotactic describes a procedure during which a target lesion is localized relative to a known three-dimensional (3D) reference system that allows for a high degree of anatomic accuracy and precision (ASTRO 2020). **Stereotactic radiosurgery (SRS)** and **stereotactic body radiotherapy (SBRT)** are non-surgical methods of delivering high doses of ionizing radiation thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues. SRS and SBRT works like other forms of radiation treatment and does not remove the tumor or lesion, but rather, it distorts the DNA of the tumor cells and causes these cells to lose the ability to reproduce and retain fluids. The tumor reduction occurs at the rate of the normal growth rate of the specific tumor cell. Both techniques, SRS and SBRT, differ from conventional external-beam radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over multiple sessions. SRS and SBRT are alternatives to invasive surgery, especially for patients who are unable to undergo surgical interventions for tumors and abnormalities.

SRS and SBRT treat a range of malignant and nonmalignant conditions. SRS and SBRT may be completed with 1 session (single fraction), however additional sessions (typically no more than 5) over a course of days, referred to as fractionated stereotactic radiotherapy, may be required. SRS refers to a single-fraction treatment of intracranial and spinal targets, whereas SBRT refers to multifractional (typically two to five fractions) treatment of intracranial, spinal, or extracranial sites, such as the lung, head and neck, liver, pancreas, and prostate (Mitin, 2021). Surgery is typically the first choice of treatment for many of the indications which SRS and SBRT is used. In cases where surgery is not possible due to size or location of lesion, SRT or SBRT may be an alternative treatment. It can also be an adjunct post-surgery to treat areas that were non-resectable. Fractionated SRS is used for brain tumors that are close to the optic chiasm (e.g., pituitary tumors) or for tumors that have normal nerves passing through their centers (e.g., acoustic neuromas and meningiomas of the cavernous sinus or skull base).

SRS and SBRT are typically conducted on an outpatient basis and, if no complications arise, patients may return to their normal daily activities 24 hours after radiosurgery. Postoperative radio surgical assessments via CT, MRI, or angiography are performed at periodic intervals to determine the effects of treatment. The neurosurgeon and radiation oncologist are the primary caregivers and are responsible for the safe and effective administration of these procedures (AANS, 2021). SRS and SBRT can be administered by several types of devices that are distinguished by their source of radiation, including particle beams (proton), gamma rays from cobalt-60 sources, or high-energy photons from linear accelerator (LINAC) systems.

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. A number of LINAC movable platforms that generate high-energy photons have been cleared for marketing by 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.

COVERAGE POLICY

Stereotactic radiosurgery (SRS) (intracranial) may be considered medically necessary when **ALL** of the applicable individual clinical criteria are met:

A. Member's general medical condition, documented by good performance status [defined as greater than or equal to 70% on the Karnofsky Scale OR < 2 on the ECOG Scale], supports aggressive treatment to a primary cancer, or in metastatic disease supports aggressive local therapy to one or more areas of cancer to achieve total clearance or clinically beneficial reduction in the overall burden of systemic disease

AND

B. The tumor burden can be completely targeted with acceptable risk to critical normal structures when used for the treatment of **ANY** of the following:

Malignant Lesions

1. Ocular
    a. Lesions within 5 mm of the optic nerves or chiasms
    OR
    b. Uveal melanoma
        - For treatment of melanoma of the choroid; **or**
        - For retreatment of a previously irradiated field.

2. Gliomas
    a. Recurrent malignant gliomas; **OR**
    b. For retreatment of a previously irradiated field; **OR**
    c. Tumor is not resectable or not a candidate for surgery.

3. Metastatic Brain Lesion
    a. Treatment of a previously irradiated field; **AND**
    b. Re-treatment with external beam radiation therapy (EBRT) would result in significant risk of spinal cord injury

4. Base of skull (such as intracranial chordomas and chondrosarcomas of the skull base)

5. Head and neck cancers (such as cancer of the tonsil, larynx, tongue, sinus, and mouth)
    a. For re-treatment of a previously irradiated field; **OR**
    b. Palliative radiation in the advanced cancer setting when curative-intent treatment is not appropriate.

6. Medulloblastoma, supratentorial primitive neuroectodermal tumors (PNET), ependymoma: Only for re-treatment of a previously irradiated field.

7. CNS lymphoma: Only for re-treatment of a previously irradiated field.

Benign Brain Tumors (not all-inclusive list)

1. Acoustic neuromas (vestibular schwannomas)

2. Arteriovenous malformations when **ALL** the following criteria are met:
    a. For treatment of intracranial arteriovenous malformations; **AND**
    b. < 3cm by imaging; **AND**
    c. Poor candidate for surgery (i.e., due to prior surgery, tumor location, or individual ability to withstand surgery).

3. Meningiomas (unresectable, residual, or recurrent)
    a. When lesion is unresectable or recurrent, or if there is residual disease following surgery; **OR**
    b. For retreatment of a previously irradiated field.

4. Pituitary adenomas
    a. When individual is symptomatic; **OR**
    b. For retreatment of a previously irradiated field.

Benign neoplasms previously treated with conventional radiotherapy:
1. Craniopharyngiomas; **OR**
2. Pineal cytomas (tumor of the pineal gland); **OR**
3. Low grade astrocytic and ganglioneuronal tumors; **OR**
4. Glomus tumors (hypervascular tumor that arises within the jugular foramen of the temporal bone); **OR**
5. Hemangioblastomas; **OR**
6. Nonacoustic schwannomas.

Neurologic Indications
1. Trigeminal neuralgia when **ONE** of the following criteria are met:
    a. Symptoms are refractory to medical treatment (i.e., anticonvulsant or baclofen trial for a minimum of 8 weeks); **OR**
    b. For retreatment of a previously irradiated field.

OR

2. Mesial temporal lobe epilepsy refractory to medical management when standard alternative surgery is not an option.

Bone Metastases
1. **ONE** of the following diagnosis:
    a. Chondrosarcoma; **OR**
    b. Chordoma; **OR**
    c. Progressive Ewing sarcoma; **OR**
    d. Unresectable giant cell tumor; **OR**
    e. Osteosarcoma with positive margins or relapsed progressive disease; **OR**
    f. Oligometastases.

AND

2. For retreatment of a previously irradiated field; **OR**
3. If re-treatment with EBRT would result in significant risk of adjacent organ injury

Stereotactic body radiotherapy (SBRT) (extracranial) is considered medically necessary when **ALL** of the applicable individual clinical criteria are met:

A. Member's general medical condition documented by good performance status [defined as greater than or equal to 70% on the Karnofsky Scale OR < 2 on the ECOG Scale] supports aggressive treatment to a primary cancer, or in metastatic disease supports aggressive local therapy to one or more areas of cancer to achieve total clearance or clinically beneficial reduction in the overall burden of systemic disease

AND

B. The tumor burden can be completely targeted with acceptable risk to critical normal structures when used for the treatment of **ANY** of the following:

1. Anal Carcinoma
    a. Only for retreatment of a previously irradiated field.

2. Bone Metastases
    a. For retreatment of a previously irradiated field; **OR**
    b. If re-treatment with EBRT would result in significant risk of adjacent organ injury

3. Genitourinary Cancer (Bladder, Penile, and Testicular)
   a. Only for retreatment of a previously irradiated field

4. Gynecologic Cancers (Cervical Cancer, Fallopian Tube, Ovarian, Uterine, and Vulvar/Vaginal)
   a. Only for retreatment of a previously irradiated field

5. Colon Cancer metastases
   a. Limited liver or lung metastases; **OR**
   b. Alternative to resection or ablative procedures

6. Cholangiocarcinoma
   a. Extrahepatic with unresectable or resected with gross residual disease; **OR**
   b. Intrahepatic with:
      - Post resection with positive regional nodes or unresectable; **OR**
      - Post resection with metastatic extra-hepatic disease

7. Cutaneous Melanoma ablative treatment for intact extracranial metastases

8. Esophageal, Gastric Cancers
   a. Only for retreatment of a previously irradiated field.

9. Gallbladder Cancer with resected gross residual disease or unresectable

Liver Cancer

10. Hepatocellular Carcinoma (HCC) (Primary or Metastatic) when **ALL** of the following are met:
    a. Unresectable, locally advanced, or recurrent HCC; **AND**
    b. **ONE** of the following:
       - As palliative treatment for individuals with liver-related symptoms; **or**
       - As an option to surgery or embolization when these therapies either have been done and failed or are contraindicated; **AND** when ALL of the following conditions are met:
         - Treatment of up to 3 lesions, **and**
         - Diameter of each lesion is less than 6 cm; **and**
         - Patients have a Child-Pugh category A or B.

         or
       - For retreatment of a previously irradiated field

11. Liver Metastasis
    a. As palliative treatment for individuals with liver-related symptoms; **OR**
    b. For retreatment of a previously irradiated field.

12. Kidney Cancer unresectable or metastases with **ANY** of the following:
    a. Relapse or Stage IV; **OR**
    b. Unresectable; **OR**
    c. Symptomatic metastases.

13. Lung metastases when **ALL** of the following criteria are met:
    a. Single metastatic lesion $\leq$ 5 cm; **and**
    b. Stable extracranial disease; **and**
    c. Tumor is not resectable or not a candidate for surgery.

14. Non-small cell lung cancer (NSCLC) when **ALL** of the following are met:
    a. Stage I or stage IIA with negative mediastinal lymph nodes; **AND**
    b. Single lesion $\leq$ 5 cm; **AND**
    c. Tumor is not resectable or not a candidate for surgery.

15. Occult Primary (Cancer of Unknown Primary)
    a. Localized adenocarcinoma or carcinoma not otherwise specified; **AND**
    b. Limited (1-3) metastatic lesions and pulmonary metastases

16. Extracranial oligometastases when **ALL** of the following are met:
    a. One to 3 metastatic lesions involving the lungs, liver, bone, adrenal glands, or spine; **AND**
    b. Primary tumor is breast, colorectal, melanoma, NSCLC, prostate, renal cell, or sarcoma; **AND**
    c. Primary tumor is controlled.

17. Pancreatic Adenocarcinoma
    a. For locally advanced or recurrent disease without evidence of metastasis; **or** for retreatment of a previously irradiated field; **AND**
    b. **ONE** of the following:
       - As neoadjuvant therapy in resectable or borderline resectable tumors, **or**
       - For palliative treatment,

       AND
    c. Not prescribed in the following case:
       - As adjuvant therapy in resected disease (i.e., treatment to the tumor bed), **or**
       - If there is direct invasion of the bowel or stomach.

18. Prostate Cancer without evidence of distant metastases when **ALL** of the following criteria are met:
    a. Other forms of radiotherapy, including but not limited to external beam and IMRT or seed implantation, cannot be as safely or effectively utilized; **AND**
    b. Low- or intermediate-risk localized prostate cancer defined as:
       - Low-risk of recurrence: State Stage T1-T2a **and** Gleason score of 6 **and** prostate-specific antigen (PSA) below 10 ng/mL; **or**
       - Intermediate-risk prostate cancer: Stage T2b to T2c **or** Gleason score of 7 or PSA of 10-20 ng/ml.

19. Rectal Cancer metastases

20. Soft Tissue Sarcoma of extremity/superficial trunk, head/neck metastases

21. Spinal or vertebral body tumors (metastatic or primary) when **ALL** of the following criteria are met:
    a. Poor candidate for surgery (i.e., due to prior surgery, tumor location, or individual ability to withstand surgery); **AND**
    b. Poor candidate for, or resistant to, conventional radiation therapy (i.e., stereotactic precision is required to avoid unacceptable radiation to unaffected tissues; patients who have received previous radiotherapy).

22. Squamous Cell Skin Cancer metastases
    a. Inoperable or not fully resectable disease; **OR**
    b. Symptomatic disease.

23. Thymomas and Thymic Carcinomas
    a. For limited focal metastases

24. Thyroid Carcinoma
    a. Locoregional recurrence for patients with unresectable, non-radioiodine-avid, and progressive disease; **OR**
    b. Unresectable locoregional recurrent/persistent disease or soft tissue metastases (e.g., lung, liver, muscle) excluding CNS metastases if metastatic lesion is progressive and/or symptomatic.

LIMITATIONS AND EXCLUSIONS

1. Only FDA approved devices can be utilized for treatments.

2. SRS typically is performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system, but can be performed in a limited number of sessions, up to a maximum of 5. If more than 1 session is required, the SBRT codes must be used.

3. SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance. Since the goal of SBRT is to intensify the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond 5 fractions is not considered SBRT and is not to be billed using these codes. SBRT is meant to represent a complete course of treatment and not be used as a boost following a conventionally fractionated course of treatment. (ASTRO; Model Policy 2020)

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above

2. Other uses of **SRS** are considered experimental, investigational, unproven and not medically necessary for the treatment of **ANY** of the following conditions:
    a. More than three (3) primary or metastatic lesions SRS is inappropriate; consideration should be given to whole brain irradiation
    b. Chronic pain
    c. Intractable pain (except tic douloureux/trigeminal neuralgia)
    d. Seizure Disorders; Epilepsy (except mesial temporal lobe epilepsy)
    e. Functional disorders (other than trigeminal neuralgia) including chronic pain and headaches
    f. Movement disorders (i.e., as Parkinson's Disease, essential tremor)
    g. Psychosis/Neuroses
    h. Robotically assisted SRS for any condition

3. Other uses of **SBRT** are considered experimental, investigational, unproven and not medically necessary for the treatment of **ANY** of the following conditions:
    a. Other Neoplasms: Lesions of bone, breast, uterus, ovary and other internal organs not listed above
    Informational Note: Current medical literature and review does not support an outcome advantage over other conventional radiation modalities.
    b. As treatment for pancreatic adenocarcinoma including ANY of the following:
        - As neoadjuvant therapy in resectable or borderline resectable tumors
        - As adjuvant therapy in resected disease (i.e., treatment to the tumor bed)
        - For palliative treatment
        - If there is direct invasion of the bowel or stomach
    c. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
    d. The tumor burden cannot be completely targeted with acceptable risk to nearby critical normal structures.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is a large body of evidence relating to SRS and SBRT consisting largely of systematic reviews, non-randomized comparative studies, noncomparative prospective and retrospective studies and case reviews. Randomized controlled trials that allow direct comparison of all of the possible variables involved in selecting specific SRS and SBRT treatment techniques are not published making it difficult to draw comparative effectiveness conclusions. Furthermore, many uses are for rare conditions where large comparative studies are not likely.

The peer-reviewed medical evidence is sufficient to determine the safety and efficacy of stereotactic radiosurgery as a treatment for arteriovenous malformations to reduce the risk of hemorrhage when the lesions are relatively small. There is also evidence to support the use of stereotactic surgery for local control of primary intracranial tumors that are not suitable for complete surgical resection or that have failed previous conventional therapies; however, the impact on survival depends on the type of tumor. There is evidence that stereotactic radiosurgery can provide high rates of tumor control and long-term progression-free survival for vestibular schwannomas. Stereotactic radiosurgery can also provide local tumor control and reduce brain recurrence for brain metastases, although impact on survival is largely dependent on extent of extracranial disease and tumor type. SRS has been demonstrated to have an advantage over traditional radiation treatment allowing higher dose delivery while minimizing radiation exposure to the surrounding normal tissue for intracranial and certain extracranial tumors such as lung and spine. SBRT has been shown to improve outcomes and reduce pain in patients with spinal (vertebral) tumors. Numerous nonrandomized, comparative studies have compared SBRT with surgery for NSCLC. These have shown that SBRT for patients with stage one NSCLC who are not candidates for surgical resection because of comorbid conditions or for those with early-stage disease who refuse surgery, survival rates may be comparable with surgical resection. Systematic reviews, nonrandomized comparative studies, noncomparative studies have reported outcomes for patients with prostate cancer and show promising initial results on the use of SBRT with seemingly low toxicity rates and relatively high rates of biochemical recurrence-free survival. Systematic reviews, comparative studies and larger case series have shown promising local control (LC rates), and outcomes are comparable to other forms of EBRT but with shorter treatment time. For renal and pancreatic cancers, smaller studies have shown promising local control rates and improved survival. A number of studies evaluated the safety and efficacy of SBRT oligometastases. Most addressed lung or liver metastases, although others addressed adrenal, bone, colorectal and other primary sites. These studies report a high rate of tumor control for isolated or few metastases (≤ 3 or ≤ 5). The local tumor control is reported at one-year to be in the range of 70% to 100%. The overall survival varied widely after two-years (21%-84%) among the studies. Although some adverse events were reported, overall rates for adverse events were low.

The peer-reviewed medical evidence is insufficient to determine the safety and efficacy of robotically assisted SRS compared with standard treatments for intra and extracranial lesions, including non-robotic SRS. The quality of evidence is low, and no conclusions can be drawn regarding the relative efficacy and safety because no studies directly compared the different systems. The level of evidence is insufficient to demonstrate the impact of SBRT on patient health outcomes in conditions that include chronic pain, epilepsy, functional disorders other that trigeminal neuralgia, movement disorders such as Parkinson's and in other disorders such as psychoneurosis. Methodological limitations noted across the studies included retrospective analysis, small size without power analysis or sample size calculations, unequal group sizes, incomplete statistical analysis, and follow-up that was insufficient or unequal across treatment groups.

National and Specialty Organizations

The **American Heart Association (AHA) and American Stroke Association (ASA)** published a 2017 scientific statement on the management of brain arteriovenous malformations (AVMs). 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 of less in volume or located in deep or eloquent regions of the brain (AHA/ASA 2017).

The **International RadioSurgery Association (IRSA)** (2009) published consensus-based guidelines on the treatment of brain or dural AVMs in 2009 which include a clinical pathway that incorporates patients' choice, AVM location and volume, and presence of residual AVM after repeat treatment to guide decisions about SRS use.

The **International Society of Stereotactic Radiosurgery (ISRS)** published a systematic review and meta-analysis in 2020 with the goal of establishing SRS practice guidelines for grade I-II AVMs (Graffeo et al., 2021). Eight studies were chosen for inclusion representing 1102 AVMs, of which 836 (76%) were grade II. Inclusion criteria included publications reporting post-SRS outcomes in ≥10 grade I-II AVMs with a follow-up of ≥ 24 months. Obliteration and hemorrhage were primary endpoints; secondary outcomes were SM parameters, dosimetric variables and "excellent" outcomes which were defined as total obliteration without new post-SRS deficit. Obliteration was achieved in 884 (80%) at a median of 37 months and 66 hemorrhages (6%) occurred during a median follow-up of 68 months. Total obliteration without hemorrhage was achieved in 78%. Of 836 grade II AVMs, SM parameters were reported in 680: 377 were eloquent brain and 178 had deep venous drainage, totaling 555/680 (82%) high-risk SRS-treated grade II AVMs. The authors concluded that SRS appears to be a safe, effective treatment for grade I-II AVM and may be

considered front-line treatment, especially for lesions in deep or eloquent locations; however, the authors also noted limitations of the small sample size and high risk of bias.

The **National Comprehensive Cancer Network (NCCN)** (2020) guidelines outline recommendations for cancer treatment by site that include the use of SRS and SBRT for certain cancers. Category 2A and above recommendations are considered medically necessary indications. NCCN provides guidelines for cancer treatment by site that include the use of SRS and SBRT for bone, CNS, colon, head and neck, hepatobiliary, lung, pancreas, prostate, kidney cancer, melanoma, uveal melanoma, soft tissue sarcoma, and thyroid. Refer to NCCN site for updated recommendations.

The **American Society for Radiation Oncology (ASTRO)** published an evidence-based guideline on SBRT in patients with early-stage NSCLC in 2017 (Videtic et al. 2017). 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 American Society of Clinical Oncology (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." (Schneider et al. 2018).

The *ASTRO Model Policy* outlines that SRS is not considered medically necessary under the following circumstances:

- Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
- Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
- Patients with poor performance status (Karnofsky Performance Status less than 40 or ECOG Performance greater than 3).
- Patients with essential tremor, coverage should be limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for invasive surgical procedure. Coverage should further be limited to unilateral thalamotomy.

SBRT model policy states that SBRT should be considered an appropriate alternative for select patients with low- to intermediate-risk prostate cancer (2014).

SUPPLEMENTAL INFORMATION

Non-Neoplastic Conditions Treated with SRS

- Arteriovenous malformations: A tangle of abnormal and poorly formed blood vessels (arteries and veins) with a higher rate of bleeding than normal vessels. AVMs can occur anywhere in the body, but brain AVMs present substantial risks when they bleed. Dural AVMs occur in the covering of the brain and are an acquired disorder that may be triggered by an injury. AVMs range in size from small, barely detectable lesions to huge lesions that can occupy an entire hemisphere. A small subset of AVMs because of their size or location cannot be excised without serious neurologic sequelae; therefore, SRS is an alternative in these patients.
- Trigeminal neuralgia: A disorder of the fifth cranial (i.e., trigeminal) nerve that causes episodes of intense, stabbing pain in the face. Trigeminal neuralgia is initially treated medically; however, 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 used an alternative to these neurosurgical treatments.

Benign Neoplastic Intracranial Lesions Treated with SRS

- Acoustic neuromas (also called vestibular schwannomas): 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. The tumors arise from the Schwann cell sheath surrounding the vestibular or cochlear branches of the eighth cranial nerve. For acoustic neuromas,

radiosurgery has been used as a primary treatment or as a treatment for recurrence after incomplete surgical resection.

- Craniopharyngiomas: Benign tumors that arise from pituitary embryonic tissue at the base of the gland. However, because of their proximity to the optic pathways, pituitary gland, and hypothalamus, these tumors may cause severe and permanent damage to these critical structures and can be life-threatening. For craniopharyngiomas, total surgical resection is often difficult.
- Glomus jugulare tumor: A rare, benign tumor arising in the skull temporal bone that involves middle and inner ear structures. No consensus exists on optimal management to control tumor burden while minimizing treatment-related morbidity.
- Pituitary adenomas**:** Benign tumors with symptoms related to hormone production (i.e., functioning adenomas) or neurologic symptoms due to tumor impingement on surrounding neural structures. 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. In patients with non-functioning adenomas, the treatment goal is to control growth; complete removal of the adenoma is not necessary. Conventional radiotherapy has been for nonfunctioning adenomas with an approximate 90% success rate and few complications. SRS has been used as a primary treatment for pituitary adenomas.

Uveal Melanoma treated with SRS: Melanoma of the uvea (choroid, ciliary body, and iris) is the most common, primary, malignant, intraocular tumor in adults. The established treatment modalities for the treatment of uveal melanoma include enucleation, local resection, brachytherapy, and proton beam radiotherapy. Photodynamic therapy with verteporfin has also been used as a primary treatment for choroidal melanoma. The main goal of treating the tumor is 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, QOL, concurrent systemic diseases, and patient expectations. SRS may be used as an alternative to enucleation of the eye.

Oligometastases: 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.

Karnofsky Performance Scale

100	Normal; no complaints, no evidence of disease
90	Able to carry on normal activity, minor signs or symptoms of disease
80	Normal activity with effort; some signs or symptoms of disease
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospitalization is indicated although death not imminent
20	Very sick; hospitalization necessary; active supportive treatment is necessary
10	Moribund, fatal processes progressing rapidly
0	Dead

ECOG Performance Status

0	Fully active, able to carry on all pre-disease performances without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours.
4	Completely disables. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

CODING & BILLING INFORMATION

Radiation oncologists and neurosurgeons have separate CPT billing codes for SRS. The comprehensive CPT code 61796, 61797, 61798, 61799, 61800, 63620 and 63621 may be billed by the neurosurgeon, as one member of the team, when and only when this physician is (a) present, (b) medically necessary and (c) fully participating, in the coded course of the procedure. The medical record must clearly indicate the critical nature of the anatomy or other circumstances necessitating the services encompassed by this code.

A radiation oncologist may bill the SRS management code 77432 for single fraction SRS (and only once per treatment course) when and only when fully participating in the management of the procedure. When SRS is administered in more than one but not more than 5 fractions, the radiation oncologist may instead bill the SBRT code 77435 to cover patient management during that course of therapy; the radiation oncologist may not bill 77432 and 77435 for the same course of therapy. In addition, a radiation oncologist may bill other appropriate radiation oncology (77xxx) codes when full participation in the coded procedure(s) is appropriately documented, as directed in Medicare policies.

One physician may not bill both the neurosurgical codes 61796-61800, 63620 or 63621 and the radiation oncology codes 77371-77435.

CPT Codes

CPT	Description
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex
61800	Application of stereotactic headframe for stereotactic radiosurgery
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), each additional spinal lesion
	CPT codes specific to SRS delivery
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
	CPT codes specific to SBRT
77373	Stereotactic body radiation therapy, treatment delivery per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions This code includes all image guidance on the days of treatment delivery; therefore, do not report 77373 in conjunction with 77014 on the days of treatment delivery. This code will be paid only once per day of treatment regardless of the number of sessions or lesions (Reference: ASTRO SBRT Model Policy 2020) • Do not report 77373 in conjunction with 77385, 77386, 77401, 77402, 77407, 77412, G6003-G6016) • For single fraction cranial lesion(s) see 77371, 77372
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions

HCPCS Codes

HCPCS	Description
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/8/2021 Policy reviewed and revised. IRO Peer Review: 12/_/2021. Practicing physician board certified in Radiation Oncology. Updated references, clinical studies and content of policy. Notable updates include:

- Added new indications and criteria accordingly:
  - Bone metastases
  - Gynecologic Cancers (previously only 'cervical cancer' but expanded diagnosis to gynecologic)
  - Genitourinary Cancer (Bladder, Penile, and Testicular)
  - Hemangiolastomas
  - Hepatocellular Carcinoma (HCC)
  - Low grade astrocytic and ganglioneuronal tumors
  - Medulloblastoma, supratentorial PNET, ependymoma
  - Mesial temporal lobe epilepsy
  - Nonacoustic schwannomas
  - Occult Primary (Cancer of Unknown Primary [CUP])
  - Oligometastatic prostate cancer
  - Thymomas and Thymic Carcinomas
  - Uveal melanoma (ocular lesion)
- Added the following criteria 'Only for retreatment of a previously irradiated field' to the existing diagnosis:
  - Thyroid cancer
  - Head and Neck Cancers
  - Esophageal, Gastric Cancers
- Revised criteria of the following indications
  - Bone Metastases (combined indications)
  - Gliomas
  - Kidney cancer
  - Squamous Cell Skin Cancer metastases
  - Trigeminal neuralgia
  - Prostate Cancer (removed 10-year life expectancy criterion)
  - Pancreatic Cancer
- Added the following to 'Limitations and Exclusions' section
  - Only FDA approved devices can be utilized for treatments.
  - SRS typically is performed in a single session… up to a maximum of 5. If more than 1 session is required, the SBRT codes must be used.
  - SBRT may be fractionated (up to 5 fractions)…. any course of radiation treatment extending beyond 5 fractions is not considered SBRT and is not to be billed using these codes. SBRT is meant to represent a complete course of treatment and not be used as a boost following a conventionally fractionated course of treatment.
  - Separated criteria for 'Other uses of SRS and SBRT are considered experimental, investigational, unproven and not medically necessary for the treatment of ANY of the following conditions.' Revision specific for SRS and SBRT in separate criteria.

12/9/2020 Policy reviewed. No changes to coverage criteria.

12/10/2019 Policy reviewed and updated based on the NCCN Guidelines that outline recommendations for SRS and SBRT. Category 2A and above recommendations are considered medically necessary indications. The 2019 NCCN Radiation Therapy Compendium was referenced for the revisions. Professional Society Guidelines, references, coding updated. IRO Peer Review: 10/10/2019. Practicing physician board certified in Radiation Oncology. The following additional references were used by peer reviewer:

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9/13/2018 Policy reviewed. No changes to coverage criteria.
12/13/2017 Policy reviewed. No changes to coverage criteria. The following revisions were added: Prostate cancer and Pineal gland tumors were included as medically necessary indications. Summary of medical evidence, professional guidelines and reference sections were updated. IRO Peer Review: 10/12/2017. Practicing physician board certified in Radiation Oncology.
9/15/2016 Policy reviewed. No changes to coverage criteria.
12/16/2015 Policy reviewed. No changes to coverage criteria.
12/18/2014 New policy.

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Peer Reviewed Publications

*Due to the large number of indications and relevant supporting literature in the policy, the following references may not be cited directly in policy:

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   - Cervical Cancer (1.2021)
   - Colon Cancer (2.2021)
   - Cutaneous melanoma (2.2021)
   - Head and Neck Cancers (3.2021)
   - Hepatobiliary Cancers (2.2021)
   - Lung (4.2021)
   - Kidney Cancer (1.2022)
   - Non-Small Cell Lung Cancer (5.2021)
   - Occult Primary (Cancer of Unknown Primary [CUP]) (2.2021)
   - Pancreatic Adenocarcinoma (2.2021)
   - Prostate Cancer (4.2021)
   - Rectal Cancer (1.2021)
   - Soft Tissue Sarcoma (2.2021)
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Medicare National Coverage: There is no national coverage determination for stereotactic radiosurgery/radiotherapy. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.