

MEDICAL POLICY

SUBJECT: STEREOTACTIC RADIOSURGERY AND STEREOTACTIC BODY RADIATION THERAPY	EFFECTIVE DATE: 01/20/00 REVISED DATE: 09/19/01, 07/18/02, 07/17/03, 08/19/04, 09/15/05, 08/17/06, 09/20/07, 10/23/08, 07/16/09, 08/19/10, 11/17/11, 09/20/12, 05/23/13, 02/20/14, 08/21/14, 11/19/15, 10/20/16, 02/15/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature:

- I. *Stereotactic radiosurgery* has been medically proven to be effective and therefore **medically appropriate** for the following indications:
 - A. Benign conditions:
 1. Arteriovenous malformations (less than 4 cm in diameter);
 2. Acoustic neuromas;
 3. Pituitary adenomas;
 4. Nonresectable, residual, or recurrent meningiomas;
 5. Craniopharyngiomas;
 6. Glomus jugulare tumor;
 7. Hemangioblastoma;
 8. Pineocytoma;
 9. Schwannoma;
 10. Cavernous malformations.
 11. Carotid body tumor;
 12. Glomus tympanicum;
 13. Glomus vagale
 - B. Primary tumors of the brain and spinal cord *that have been previously irradiated.*
 - C. Primary spinal tumor with compression or intractable pain. (Literature doesn't support – ASTRO recommends in clinical trial)
 - D. Brain metastases under the following conditions:
 1. Initial treatment:
 - a. Any number of lesions to be treated with no lesion greater than 3 cm; and
 - b. Patient has a good performance status; and
 - c. Systemic disease is limited and under control (or good options for systemic treatment are available); and all lesions can be encompassed in a single treatment plan; and
 - d. The total volume of treated lesions should be considered safe to deliver SRS.
 2. Previous whole brain irradiation (WBRT):
 - a. Patient has a good performance status; and
 - b. Systemic disease is under control.
 3. No previous WBRT:
 - a. Recurrence with 1- 5 lesions; and
 - b. More than 6 months has elapsed since RT; and
 - c. Patient has a good performance status; and
 - d. Systemic disease is under control.

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- E. The following indications when refractory to medical management and/or invasive neurosurgical treatment:
1. Trigeminal neuralgia;
 2. Movement disorders (e.g., epilepsy, Parkinson's disease, essential tremor, or familial tremor) classifications with major systemic disease.
- II. *Stereotactic body radiation therapy (SBRT)* has been medically proven to be effective and therefore **medically appropriate** for the following indications:
- A. Recurrent or residual nasopharyngeal, carcinoma at primary site when radiation therapy treatments such as three-dimensional conformal or IMRT cannot be utilized;
- B. Spinal or vertebral body tumors (metastatic or primary) in patients who have received prior radiation therapy;
- C. Inoperable stage I or II Non-small cell lung cancer (NSCLC);
- D. Pancreas:
1. Preoperative (neoadjuvant resectable or borderline resectable), following a minimum of 2 cycles of chemotherapy, and restaging in which there is no evidence of tumor progression; or
 2. Definitive treatment for medically inoperable or locally advanced, following a minimum of 2 cycles of chemotherapy and restaging when there is no evidence of tumor progression, and the disease volume can be entirely encompassed in the radiation treatment volume; or
 3. Postoperative (adjuvant) when there is residual gross disease or positive microscopic margins that can be entirely encompassed in the radiation treatment volume;
 4. For palliative situations SBRT is considered **not medically necessary**.
- E. Primary Liver Cancer (Hepatocellular Carcinoma [HCC]) in the definitive setting to treat concurrently one or more tumors when there is evidence of the ability to protect an adequate volume of uninvolved liver.
- F. Any of the following neoplasms presenting with 1 to 3 metastases in the synchronous setting when local control is expected and treatment of the metastases may result in an increased disease-free interval and possible survival:
1. For an individual with non-small cell lung cancer who:
 - a. has had or who will undergo curative treatment of the primary tumor (based on T and N stage) and
 2. For an individual with colorectal cancer who:
 - a. has had or who will undergo curative treatment of the primary tumor and
 - b. whose metastases are in the lung or liver and
 - c. for whom surgical resection is not possible.
- G. Any of the following neoplasms where the primary tumor was previously controlled and metachronous metastases have presented under all of the following circumstances:
1. Clinical presentation of 1 to 3 metastases of the adrenal gland, lung, liver, or bone when the following criteria are met:
 - a. histology is non-small cell lung, colon, breast, sarcoma, renal cell or melanoma;
 - b. disease free interval of greater than one (1) year from the initial diagnosis;
 - c. primary tumor received curative therapy and is controlled;
 - d. no prior evidence of metastatic disease (cranial or extracranial); or
 2. An individual with sarcoma, renal, or melanoma metastases who meets the following criteria:
 - a. disease free interval of > 1 year from the initial diagnosis; and
 - b. primary tumor received curative therapy and is controlled; and
 - c. no prior evidence of metastatic disease.
 3. An individual with breast cancer who meets the following criteria:
 - a. has 1 to 3 sites of disease limited to the lung, liver, or bone;

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- b. disease free interval of greater than one (1) year from the initial diagnosis;
- c. primary tumor received curative therapy to the primary tumor.

4. SBRT to greater than 3 sites other than those indications listed above is considered **experimental/investigational**.

H. Prostate cancer; clinically localized disease when used as definitive treatment low-, intermediate-, and high-risk and negative bone scan within the last 6 months (bone scans not recommended for patients with low risk prostate cancer – PSA less than 10 and GS less than 7 and stage 1c/2a). \

I. Locally recurrent soft tissue sarcoma that is within or immediately adjacent to an area that has received radiation treatments as part of the primary management.

III. *Stereotactic body radiation therapy* has not been medically proven to be effective and is considered **not medically necessary** for extrahepatic bile duct cancer (cholangiocarcinoma), gall bladder cancer.

IV. *Stereotactic radiosurgery* has not been medically proven to be effective and is considered **not medically necessary** for the treatment of chronic pain.

V. *Stereotactic body radiation therapy* has not been medically proven to be effective and is considered **investigational** as a boost for prostate cancer.

Refer to Corporate Medical Policy #6.01.11 regarding Proton Beam Radiation.

Refer to Corporate Medical Policy #6.01.24 regarding Intensity Modulated Radiation Therapy (IMRT).

Refer to Corporate Medical Policy #7.01.23 regarding Deep Brain Stimulation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Stereotactic radiosurgery (SRS). SRS is a method of delivering high doses of ionizing radiation to small targets. This technique differs from conventional radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over a number of sessions. SRS entails delivering highly focused convergent beams in a single session so that only the desired target is radiated, sparing adjacent structures.

Stereotactic body radiation therapy (SBRT). As stated in the guideline developed by the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO), stereotactic body radiation therapy (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. Specialized treatment planning results in high target dose and steep dose gradients beyond the target. The ability to deliver a single or a few fractions of high-dose ionizing radiation with high targeting accuracy and rapid dose falloff gradients encompassing tumors within a patient provides the basis for the development of SBRT. SBRT can be applied using noninvasive or minimally invasive stereotactic localization and radiation delivery techniques. It requires significantly improved delivery precision over that required for conventional radiotherapy. Specialized imaging techniques may be required to either limit or compensate for target movement during treatment planning and delivery.

RATIONALE:

The addition of stereotactic radiosurgery as a treatment regimen for intracranial masses less than 4 cm in diameter (e.g., gliomas, brain metastases, and meningiomas) has improved health outcomes by providing local tumor control

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and increasing survival rates. Radiosurgery in patients with lesions over 4 cm is associated with increased complications (e.g., radionecrosis, CNS toxicity) and lowers probability of reaching effective radiation doses.

Radiosurgery performed on inoperable *arteriovenous malformations* (AVM's) with diameters less than 4 cm have found to have obliteration rates up to 94%.

Stereotactic radiosurgery for *trigeminal neuralgia* refractory to medical management has similar outcomes compared to alternative treatments (e.g., microvascular decompression), is the least invasive non-pharmacologic treatment and is associated with less complications (facial paresis, pain recurrence) than alternative treatments. Outcomes of Gamma radiosurgery for acoustic neuroma include local tumor control, preservation of hearing and facial nerve function.

While data is minimal investigating whether the cumulative higher radiation provides improved patient outcomes such as medium survival or quality of life for patients with *malignancies*, it is felt fractionated radiosurgery (stereotactic radiotherapy) provides a palliative benefit and can offer a chance of prolonged survival. Its use for the treatment of *acoustic neuroma* increases the preservation of facial nerve function and decreases hearing loss associated with alternative treatments. A single-institution study reported outcomes of single fractions vs. fractionated LINAC-based stereotactic radiosurgery in 129 patients with acoustic neuromas. With an average follow-up of 33 months, there was no difference in outcome in terms of local tumor control, facial nerve preservation, and hearing preservation.

Small case series examined the role of gamma knife radiosurgery in the treatment of *refractory movement disorders*, although radiofrequency ablation or deep brain stimulation would be considered the gold standard therapies for this indication. The ordering provider must certify that the usual and customary treatments outlined above would not be successful in managing the member's condition.

Several small prospective studies of stereotactic radiosurgery of *spinal cord lesions*, metastatic and primary, conclude that radiation-induced toxicity is minimal with axial and radicular pain improvement as high as 96%. Major benefits are relatively short treatment time in an outpatient setting combined with potentially better local control of the tumor with minimal risk of side effects. Stereotactic technique also allows for the treatment of lesions previously irradiated with conventional external beam irradiation.

Literature has increased regarding stereotactic radiosurgery/radiotherapy of other extracranial sites. Numerous studies address SRS/SRT of the lung and liver (for both primary and metastatic lesions), renal cell carcinoma (for both primary and metastatic lesions), pancreas, adrenal glands, and for oligometastases. These studies are generally of small sample size but show that the control rate is similar to the control rate for brain metastases (e.g. over 90%).

Literature is active with respect to the use of SRT for treatment of low to intermediate risk prostate cancer. Studies are small but improvements in quality of life and mild (grade I-II) toxicities have been reported. SBRT using a hypofractionation regimen for treatment of prostate cancer has been suggested as a more cost-effective alternative to IMRT because the treatment time is shorter, it utilizes resources more effectively, and this regimen is more convenient to the patient with less time away from work and savings in transportation and housing if the treatment center is located away from the patient's home. Preliminary modeling comparing costs of IMRT, radical prostatectomy and SBRT show SBRT is more cost-effective. However the models assume the efficacy, treatment-related toxicities and costs of treating the toxicities are the same for all treatment modalities. Since the period of follow-up is currently much shorter for SBRT than the other modalities, there is uncertainty of the frequency and severity of late effects. Thus the current models may show a greater difference in costs and savings than those reported once SBRT late effects are known. Current studies all recommend larger study sizes and longer follow-up to determine late toxicities of treatment of prostate cancer using hypofractionated stereotactic body radiation therapy. Recommendations on SBRT for prostate cancer treatment after the 2010 ASTRO conference concluded that SBRT for prostate cancer is technically feasible with little reported morbidity. Very early results of limited statistical power suggest that the initial PSA response is equivalent to that observed with conventional fractionated RT with follow up beyond 5 years but less than 10 yrs. SBRT for low and intermediate risk prostate cancer in selected and well-informed patients is considered an acceptable first line of treatment. However comparative studies are still needed.

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Literature regarding stereotactic radiosurgery/radiotherapy as first-line treatment of meningioma consists of prospective and retrospective case series that conclude SRS provides high rates of tumor growth control or regression in patients with benign meningiomas with low risk, and in patients with cavernous sinus meningioma.

Due to a lack of clinical trials, there is insufficient evidence to permit conclusions about health outcomes for the treatment of chronic pain.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with placement of fiducial markers, single or multiple
	31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure(s))
	32553	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
	49411	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple
	49412	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), open, intra-abdominal, intrapelvic, and/or retroperitoneum, including image guidance, if performed, single or multiple (List separately in addition to code for primary procedure)
	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s), consisting of one session; multi-source cobalt 60 based
	77372	linear accelerator based
	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one 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, pretreatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions
	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 lesions, simple (List separately in addition to code for primary procedure)
	61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion

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- 61799 Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)
- 61800 Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)
- 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 (List separately in addition to code for primary procedure)

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HCPCS: Medically appropriate for diagnosis codes listed below:

- G0339 Image guided robotic linear accelerator base 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

ICD10:

- C22.0-C22.9 Malignant neoplasm of liver and intrahepatic bile ducts (code range)
- C34.00-C34.92 Malignant neoplasm of bronchus and lung (code range)
- C41.0 Malignant neoplasm of bones of skull and face
- C41.2 Malignant neoplasm of vertebral column
- C61 Malignant neoplasm of prostate
- C64.1-C64.9 Malignant neoplasm of kidney, except renal pelvis (code range)
- C65.1-C65.9 Malignant neoplasm of renal pelvis (code range)
- C70.0-C70.9 Malignant neoplasm of meninges (code range)
- C71.0-C71.9 Malignant neoplasm of brain (code range)
- C72.0-C72.1 Malignant neoplasm of spinal cord and cauda equine (code range)
- C75.1-C75.3 Malignant neoplasm of other endocrine glands and related structures (code range)
- C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct
- C79.00-C79.02 Secondary malignant neoplasm of kidney and renal pelvis (code range)
- C79.31 Secondary malignant neoplasm of brain
- D01.5 Carcinoma in situ of liver, gallbladder and bile ducts
- D18.02 Hemangioma of intracranial structures
- D32.0-D32.9 Benign neoplasm of meninges (code range)
- D33.0-D33.4 Benign neoplasm of brain and other parts of central nervous system (code range)
- D52.2-D52.4 Benign neoplasm of other and unspecified endocrine glands (code range)

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D37.6	Neoplasm of uncertain behavior of liver, gallbladder and bile ducts
D42.0-D42.9	Neoplasm of uncertain behavior of meninges (code range)
D43.0-D43.4	Neoplasm of uncertain behavior of brain and central nervous system (code range)
D44.3-D44.5	Neoplasm of uncertain behavior of pituitary gland and craniopharyngeal duct (code range)
G50.0	Trigeminal neuralgia
Q04.9	Congenital malformation of brain, unspecified
Q06.9	Congenital malformation of spinal cord, unspecified
Q07.9	Congenital malformation of nervous system, unspecified
Q27.9	Congenital malformation of peripheral vascular system, unspecified
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

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<p>SUBJECT: STEREOTACTIC RADIOSURGERY AND STEREOTACTIC BODY RADIATION THERAPY</p> <p>POLICY NUMBER: 6.01.12 CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 01/20/00 REVISED DATE: 09/19/01, 07/18/02, 07/17/03, 08/19/04, 09/15/05, 08/17/06, 09/20/07, 10/23/08, 07/16/09, 08/19/10, 11/17/11, 09/20/12, 05/23/13, 02/20/14, 08/21/14, 11/19/15, 10/20/16, 02/15/18</p> <p>PAGE: 9 OF: 9</p>
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KEY WORDS:

CyberKnife, Fractionated stereotactic radiosurgery, Gamma knife, Linac, Linear accelerator, Stereotactic radiotherapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, stereotactic radiosurgery is not addressed in a Regional or a National coverage determination or policy.