Clinical Policy Bulletin: Stereotactic Radiosurgery

Number: 0083

Policy

Aetna considers stereotactic radiosurgery medically necessary according to the following selection criteria.

I. Cranial stereotactic radiosurgery with a Cyberknife, gamma knife, or linear accelerator (LINAC) is considered medically necessary when used for any of the following indications:

   A. For treatment of members with symptomatic, small (less than 3 cm) arteriovenous (AV) malformations, aneurysms, and benign tumors (acoustic neuromas (vestibular schwannomas), craniopharyngiomas, hemangiomas, meningiomas, pituitary adenomas, and neoplasms of the pineal gland) if the lesion is unresectable due to its deep intracranial location or if the member is unable to tolerate conventional operative intervention; or
   
   B. For members with trigeminal neuralgia that has not responded to other more conservative treatments (see CPB 0374 - Trigeminal Neuralgia Procedures); or
   
   C. For treatment of brain malignancies (primary tumors and/or metastatic lesions) (see appendix).

II. Stereotactic body radiation therapy with a Cyberknife, gamma knife, or linear accelerator (LINAC) is considered medically necessary for localized malignant conditions within the body where highly precise application of high-dose radiotherapy is required and clinically appropriate (see appendix).

III. Fractionated stereotactic radiotherapy is considered medically necessary when criteria for stereotactic radiosurgery are met. Fractionated stereotactic radiotherapy is useful for treatment of tumors in hard-to-reach locations, tumors with very unusual shapes, or for tumors located in such close proximity to a vital structure (e.g., optic nerve or hypothalamus) that even a very accurate high-dose single fraction of stereotactic radiosurgery could not be tolerated.
IV. Stereotactic proton beam radiosurgery: please see CPB 0270 - Proton Beam and Neutron Bean Radiotherapy.

Aetna considers stereotactic radiosurgery experimental and investigational for all other indications because its effectiveness for these indications has not been established including:

- Cluster headaches
- Epilepsy (except when associated with treatment of AV malformations or brain tumors)
- Mammographic microcalcification
- Parkinson's disease.

Background

With any external beam radiation therapy, the highest dose of radiation develops where multiple beams intersect. Thus, the fewer beams there are, the greater the dose reaching other areas traversed by the beams. For example, if only 2 beams are used, the highest dose would develop at the site where the beams intersect, but a significant portion of the dose would be distributed to fields anterior and posterior to the intersection.

Stereotactic radiosurgery (SRS) uses the above principle to deliver a highly focused ionizing beam so that the desired target is obliterated, leaving adjacent structures nearly unaffected. Guidance is provided by a variety of imaging techniques, including angiography, computerized tomography (CT), and magnetic resonance imaging (MRI). The key to SRS is immobilization of the patient so that targeting can be accurate and precise.

Stereotactic radiation is also used in extra-cranial sites, in a procedure called stereotactic body radiation therapy (SBRT). A body frame has been designed to immobilize patients for such treatment. In addition, frameless methods of administering SBRT to the body have been developed. These frameless systems rely on skeletal landmarks or implanted fiducial markers to locate and guide the therapy beam to treatment targets within the body.

Based upon professional opinion, a coding guide from the American Society for Therapeutic Radiation and Oncology (ASTRO, 2007) stated that SBRT is considered appropriate for the treatment of the following conditions:

- Lung or liver metastases not amenable to surgery
- Medically inoperable early stage lung cancer
- Primary liver cancer not amenable to surgery
- Recurrent lung cancer amenable to salvage therapy
- Recurrent pelvic tumors
- Retroperitoneal tumors
- Spinal and para-spinous tumors
- Other recurrent cancers or tumors.

The radioactive particles used in SRS and SBRT may come from various sources. The Gamma Knife uses Cobalt-60. Over 200 finely focused beams of gamma radiation simultaneously intersect at the precise location of the brain disorder. Proton beam radiosurgery derives its advantage from the so-called "Bragg peak", a term that describes the pattern of deposition of proton beam radiation. Protons decelerate as they travel through tissue, depositing disproportionately more radiation at greater depths. The protons
deposit most of their energy at their depth of maximal penetration, resulting in a "peak" of radiation at that tissue depth. The depth of peak radiation can be precisely defined by the energy the cyclotron imparts to the proton beam.

A linear accelerator, or LINAC, creates photons by accelerating electrons along a linear path where they collide with a metal target. This produces a single, intense photon beam. To reduce the effect of the radiation on adjacent healthy tissues, a moving frame is used to target the abnormality with "arcs" from different directions. LINAC treatments may be given in multiple sessions over several days, which are referred to as fractionated radiotherapy. With fractionated radiotherapy, radiation is delivered to the tumor or lesion at different points in the cell division cycle. This may be the preferred form of treatment in some circumstances. Fractionated treatments may continue for up to 30 days. "Hypo-fractionated" treatments are given over 5 to 8 treatment days.

Precise stereotactic localization is necessary for treatment of intra-cranial structures, because of their deep location and because of the close proximity of vital structures in the brain. During radiotherapy administration, the cranium can be completely immobilized using a frame.

Fractionated stereotactic radiotherapy (FSRT) involves multiple low-dose radiation treatments. Fractionated stereotactic radiotherapy is used to treat tumors in hard-to-reach locations or with very unusual shapes. Fractionated stereotactic radiotherapy is also used to treat tumors which are located in close proximity to vital structures, such as the optic nerve or hypothalamus, where even a very accurate high-dose single fraction of stereotactic radiosurgery could not be tolerated.

For this procedure, patients are required to wear a special customized fiberglass helmet. (For other stereotactic radiation techniques of the head, the patient's head must be immobilized in a special head-ring frame, which is applied under local anesthetic.) After the patient undergoes the usual stereotactic imaging such as CT or MRI, small doses of radiation are accurately applied each day. The customized fiberglass helmet harnesses the patient while receiving low, daily doses. Fractionated stereotactic radiotherapy is also an excellent way to administer radiation treatments to infants or small children whose fast-growing brains cannot tolerate standard radiation. In the past, oncologists were limited to treating infants and small children with chemotherapy alone. This technique also shows great promise in the treatment of benign tumors such as pituitary adenomas or meningiomas. The use of fractionated stereotactic radiotherapy permits excellent control of the tumor but spares the brain from such cognitive side-effects as impaired cognition and memory that commonly occur with standard radiation treatment.

An assessment conducted by the Alberta Heritage Foundation for Medical Research (Hailey, 2002) concluded that there is limited evidence that fractionated stereotactic radiotherapy may have an advantage over stereotactic radiosurgery in treatment of acoustic neuromas and brain tumors.

There are clinical reports of the effectiveness of SBRT for radiosensitive CNS tumors invading the spine. SBRT is useful to treat surgically unresectable ependymomas and other radiosensitive primary central nervous system tumors if they are invading the spine and spinal cord. SBRT has not been as successful when used on metastatic tumors to the spine, because these metastatic lesions are not usually radiosensitive. SBRT of the spine has been performed using an immobilizing frame. In addition, frameless methods of administering SBRT to the spine are in development. These frameless systems rely on skeletal landmarks or implanted fiducial markers to locate and guide the therapy beam to treatment targets within the spine or spinal cord.
With the development of a stereotactic body frame analogous to the stereotactic head frames used for intra-cranial targets, stereotactic techniques have been used to treat tumors in extra-cranial sites other than the spine. Available evidence for SBRT is from dose analysis studies showing theoretical advantage to this form of treatment, and phase II studies evaluating local control and toxicity.

A number of studies have examined SBRT of primary lung cancer. Nyman et al (2005) from Finland reported experience of SBRT in 45 patients with stage I non-small cell lung cancer. The investigators reported 80 % 1-year survival and 30 % 5-year survival, and median survival of 39 months. Nagata et al (2005) reported on experience from Japan on SBRT in 45 patients with stage IA and IB lung cancer. Sixteen percent of tumors showed complete response, and 84 % of tumors showed partial response. With a median follow-up of 30 months, no pulmonary complications greater than grade 3 were found and no other vascular, cardiac, esophageal or neurologic toxicities encountered. The investigators reported that, for stage IA lung cancer, the disease-free and overall survival rates after 1 and 3 years were 80 % and 72 %, and 92 % and 83 %, respectively, whereas for stage IB lung cancer, the disease-free survival and overall survival rates were 92 % and 71 %, and 82 % and 72 %, respectively. McGarry et al (2003) from Indiana University reported on a phase I dose escalation study of SBRT in 47 patients with inoperable stage I lung cancer. Dose-limiting toxicity included predominantly bronchitis, pericardial effusion, hypoxia, and pneumonitis. Local failure occurred in 4 of 19 T1 and 6 of 28 T2 patients. Local failures occurred between 3 and 31 months from treatment. Within the T1 group, 5 patients had distant or regional recurrence as an isolated group, whereas 3 patients had both distant and regional recurrence. Within the T2 group, 2 patients had solitary regional recurrences, and the 4 patients who failed distantly also failed regionally.

An earlier report from Indiana University details phase I trial experience with 37 patients with stage I non-small cell lung cancer treated with SBRT (Timmerman et al, 2003). Significant toxicity was limited to 1 case of grade 3 pneumonitis and 1 case of hypoxia. Minor transient pulmonary function changes were commonly seen, and 1 case of asymptomatic pericardial effusion was noted. Twenty-seven patients had a complete response to treatment, and 60 % of patients had a partial response. After a median follow-up period of 15.2 months, 6 patients experienced local failure, all at lower dose levels than currently employed. A 2003 Korean study reported experience using SBRT in 28 patients with primary or metastatic lung tumors (Lee et al, 2003). A hypo-fractionated 3 or 4 treatment regimen was used. Thirty-nine percent complete and 43 % partial response rates were noted. Whyte et al (2003) from Stanford University reported on a phase I clinical trial of SBRT in 23 patients with lung cancer. Complete radiographic responses were seen in 2 patients, partial responses in 15 patients, and no response or progression in 6 patients. Three pneumothoraces resulted from fiducial placement. A 2001 Japanese report detailed a 5-year experience in treating 50 patients with stage I non-small cell lung cancer. In 18 of these patients, SBRT was boost treatment after conventional radiotherapy. With a median 36-month follow-up, 30 patients were alive and disease-free. The 3-year case-specific survival rate was 88 %. The Radiation Therapy Oncology Group has an ongoing clinical study of SBRT in patients with inoperable stage I/II non-small cell lung cancer.

There are studies of SBRT in body sites other than the spine and lung. Schefter et al (2001) reported on a phase I clinical trial of stereotactic body radiotherapy in 18 patients with metastatic liver cancer. The study was limited to patients with 1 to 3 liver metastases, tumor diameter less than 6 cm, and adequate liver function. These investigators reported that no patients experienced acute grade 3 liver or intestinal toxicity or any acute grade 4 toxicity.
Hoyer et al (2005) from Denmark reported on a phase II study of SBRT in pancreatic cancer. A total of 22 patients with locally advanced and surgically non-resectable, histological proven pancreatic carcinoma were included into the trial. The investigators reported that only 2 patients were found to have a partial response, and the remaining patients had no change or progression after treatment. Six patients had local tumor progression, but only 1 patient had an isolated local failure without simultaneous distant metastasis. The investigators reported that median time to local or distant progression was 4.8 months. Median survival time was 5.7 months and only 5 % of patients were alive 1 year after treatment. The investigators noted that acute toxicity reported 14 days after treatment was pronounced. The investigators stated that there was a significant deterioration of performance status, significantly more nausea and significantly more pain after 14 days compared with baseline. However, 8 of 12 patients improved in performance status, scored less nausea, pain, or needed less analgesic drugs at 3 months after treatment. Four patients suffered from severe mucositis or ulceration of the stomach or duodenum and one of the patients had a non-fatal ulcer perforation of the stomach. The investigators concluded that SBRT “was associated with poor outcome, unacceptable toxicity and questionable palliative effect and cannot be recommended for patients with advanced pancreatic carcinoma.”

Wersall et al (2005) from Sweden investigated the results of using SBRT in 58 patients with renal cell carcinomas. The investigators reported that tumor lesions regressed totally in 30 % of the patients at 3 to 36 months, whereas 60 % of the patients had a partial volume reduction or no change after a median follow-up of 37 months for censored and 13 months for uncensored patients. The investigators reported that side effects were generally mild. The investigators reported that 3 of 162 treated tumors recurred, yielding a local control rate of 90 to 98 %, considering the 8 % non-evaluable sites.

Hoyer and colleagues (2006) evaluated the effectiveness of SBRT in the treatment of inoperable patients with colorectal cancer metastases. Sixty-four patients with a total number of 141 colorectal cancer metastases in the liver (n = 44), lung (n = 12), lymph nodes (n = 3), suprarenal gland (n = 1) or 2 organs (n = 4) were treated with SBRT. After 2 years, actuarial local control was 86 % and 63 % in tumor and patient based analysis, respectively. Nineteen percent were without local or distant progression after 2 years and overall survival was 67, 38, 22, 13, and 13 % after 1, 2, 3, 4 and 5 years, respectively. The investigators reported that 1 patient died due to hepatic failure, 1 patient was operated for a colonic perforation and 2 patients were conservatively treated for duodenal ulcerations. In addition, moderate toxicities such as nausea, diarrhea and skin reactions were observed.

Tse and colleagues (2008) reported outcomes of a phase I study of individualized SBRT for unresectable hepatocellular carcinoma (HCC) and intra-hepatic cholangiocarcinoma (IHC). Patients with unresectable HCC or IHC, and who are not suitable for standard therapies, were eligible for 6-fraction SBRT during 2 weeks. Radiation dose was dependent on the volume of liver irradiated and the estimated risk of liver toxicity based on a normal tissue complication model. Toxicity risk was escalated from 5 % to 10 % and 20 %, within 3 liver volume-irradiated strata, provided at least 3 patients were without toxicity at 3 months after SBRT. A total of 41 patients with unresectable Child-Pugh A HCC (n = 31) or IHC (n = 10) completed 6-fraction SBRT. Five patients (12 %) had grade 3 liver enzymes at baseline. The median tumor size was 173 ml (9 to 1,913 ml). The median dose was 36.0 Gy (24.0 to 54.0 Gy). No radiation-induced liver disease or treatment-related grade 4/5 toxicity was seen within 3 months after SBRT. Grade 3 liver enzymes were seen in 5 patients (12 %). Two patients (5 %) with HCC developed transient biliary obstruction after the first few fractions. Seven patients (5 HCC, 2 IHC) had decline in liver function from Child-Pugh class A to B within 3 months after SBRT. Median survival of HCC and IHC patients was
11.7 months (95 % confidence interval [CI]: 9.2 to 21.6 months) and 15.0 months (95 % CI: 6.5 to 29.0 months), respectively. The authors concluded that individualized 6-fraction SBRT is a safe treatment for unresectable HCC and IHC.

Goodman et al (2010) performed a phase I dose-escalation study to explore the feasibility and safety of treating primary and metastatic liver tumors with single-fraction SBRT. Between February 2004 and February 2008, a total of 26 patients were treated for 40 identifiable lesions: 19 patients had hepatic metastases, 5 had IHC, and 2 had recurrent HCC. The prescribed radiation dose was escalated from 18 to 30 Gy at 4-Gy increments with a planned maximum dose of 30 Gy. Cumulative incidence functions accounted for competing risks to estimate local failure (LF) incidence over time under the competing risk of death. All patients tolerated the single-fraction SBRT well without developing a dose-limiting toxicity. Nine acute grade 1 toxicities, 1 acute grade 2 toxicity, and 2 late grade 2 gastro-intestinal toxicities were observed. After a median of 17 months follow-up (range of 2 to 55 months), the cumulative risk of LF at 12 months was 23 %. Fifteen patients have died: 11 treated for liver metastases and 4 with primary liver tumors died. The median survival was 28.6 months, and the 2-year actuarial overall survival was 50.4 %. The authors concluded that it is feasible and safe to deliver single-fraction, high-dose SBRT to primary or metastatic liver malignancies measuring less than or equal to 5 cm. Moreover, single-fraction SBRT for liver lesions demonstrated promising local tumor control with minimal acute and long-term toxicity. Single-fraction SBRT appears to be a viable non-surgical option.

Kopek et al (2010) reported outcomes of a single institution study of SBRT for unresectable cholangiocarcinoma. The dose-volume dependency of the observed gastro-intestinal toxicity was explored. A total of 27 patients with unresectable cholangiocarcinoma (IHC, n = 1; Klatskin tumors, n = 26 ) were treated by linac-based SBRT. The dose schedule was 45Gy in 3 fractions prescribed to the isocenter. The median progression-free survival and overall survival were 6.7 and 10.6 months, respectively. With a median follow-up of 5.4 years, 6 patients had severe duodenal/pyloric ulceration and 3 patients developed duodenal stenosis. Duodenal radiation exposure was higher in patients developing moderate- to high-grade gastro-intestinal toxicity with the difference in mean maximum dose to 1cm(3) of duodenum reaching statistical significance. A statistically significant association between grade 2 ulceration and volume of duodenum exposed to selected dose levels was not established. The authors concluded that the outcomes of SBRT for unresectable cholangiocarcinoma appear comparable to conventionally fractionated chemoradiotherapy with or without brachytherapy boost. The practical advantages of SBRT are of particular interest for such poor prognosis patients. Patient selection, however, is key in order to avoid compromising such practical gains with excessive gastrointestinal toxicity.

A structured evidence review by the Alberta Heritage Foundation for Medical Research (Hailey, 2002) concluded that "the place of SRS [stereotactic radiosurgery] in the treatment of Parkinson's disease does not appear to be established." In addition, the review concluded that "[t]he efficacy of SRS in the management of epilepsy appears not to have been established, other than in association with its use in treatment for AVMs or brain tumors."

Bartolomei et al (2008) reported the effectiveness and tolerance of gamma knife (GK) radiosurgery in mesial temporal lobe epilepsy (MTLE) after a follow-up more than 5 years. Patients presenting with MTLE and treated with a marginal dose of 24 Gy were included in the study (n = 15) -- 8 were treated on the left side, and 7 were treated on the right. The mean follow-up was 8 years (range of 6 to 10 years). At the last follow-up, 9 of 16 patients (60 %) were considered seizure-free (Engel Class I) (4/16 in Class IA, 5/16 in Class IB).
Seizure cessation occurred with a mean delay of 12 months (+/- 3) after GK radiosurgery, often preceded by a period of increasing aura or seizure occurrence (6/15 patients). The mean delay of appearance of the first neuroradiological changes was 12 months (+/- 4). Nine patients (60 %) experienced mild headache and were placed on corticosteroid treatment for a short period. All patients who were initially seizure-free experienced a relapse of isolated aura (10/15, 66 %) or complex partial seizures (10/15, 66 %) during anti-epileptic drug (AED) tapering. Restoration of treatment resulted in good control of seizures. The authors concluded that GK radiosurgery is an effective and safe treatment for MTLE. Results are maintained over time with no additional side effects. Long-term results compare well with those of conventional surgery. The authors also noted that the main disadvantage of this approach is the delay of seizure remission, often preceded by a period of increasing seizure frequency. Patients must also be warned that a long-lasting AED treatment must be maintained (usually at a lower dose) following the procedure.

In an editorial that accompanied the afore-mention article, Spencer (2008) stated that GK treatment in MTLE is still searching for a place; its disadvantages (slightly lower seizure response rate, delayed response, absolute requirement for continued medication, higher mortality) compared to anterior medial temporal resection seem to outweigh its non-invasive status, which so far does not appear to carry any clear benefits in terms of neurological or cognitive function, or seizure response. Furthermore, whether GK treatment should be considered for intractable epilepsy arising in other functional cortical regions that cannot be treated with resection remains unexplored.

In a review on the application of SRS to disorders of the brain, Kondziolka et al (2008) noted that radiosurgery has had an impact on the management of patients with vascular malformations, all forms of cerebral neoplasia, and selected functional disorders such as trigeminal neuralgia and tremor. Epilepsy, behavioral disorders, and other novel indications are the topics of current investigation. This is in agreement with the observation of Quigg and Barbaro (2008) who stated that further studies are needed to ascertain if the effectiveness of SRS for treatment of epilepsy attains that of traditional surgery while offering a non-invasive technique with potentially lower morbidity.

Stereotactic radiosurgery is being investigated as a treatment for cluster headache. In a prospective open trial, Donnet et al (2005) examined the effectiveness of gamma knife radiosurgery of the trigeminal nerve in the treatment of patients with chronic cluster headache (CCH). A total of 10 patients (9 men, 1 woman; mean age of 49.8 years) were enrolled. They presented with severe and drug resistant CCH (mean duration of 9 years). The cisternal segment of the trigeminal nerve was targeted with a single 4-mm collimator (80 to 85 Gy max). The mean follow-up was 13.2 months. No improvement was observed in 2 patients, while 3 patients had no further attacks. Three patients showed dramatic improvement with a few attacks per month or very few attacks over the last 6 months. Two patients were pain-free for only 1 week and 2 weeks, respectively, and their headaches recurred with the same severity as before. Three patients developed paresthesia with no hypoesthesia, 1 developed hypoesthesia, and 1 developed de-afferentation pain. These investigators considered the morbidity to be significant for the low rate of pain cessation, making this procedure less attractive even for the more severely affected subgroup of patients.

In a phase I clinical trial, Boike et al (2011) evaluated the tolerability of escalating doses of stereotactic body radiation therapy in the treatment of localized prostate cancer. Eligible patients included those with Gleason score 2 to 6 with prostate-specific antigen (PSA) less than or equal to 20, Gleason score 7 with PSA less than or equal to 15, less than or equal to T2b, prostate size less than or equal to 60 cm(3), and American Urological Association (AUA) score less than or equal to 15. Pre-treatment preparation required an enema and...
placement of a rectal balloon. Dose-limiting toxicity (DLT) was defined as grade 3 or worse GI/genitourinary (GU) toxicity by Common Terminology Criteria of Adverse Events (version 3). Patients completed quality-of-life questionnaires at defined intervals. Groups of 15 patients received 45 Gy, 47.5 Gy, and 50 Gy in 5 fractions (45 total patients). The median follow-up is 30 months (range of 3 to 36 months), 18 months (range of 0 to 30 months), and 12 months (range of 3 to 18 months) for the 45 Gy, 47.5 Gy, and 50 Gy groups, respectively. For all patients, GI greater than or equal to 2 and grade greater than or equal to 3 toxicity occurred in 18 % and 2 %, respectively, and GU grade greater than or equal to 2 and grade greater than or equal to 3 toxicity occurred in 31 % and 4 %, respectively. Mean AUA scores increased significantly from baseline in the 47.5-Gy dose level (p = 0.002) as compared with the other dose levels, where mean values returned to baseline. Rectal quality-of-life scores (Expanded Prostate Cancer Index Composite) fell from baseline up to 12 months but trended back at 18 months. In all patients, PSA control is 100 % by the nadir + 2 ng/ml failure definition. The authors concluded that dose escalation to 50 Gy has been completed without DLT. They stated that a multi-center phase II trial is underway treating patients to 50 Gy in 5 fractions to further evaluate this experimental therapy.

The Agency for Healthcare Research and Quality (AHRQ)'s Effective Health Care Program released a new technical brief (2011) that provides a broad overview of the current state of evidence on the use of stereotactic body radiation therapy for targeting solid malignant tumors. The brief, Stereotactic Body Radiation Therapy, identifies gaps in the scientific data regarding the theoretical advantages of stereotactic body radiation therapy over other radiotherapies in actual clinical use. While stereotactic body radiation therapy appears to be widely used for treatment of a variety of cancer types, none of the currently available studies includes comparison groups. The researchers noted that in order to assess fully the benefits and risks of stereotactic body radiation therapy, comparative studies are needed. These studies should preferably be randomized trials but, at a minimum, there is a need for trials with concurrent controls. The technical brief also provides a review of key research questions that remain unanswered and may be helpful to radiology researchers in prioritizing future research.

The Expert Panel on Radiation Oncology-Gynecology/American College of Radiology's Appropriateness Criteria on "Definitive therapy for early stage cervical cancer" (Small et al, 2012) stated that "Stereotactic body RT (SBRT) has been shown to be a useful treatment option in other tumor sites, especially in early stage lung cancer. There are preliminary data on its use in treating cervical cancer, but, given target definition, tumor motion, and the proven track record of brachytherapy, SBRT should not be considered a substitute for brachytherapy".

Yamada et al (2013) stated that en bloc wide-margin excision significantly decreases the risk of chordoma recurrence. However, a wide surgical margin cannot be obtained in many chordomas because they arise primarily in the sacrum, clivus, and mobile spine. Furthermore, these tumors have shown resistance to fractionated photon radiation at conventional doses and numerous chemotherapies. These researchers analyzed the outcomes of single-fraction SRS in the treatment of chordomas of the mobile spine and sacrum. A total of 24 patients with chordoma of the sacrum and mobile spine were treated with high-dose single-fraction SRS (median dose of 2,400 cGy); 21 primary and 3 metastatic tumors were treated; 7 patients were treated for post-operative tumor recurrence. In 7 patients, SRS was administered as planned adjuvant therapy, and in 13 patients, SRS was administered as neoadjuvant therapy. All patients had serial magnetic resonance imaging follow-up. The overall median follow-up was 24 months. Of the 24 patients, 23 (95 %) demonstrated stable or reduced tumor burden based on serial magnetic resonance imaging. One patient had radiographic progression of tumor 11
months after SRS; 6 of 13 patients who underwent neoadjuvant SRS proceeded to surgery. This decision was based on the lack of radiographic progression and the patient's preference. Complications were limited to 1 patient in whom sciatic neuropathy developed and 1 with vocal cord paralysis. The authors concluded that high-dose single-fraction SRS provides good tumor control with low treatment-related morbidity. Moreover, they stated that additional follow-up is needed to determine the long-term recurrence risk.

Appendix:

Stereotactic radiosurgery for treatment of brain malignancies (primary tumors and/or metastatic lesions) is considered medically necessary in members with a good performance status, controlled systemic disease, and no more than 4 metastatic lesions. For treatment to additional lesions, further clinical justification may be needed.

Stereotactic body radiation therapy is considered medically necessary for localized malignant conditions within the body where highly precise application of high-dose radiotherapy is required and clinically appropriate, including:

- Prostate cancer – low risk disease as definitive treatment
- Lung cancer that is early stage and medically inoperable
- Metastatic lesions to the spine that are radio-resistant (melanoma, renal cell)
- Recurrent metastatic disease in a previously irradiated area
- Recurrent localized head and neck cancer
- Metastatic lesions to the liver when they are the sole site of disease and cannot be surgically resected or undergo accepted ablation techniques
- Metastatic disease to the lung when clinically appropriate and on a case by case basis

All other clinical sites or indications are considered experimental and investigational but will be considered on a case by case basis.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

20660  Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)

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  each additional cranial lesion, simple (List separately in addition to code for primary procedure)

61798  1 complex cranial lesion

+ 61799  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)
Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion

63621 each additional spinal lesion (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 1 session; multi-source Cobalt 60 based

77372 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 1 session)

77435 Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

HCPCS codes covered if selection criteria are met:

G0173 Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session

G0251 Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum 5 sessions per course of treatment

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 5 sessions per course of treatment

Other HCPCS codes related to the CPB:

A4648 Tissue marker, implantable, any type, each

A4650 Implantable radiation dosimeter, each

ICD-9 codes covered if selection criteria are met:

140.0 - 239.9 Neoplasms

350.1 Trigeminal neuralgia

437.3 Cerebral aneurysm, nonruptured

747.81 Anomalies of cerebrovascular system

ICD-9 codes not covered for indications listed in the CPB:
Stereotactic Radiosurgery

- 332.0 - 332.1 Parkinson's disease
- 339.00 - 339.02 Cluster headache
- 345.00 - 345.91 Epilepsy and recurrent seizures
- 780.33 Post traumatic seizures
- 780.39 Other convulsions
- 793.81 Mammographic microcalcification

Other ICD-9 codes related to the CPB:

- V58.0 Encounter for radiotherapy

The above policy is based on the following references:


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