| Subject: Stereotactic Radiosurgery and Stereotactic Body Radiotherapy | | Original Effective Date: 12/18/2014 |
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## DISCLAIMER

*This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.*[1]

## DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [39-46]

Stereotactic radiosurgery (SRS) is a method of delivering high doses of ionizing radiation to small intracranial targets delivered via stereotactic guidance with ~1 mm targeting accuracy in a single fraction. This is achieved by using multiple, non-parallel radiation beams that converge on the target lesion sparing adjacent structures. The full therapeutic dose is limited to the area where all of the beams overlap, while non-target areas receive much smaller doses from one or a limited number of the radiation beams. SRS thus requires accurate localization of the lesion and patient positioning during treatment. SRS can be delivered using a medical linear accelerator, a gamma-ray treatment device, or a particle beam accelerator. Photon-based SRS (Gamma Knife, Linac, CyberKnife) are the three systems most widely available.

Stereotactic body radiotherapy (SBRT) is an external beam radiation therapy method used to very precisely deliver a high dose of radiation to an extracranial target within the body, using either a single dose or a small number of fractions. SBRT combines multiple radiation beams to deliver an accurate, high dose of radiation to a carefully defined location. There are several terms that have been used interchangeably for SBRT. These terms include stereotactic radiotherapy, fractionated stereotactic radiosurgery, hypofractionated stereotactic radiosurgery, and staged radiosurgery. Consensus does not exist for the definition of SBRT with respect to a maximum number of radiation fractions, the minimum radiation dose per fraction, or the maximum number and diameter of lesions to be treated.

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 radiosurgical assessments via CT, MRI, or angiography are performed at periodic intervals to determine the effects of treatment.

**RECOMMENDATION** [4-30 31-38 39-46 48]

Stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) may be considered medically necessary and may be authorized when ALL of the applicable individual clinical criteria are met:

1. The patient's general medical condition (performance status > 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

2. The tumor burden can be completely targeted with acceptable risk to critical normal structures when used for the treatment of ANY of the following:
   - ❑ Acoustic neuromas also known as Vestibular Schwannomas
   - ❑ Craniopharyngiomas
   - ❑ Gliomas high grade (III and IV): initial treatment or recurrent when the following criteria is met:
     - o tumor is not resectable or not a candidate for surgery
   - ❑ Glomus jugulare tumors
   - ❑ Intracranial chordomas and chondrosarcomas of the skull base
   - ❑ Intracranial Arteriovenous (AV) Malformations when all of the following criteria are met: [39 48]
     - o ≤ 3cm by imaging
     - o poor candidate for surgery (i.e. due to prior surgery, tumor location, or individual ability to withstand surgery) [39]
   - ❑ Lung metastases when all of the following criteria are met:
     - o single metastatic lesion ≤ 5 cm; and
     - o stable extracranial disease
     - o tumor is not resectable or not a candidate for surgery
   - ❑ Meningioma: non-resectable, residual, or recurrent
   - ❑ Metastatic brain lesions when all of the following criteria are met: [48]
     - o stable disease
     - o lesion(s) margins are radiographically distinct
     - o ≤ 1-3 lesions
     - o lesions are ≤ 3cm by imaging
   - ❑ Non-small cell lung cancer (NSCLC) when all of the following are met:
     - o Single lesion ≤ 5 cm; and
     - o tumor is not resectable or not a candidate for surgery
   - ❑ Pituitary adenomas
   - ❑ Pineal gland neoplasms
   - ❑ Prostate Cancer when all of the following criteria are met:

- Low grade prostate cancer defined by a Gleason score = to 6 and prostate-specific antigen (PSA) < than 10 ng/mL; and/or
- Intermediate risk prostate cancer defined by a Gleason score of 7 or less and PSA < than 20 ng/ml; AND all of the following:
- Minimal disease defined as < than 4 cores positive; and
- No evidence of extraprostatic disease; and
- Life expectancy of > than 10 years.

❑ Spinal or vertebral body tumors (metastatic or primary) when all of the following criteria are met:
- Poor candidate for surgery (i.e. due to prior surgery, tumor location, or individual ability to withstand surgery)
- Poor candidate for conventional radiation therapy (i.e. stereotactic precision is required to avoid unacceptable radiation to unaffected tissues).

❑ Trigeminal neuralgia when all of the following criteria are met: [48]
- refractory to medical treatment: (i.e. anticonvulsant or baclofen trial for a minimum of 8 weeks)
- stabbing pain in the trigeminal nerve distribution

**Exclusions:** Other uses of SRS and SBRT are considered experimental, investigational, unproven and not medically necessary [31-46] for the treatment of any of the following conditions:

- Chronic pain
- Epilepsy
- Functional disorders other than trigeminal neuralgia
- Other extracranial sites (i.e. Primary or metastatic cancers of the kidney, liver, colon and pancreas.)
- Parkinson's and other movement disorders (i.e. essential tremor)
- Psychoneurosis
- Robotically assisted stereotactic radiosurgery (SRS) for any condition [40 41 43]

## SUMMARY OF MEDICAL EVIDENCE [2 4-30]

The peer reviewed medical evidence is insufficient to determine the safety and efficacy of robotically assisted stereotactic radiosurgery (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 of these systems 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, extracranial tumors of the ovaries, primary and metastatic tumors of the liver, pancreas, kidney, adrenal glands, and pelvis; movement disorders such as parkinson's and in other disorders such as psychoneurosis.

The peer reviewed medical evidence from prospective and retrospective studies is sufficient to determine the safety and efficacy of stereotactic radiosurgery as a treatment for arteriovenous malformations (AVMs) 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. There is a large body of literature therefore only a summary of the most relevant studies is provided below.

*Brain Metastases* [4 5 6 33 37 48]

The published literature on SRS for the treatment of brain metastases suggests some benefit, including local control and reduction of recurrence. A Randomized controlled trial of 132 patients with 1 to 4 brain metastases, each less than 3 cm in diameter was performed to determine if WBRT combined with SRS results in improvements in survival, brain tumor control, functional preservation rate, and frequency of neurologic death. The median survival time and the 1-year actuarial survival rate were 7.5 months and 38.5% in the WBRT + SRS group and 8.0 months and 28.4% for SRS alone. The 12-month brain tumor recurrence rate was 46.8% in the WBRT + SRS group and 76.4% for SRS alone group. Salvage brain treatment was less frequently required in the WBRT + SRS group (n = 10) than with SRS alone (n = 29). [4] A Cochrane review showed that for patients with one brain metastasis median survival was significantly longer in WBRT plus SRS group (6.5 months) versus WBRT group (4.9 months; P = 0.04). Patients in the WBRT plus SRS group had decreased local failure compared to patients who received WBRT alone (HR 0.27; 95% CI 0.14 to 0.52). Furthermore, a statistically significant improvement in performance status scores and decrease in steroid use was seen in the WBRT plus SRS group. Unchanged or improved Karnofsky Performance Scale (KPS) at 6 months was seen in 43% of patients in the combined therapy group versus only 28% in WBRT group (P = 0.03). [5]

*Gliomas* [24 25]

Glioblastoma multiforme (GBM) is the most common malignant primary brain tumor with a survival prognosis of 14-16 mos for the highest functioning patients. Studies have compared recent survival and quality of life outcomes following Gamma Knife radiosurgery (GKRS) salvage therapy. Salvage SRT was safe and effective for recurrent glioma, especially non-diffuse recurrences. The OS and local control probability after SRT were 83% and 56% at 6 months after SRT, respectively. [25] The greatest survival advantages were seen in patients who received GKRS salvage therapy with median progression-free survival (range: 4.6-14.9 mo). [25]

*Lung Cancer* [12-18]

Surgical resection is considered the standard treatment of NSCLC but SBRT has been studied as a treatment of inoperable NSCLC or in those whose clinical status excludes surgery. Forty-four individuals with T1 tumors and eleven participants with T2 tumors that were less than five cm in diameter were enrolled in a Phase II North American multicenter study of SBRT for inoperable early stage lung cancer with a mean follow-up of 34.4 months (range, 4.8-49.9 mos.). The 3-year primary tumor control rate was 97.6%. Although the overall survival rate was 55.8%, the 3-year rate of disseminated failure was 22.1%. The authors determined this trial demonstrated successful SBRT is possible with proper facilities and support services and that further studies are

necessary that address disseminated failure post treatment as well as effective dosing for central lung and peripheral tumors. [18]

SBRT has also been proposed as a treatment of lung metastases. A retrospective analysis of 61 individuals with lung metastases (77 tumors) treated with SBRT was reported in individuals with one to three lung metastases and a maximum tumor diameter smaller than 50mm. Median follow-up time was 20.4 months. At 2 years, local control was 89%, overall survival was 66.5%, cancer-specific survival was 75.4%, and progression-free survival was 32.4%. Median survival time was 42.8 months. Median progression-free survival time was 11.9 months. The group of individuals (n=24) with small single metastasis had a progression-free survival rate of 70% at 1 year and 52.8% at years 2 and 3. [16]

*Prostate Cancer* [26-30]

A small body of evidence suggests that SBRT with the CyberKnife system has similar oncologic efficacy and safety as IMRT, EBRT, or HDR brachytherapy, as reflected by a measure of bFFS rates, and toxicities, including GI, GU, and sexual function domains. A study by Katz (2014) reported on the 7-year outcomes for individuals with low- to intermediate-risk prostate cancer who received SBRT. A total of 477 men were included in the study. All of the men had biopsy-proven, newly diagnosed non-metastatic prostate cancer. Fifteen of the men were treated prospectively to assess the feasibility of the approach. The rest of the participants were treated to the approved protocol, but not in a prospective fashion. Their outcomes were incorporated as a retrospective study. Only low-risk (n=324) and intermediate-risk participants (n=153) were included. For this study, low risk was defined as PSA less than 10 ng/mL and Gleason less than 7. Intermediate risk was defined as PSA 10-20 ng/mL or Gleason equal to 7. With a median follow-up of 72 months, the biochemical disease-free survival rate was 93.7% for all participants. For low risk it was 95.9% and for intermediate risk it was 89.3%. The overall median PSA at 7 years was 0.11 ng/mL. There was no grade 3-4 acute genitourinary or gastrointestinal toxicity. Nine participants had late grade 3 genitourinary toxicity. [27]

*Solid Malignant Tumors* [2]

A systematic review of the literature conducted by AHRQ (2011) was published regarding the treatment of stereotactic body radiation therapy (SBRT) for solid malignant tumors. A total of 124 relevant prospective and retrospective single group studies were identified. The bulk of the studies examined SBRT for tumors of the lung/thorax (k = 68). 27 studies were found of tumors located in the pancreas, liver, colon, and fewer than 10 studies each for sites within uterus, pelvis, sacrum, kidney, prostate, and thyroid. There were 10 studies that included multiple treatment sites within the study. Study size varied from 3 to 398 patients. The shortest mean and median follow-up was within the multiple site category (12.9 and 8.2 months [1-95 months] respectively). Studies of the tumors involving the pelvis, sacrum, and uterus had the longest mean/median follow-up (31 and 33 months [range 2-77 months]). The reported outcomes include tumor control/response, toxicity, and overall survival. SBRT appears to be widely disseminated for treatment of a variety of cancer types, although a majority of studies have only focused on treatment of thoracic tumors. The study reported that SBRT requires accuracy in delivery of the high dose of radiation, patient immobilization, target localization, maneuvers to either limit or compensate for target movement (tracking software), and the use of stereotaxy. It can be completed in one to five fractions and may be a treatment option for patients who refuse surgery, for tumors considered inoperable, or when traditional RT is not an option. [2]

*Spine* [19-22]

Extracranial tumors in the spinal cord have been reported to be effectively treated with SBRT. In 51 participants with 72 primary or metastatic spinal cord lesions treated with SBRT pain was significantly decreased both at four weeks ($p<0.001$) and at one year ($p=0.002$). Quality of life was maintained throughout the study period. [19] A large cohort of 500 cases of spinal metastases who underwent radiosurgery demonstrated long-term tumor control in 90% of lesions treated with radiosurgery as a primary treatment modality and in 88% of lesions treated for radiographic tumor progression. Long-term pain improvement occurred in 290 of 336 cases (86%). A total of 27 out of 32 cases (84%) with a progressive neurologic deficit before treatment experienced at least some clinical improvement. [21] A 2012 phase I/II study examined149 individuals with non-cord-compression spinal metastases who were treated with SBRT. The median overall survival time was 23 months following SBRT. Individuals reported a reduction in pain from baseline and four weeks post SBRT treatment and between baseline and six months post SBRT treatment. There was also a reduction in opioid use from baseline to three months and baseline to six months following SBRT treatment. [22]

*Vestibular Schwannomas (VS)*[8 9 23]

A prospective cohort study described 82 patients with unilateral, unoperated VS less than 3 cm undergoing surgical resection (n = 36) or radiosurgery (n = 46). Patients undergoing resection were younger (48.2 yr. versus 53.9 yr.). The groups were similar with regard to hearing loss, associated symptoms, and tumor size. The mean follow-up period was 42 months (range, 12-62 mos.). Normal facial movement and preservation of serviceable hearing was more frequent in the radiosurgical group at 3 months 1 year and at the last follow-up examination compared with the surgical resection group. Early outcomes were better for VS patients undergoing stereotactic radiosurgery compared with surgical resection. [24] A meta-analysis reported that stereotactic radiation showed significantly better long-term hearing preservation outcome rates than microsurgery. [8]

**CODING INFORMATION** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| CPT | Description |
|---|---|
| 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 |
| 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 |
| 77373 | Stereotactic body radiation therapy, treatment delivery per fraction to 1 or more lesions, including |

| | |
|---|---|
| | image guidance, entire course not to exceed 5 fractions |
| 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 | 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 |

| ICD-10 | Description: [For dates of service on or after 10/01/2015] |
|---|---|
| C34.00-C34.92 | Primary lung cancer |
| C41.0 | Malignant neoplasm of bones of skull and face (Chordoma) |
| C41.9 | Malignant neoplasm of bone and articular cartilage, site unspecified (Chondrosarcoma) |
| C70-C72.9 | Malignant neoplasm brain, meniges, spinal cord |
| C78.00-C78.02 | Lung metastasis |
| C79.3-C79.49 | Secondary malignant neoplasm of brain, cerebral meninges; other parts of nervous system (spinal cord) |
| D32.0-D32.9 | Benign neoplasm of meninges |
| D33.3-D33.4 | Benign neoplasm of cranial nerves [specified as acoustic neuroma or schwannoma]; spinal cord |
| D35.2-D35.4 | Benign neoplasm of pituitary gland, craniopharyngeal duct [craniopharyngioma], pineal gland |
| D43.3-D43.4 | Neoplasm of uncertain behavior of cranial nerves [specified as acoustic neuroma or schwannoma]; spinal cord |
| D44.3 | Neoplasm of uncertain behavior of pituitary gland |
| D44.4 | Neoplasm of uncertain behavior of craniopharyngeal duct [craniopharyngioma] |
| G50-G50.9 | Trigeminal neuralgia |
| Q28.2 | Arteriovenous malformation of cerebral vessels |

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***Review/Revision History:***

*12/18/14: New Policy*

*12/16/15 & 9/15/16: Policy reviewed, no changes to criteria.*

*12/13/17: 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.*

*9/13/18 & 9/18/19: Policy reviewed, no changes.*