Subject: Stereotactic Radiosurgery and Stereotactic Body Radiotherapy		Original Effective Date: 12/18/14
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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 [40]

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.

CLINICAL CRITERIA [4-30 31-43 44-99]

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. Please review NCCN current guidelines for the most up to date clinical scenarios and SRS SBRT therapy recommendations. Category 2A and above are considered medically necessary:

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
   - ❑ Anal Carcinoma [37]
   - ❑ Cervical Cancer [37]
   - ❑ Colon Cancer [37] metastases with any of the following:
     - Limited liver or lung metastases
     - Alternative to resection or ablative procedures
   - ❑ Chondrosarcoma [37]
   - ❑ Craniopharyngiomas
   - ❑ Cholangiocarcinoma [37] with any of the following:
     - Extrahepatic with:
       - ➢ unresectable or resected with gross residual disease
     - Intrahepatic with:
       - ➢ post resection with positive regional nodes or unresectable
       - ➢ post resection with metastatic extra-hepatic disease
   - ❑ Cutaneous Melanoma [37] ablative treatment for intact extracranial metastases
   - ❑ Ewing Sarcoma [37]
   - ❑ Head and Neck Cancers [37]
   - ❑ Gallbladder Cancer [37] with resected gross residual disease or unresectable
   - ❑ Gliomas high grade (III and IV): initial treatment or recurrent when the following criteria is met:
     - 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:
  - o ≤ 3cm by imaging
  - o poor candidate for surgery (i.e. due to prior surgery, tumor location, or individual ability to withstand surgery) [39]
- ❑ Kidney Cancer [37] unresectable or metastases with any of the following:
  - o Relapse or Stage IV
  - o Bone Metastases
  - o Brain metastases
  - o Symptomatic metastases
- ❑ 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
- ❑ Limited metastatic brain lesions [37] with any the following:
  - o Newly diagnosed
  - o stable systemic disease
  - o reasonable systemic treatment options exist
- ❑ Extensive Brain Metastases [37] with the following:
  - o Recurrence after brain RT
  - o Stable systemic disease or systemic treatment options
- ❑ 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
- ❑ Osteosarcoma [37]
- ❑ Pancreatic Adenocarcinoma [37] with any of the following:
  - o locally advanced
  - o local recurrence in the pancreatic operative bed after surgery
  - o metastases
  - o progression
- ❑ Pituitary adenomas
- ❑ Pineal gland neoplasms
- ❑ Prostate Cancer when all of the following criteria are met: [36]
  - o Low grade prostate cancer defined by a Gleason score = to 6 and prostate-specific antigen (PSA) < than 10 ng/mL; and/or
  - o Intermediate risk prostate cancer defined by a Gleason score of 7 or less and PSA < than 20 ng/ml; AND all of the following:
  - o Minimal disease defined as < than 4 cores positive; and
  - o No evidence of extraprostatic disease; and
  - o Life expectancy of > than 10 years.
- ❑ Rectal Cancer [37] metastases
- ❑ Soft Tissue Sarcoma [37] of extremity/superficial trunk, head/neck metastases
- ❑ Spinal or vertebral body tumors (metastatic or primary) when all of the following criteria are met:
  - o 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).

- ❑ Squamous Cell Skin Cancer [37] metastases
- ❑ Thyroid Carcinoma [37]
- ❑ 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

LIMITATIONS

Other uses of SRS and SBRT are considered experimental, investigational, unproven and not medically necessary for the treatment of any of the following conditions: [31-40]

- Chronic pain
- Epilepsy
- Functional disorders other than trigeminal neuralgia
- Parkinson's and other movement disorders (i.e. essential tremor)
- Psychoneurosis
- Robotically assisted stereotactic radiosurgery (SRS) for any condition [40]

SUMMARY OF MEDICAL EVIDENCE [2 4-30 44-99]

There is a large body of evidence relating to SRS and SBRT consisting largely of systematic reviews, nonrandomized 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 (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. 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, the 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.

PROFESSIONAL SOCIETY GUIDELINES

Professional Society Guidelines [31-39]

The American Heart Association and American Stroke Association 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 cm3 of less in volume or located in deep or eloquent regions of the brain. [39]

The National Comprehensive Cancer Network (NCCN) Guidelines [37] outline recommendations for SRS and SBRT. Category 2A and above recommendations are considered medically necessary indications. At the time of this revision the 2019 NCCN Radiation Therapy Compendium outlined specific clinical scenarios available online at this link: https://www.nccn.org/professionals/radiation/default.aspx

The ASTRO Model Policy [36] 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.

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
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
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

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    - Colon Cancer
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    - Hepatobiliary Cancers
    - Kidney Cancer
    - Non-Small Cell Lung Cancer
    - Occult Primary
    - Pancreatic Adenocarcinoma
    - Prostate Cancer
    - Rectal Cancer
    - Soft Tissue Sarcoma
    - Squamous Cell Skin Cancer
    - Thyroid Cancer
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REVIEW/REVISION HISTORY

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: Policy reviewed, no changes.
12/10/19: Policy reviewed and updated based on the National Comprehensive Cancer Network (NCCN) Guidelines that outline recommendations for SRS and SBRT. Category 2A and above recommendations are considered medically necessary indications. At the time of this revision the 2019 NCCN Radiation Therapy Compendium was referenced for the revisions. Professional Society Guidelines, references, coding updated.
12/9/20: Policy reviewed, no changes.