Medical Policy
Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

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Subject: Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Overview: Stereotactic Radiosurgery (SRS) is a distinct discipline that utilizes externally generated ionizing radiation in certain cases to inactivate or eradicate (a) defined target(s) in the head and spine without the need to make an incision. The target is defined by high-resolution stereotactic imaging. SRS typically is performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system, but can be performed in a limited number of sessions, up to a maximum of five.

Stereotactic body radiation therapy (SBRT) refers to stereotactic radiation therapy being performed on parts of the body other than the brain. The stereotactic radiation therapy procedure involves the use of three-dimensional imaging (e.g., magnetic resonance imaging [MRI] or computed tomography [CT] scan) to identify and locate the tumor(s) to be treated. Radiation is then delivered in a concentrated form of beams directed at the tumor(s), aiding in decreasing damage to surrounding healthy tissue.

Policy and Coverage Criteria:

NOTE: Prior Authorization is NOT required.

Stereotactic radiosurgery is covered for the following conditions:

- Arteriovenous malformations of the brain or spine
- Trigeminal neuralgia which is refractory to conventional treatment or surgery or for a Member who is not eligible for conventional surgery due to advanced age or medical comorbidity
- Pituitary adenoma
- Brain tumors
- Schwannoma
- Acoustic neuroma

Stereotactic Body Radiation Therapy is considered medically necessary when used in the treatment of:

- Primary or recurrent tumors within the spine, OR metastases to the spine from other primary sites, that are BOTH:
  - Not amenable to surgery; and
  - Not amenable to conventional radiation therapy
- early stage (T1 or T2) non small-cell lung cancer (NSCLC) in an individual who is not a surgical candidate or refuses surgery
- symptomatic pulmonary metastasis in an individual with good performance status and controlled systemic disease
- Low- to intermediate-risk, localized prostate cancer
- Inoperable, recurrent hepatocellular carcinoma
- Unresectable pancreatic cancer

Exclusions: SRS and SBRT for conditions other than those listed above.

Supporting Information:
1. Technology Assessment: Stereotactic radiosurgery (SRS), also known as stereotactic radiation therapy or stereotactic radiotherapy (SRT), targets a tumor from many different directions so the beams of radiation converge on the tumor. No actual incision is made in SRS. The goal of SRS is to deliver enough radiation to destroy or stop the growth of a lesion without adversely affecting surrounding tissue. Normal tissues are protected both by selectively targeting only the abnormal lesion and by using cross-firing techniques to minimize the exposure of the adjacent anatomy. In that way, the amount of radiation needed to destroy tumor cells is delivered directly to the neoplasm, and the amount of exposure to the area surrounding the tumor is limited. With SRS, high doses of radiation can be delivered with sub-millimeter accuracy.

2. Literature Review:

Stereotactic radiosurgery is a widely accepted treatment for a number of medical conditions. SRS is considered standard of care in the treatment of unresectable arteriovenous malformations (AVM) of the brain or spine, vestibular schwannoma/acoustic neuroma, trigeminal neuralgia refractory to conventional treatment, and brain metastases (International RadioSurgery Association).


AVM: In a 2001 statement from the American Heart Association, authors noted SRS to be most appropriate for patients with small AVMs thought to be at high risk from a surgical or endovascular standpoint (Ogilvy et al., 2001). A 2009 Practice Guideline from the International RadioSurgery Association stated: “AVM outcomes are best for those patients with small volume AVMs located in non-critical locations.” The efficacy of SRS in the treatment of AVMs is well documented in clinical literature and accepted by a number of medical professional societies and organizations (IRSA).

The IRSA also supports the use of SRS for the treatment of acoustic neuromas and pituitary tumors (including adenomas). There is strong clinical evidence for the use of SRS in newly diagnosed acoustic neuromas, residual vestibular schwannomas after microsurgery, and recurrent vestibular schwannomas. Clinical literature reports solid long-term results.

Trigeminal Neuralgia: The use of SRS for refractory trigeminal neuralgia, especially those patients with concomitancies, high-risk medical illness, or pain refractory to prior surgical procedures, is recommended by the IRSA. To date, the largest reported series are still characterized by a wide spectrum of success rates after radiosurgery with Grade I outcome in 21–76.8% of patients and Grade II outcome in 65–88% of patients. Regis et al. reported that 87% of patients were initially free of pain in their series of 57 patients treated with a maximum dose of 75–90 Gy (1998, 2001, 2006). Predictive factors such as the absence of multiple sclerosis, greater radiation dose, no previous surgery, typical pain features, and proximity of the isocenters to the brainstem edge are associated with more positive SRS results (Rogers et al., 2000; Brisman et al., 2002; Young et al., 1998; Maesawa et al., 2001).

Four randomized trials (Kondziolka et al., 1999; Andrews et al., 2004; Aoyama et al., 2006; Muacevic et al., 2008) and a number of nonrandomized or case series studies evaluated the safety and efficacy of SRS with or without WBRT and microsurgery for patients with brain metastases. SRS was associated with good local tumor control and reduction in brain recurrence, although impact on survival was only seen in patients with good prognostic indicators and limited extracranial disease. In the reviewed studies, tumor control, recurrence rates, and overall survival varied widely depending on the type of tumor and the extent of disease, as well as other patient factors. Some studies reported better results with combination therapy (surgical excision, WBRT, and stereotactic radiosurgery), while others reported that addition of WBRT did not enhance the effect of stereotactic radiosurgery.

The National Comprehensive Cancer Network released a 2008 practice guideline for central nervous system cancers and noted that SRS may be used for a limited number of small, deep, non-symptomatic lesions, but that surgery may be more appropriate for larger, more symptomatic lesions. Patients with greater than 3 metastatic lesions should be treated with WBRT with or without SRS in selected cases.
Parkinson's Disease/Essential Tremor: There is limited evidence evaluating the use of SRS in the treatment of medically/pharmacologically refractory Parkinson's Disease/essential tremor. Some studies have reported positive findings, but there is also the risk of neurological damage from the SRS treatments with Gamma Knife. Further studies are needed to better identify patient selection and risk of complications.

Young et al. (2000) evaluated 102 patients with tremor related to Parkinson's, 52 patients with essential tremor, and 4 with tremor related to other conditions/circumstances. Follow-up extended to up to 8 years. Results found 88% of individuals with Parkinsonian tremor and 88% with essential tremor experienced long-term relief of symptoms after treatment with SRS using Gamma Knife thalamotomy. The results were significantly improved from baseline measurements. A 2009 study by Young et al. reported on results of 161 patients who underwent a total of 203 thalamotomies to treat essential tremor. Statistically significant improvements were seen in tremor scores for both writing and drawing. Mean post-operative follow up was 44 months +/- 33. The authors concluded the nucleus ventralis intermedius thalamotomy with the Gamma Knife to be a safe and effective alternative to surgical intervention for treatment of essential tremor, particularly for patients who are not good candidates for deep brain stimulation. Kondziolka et al. (2008) also found Gamma Knife treatment to be safe and effective for essential tremor patients ineligible for RF thalamotomy or deep brain stimulation. They evaluated results of 26 individuals with disabling essential tremor after medical therapy had failed. Most were elderly or had concomitant medical issues. Mean follow up was 36 months. 69% of patients showed improvement in both action tremor and writing score, 23% in only action tremor score, and 12% did not show significant improvement. Permanent mild right hemiparesis and speech impairment occurred 6 months after treatment in one patient. The authors cautioned that while they determined the procedure to be safe and effective, patients need to be counseled on potential complications.

A 2005 Quality Standards Subcommittee of the American Academy of Neurology found insufficient evidence regarding the surgical treatment of head and voice tremor and the use of gamma knife thalamotomy for the treatment of essential tremor. The IRSA does not have a formal Practice Guideline on SRS for the treatment of Parkinson's or tremor.

Stereotactic Body Radiation Therapy (SBRT): Similar to SRS for cranial conditions, SBRT can employ a body frame designed to immobilize patients during treatment. However, frameless methods of administering SBRT to the have also been developed. Frameless procedures rely on skeletal landmarks or implanted markers to locate and guide the beam to targeted areas.

Spinal Tumors: There is sufficient evidence in clinical literature to support the use of SBRT to treat spinal tumors of primary and secondary origin. Tumors in the spinal cord have effectively been treated with stereotactic body radiation therapy (SBRT) also called extracranial stereotactic radiosurgery (ESR). Treatment of spinal cord lesions with SBRT has been studied by Degen and colleagues (2005) and Gerszten and colleagues (2004, 2007).

Degen et al. (2005) measured visual analog scale (VAS) pain assessment, and completed the 12-item Short Form Health Survey (SF-12) before treatment and at 1, 3, 6, 8, 12, 18, and 24 months following treatment. Fifty-one participants with 72 lesions (58 metastatic and 14 primaries) were treated. The mean follow-up period was 1 year. Pain was improved, with the mean VAS score decreasing significantly from 51.5 to 21.3 at 4 weeks (p <0.001). This effect on pain was durable, with a mean score of 17.5 at 1 year, which was still significantly decreased (p = 0.002). Quality of life was maintained throughout the study period. After 18 months, physical well-being was 33 (initial score 32; p = 0.96) and mental well-being was 43.8 (initial score 44.2; p = 0.97). Gerszten et al. (2004) evaluated a SRS technique in a prospective cohort of 125 spinal lesions in 115 consecutive individuals. These individuals were treated with a single-fraction radiosurgery technique (45 cervical, 30 thoracic, 36 lumbar, and 14 sacral). There were 17 benign tumors and 108 metastatic lesions. All dose plans were calculated on the basis of CT images. Tumor volume ranged from 0.3 to 232 cm³ (mean, 27.8 cm³). Seventy-eight lesions had received external beam irradiation previously. Tumor dose was maintained at 12 to 20 gray units (Gy) to the 80% isodose line (mean, 14 Gy); canal volume receiving more than 8 Gy ranged from 0.0 to 1.7 cm³ (mean, 0.2 cm³). No acute radiation toxicity or new neurological deficits occurred during the follow-up period (range, 9-30 months; median, 18 months). Axial and radicular pain improved in 74 of 79 individuals who were symptomatic before treatment.

A 2007 study from Gerszten et al. evaluated a cohort of 500 cases of spinal metastases who underwent radiosurgery. Long-term tumor control was demonstrated 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%). Twenty-seven of 32 cases (84%) with a progressive neurologic deficit before treatment experienced at least some clinical improvement. Heron et al. (2012) compared effectiveness of single-session and multisession SRS for treatment of spinal metastases. The authors conducted a retrospective review of 348 lesions in 228 patients treated with SRS. 195 lesions were treated using a single session approach. 153 lesions were treated using the multisession. The primary end point measured was pain control. Secondary measures were neurological deficit improvement, toxicity, local tumor control, need for retreatment and overall survival. Heron et al. found pain control was significantly improved in the SS group for all measured time points up to 1 year post-treatment. Rates of toxicity and neurological deficit improvement were not statistically different. Local tumor control was significantly better in the MS group up to 2 years post-treatment. The need for retreatment was significantly lower in the MS group. Overall survival was also significantly greater in the MS than SS group. The authors concluded that while SS and MS SRS regimens are both effective in the treatment of spinal metastases, SS provides greater early pain control, but MS achieves greater tumor control and less need for retreatment in long-term survivors.

Sohn and Chung (2012) conducted a systematic review of literature evaluating SRS for spinal metastases. Their review found SRS provides high rates of tumor control, regardless of histologic diagnosis and can be used in previously irradiated patients.

Lung Metastases: Ricardi et al. (2012) published a retrospective analysis of 61 patients with 77 lung tumors treated with SBRT. Lung metastases had a maximum diameter smaller than 50mm. The primary endpoint of the study was local control. Secondary endpoints included overall survival, cancer-specific survival, progression-free survival and treatment-related toxicity. Median follow-up was 20.4 months. A two year follow-up, 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. Patients with a small, single metastasis had a progression-free survival rate of 70% at 1 year and 52.8% at years 2 and 3.

Timmerman et al. (2010) reported Phase II trial results of a study of SBRT for inoperable early stage lung cancer. The primary endpoint was 2 year primary tumor control. Secondary endpoints were disease-free survival, radiation toxicity, and overall survival. The study evaluated 44 patients with T1 tumors and 11 with T2 tumors that were less than 5cm in diameter. Mean follow-up was 34.4 months. Results showed the 3-year primary tumor control rate was 97.6%. 3-year primary tumor and involved lobe (local) control rate was 90.6%. Overall survival was 55.8%. The researchers noted many of the patients may have had occult tumors undetected by initial CT and PET. Based on the results the researchers felt the trial demonstrated that successful SBRT is possible with appropriate facilities and support services and that more studies are needed to address disseminated failure post treatment as well as effective dosing for central lung and peripheral tumors.

Coon et al. (2008) found SBRT to be safe and effective for primary, recurrent, and metastatic lung cancer. The study population was 51 patients, 51% with primary NSCLC, 24% with recurrent disease, and 25% with metastatic disease. At final follow-up, local tumor control was achieved in 85% of primary tumors, 92% of recurrent tumors, and 62% of metastases.

Vahdat et al. (2010) evaluated 20 consecutive patients with inoperable stage 1A NSCLC. After treatment with SBRT no regional or distant spread of tumor occurred. Actuarial analysis showed at 2 years post-treatment local tumor control was 95% and overall patient survival was 90%. The researchers concluded SBRT may be safe and effective for inoperable early-stage NSCLC.

Van der Voort van Zyp et al. published a study in 2009 that discussed results of 70 patients with NSCLC T1-T2 tumors with no spread to lymph nodes or distant metastases. Outcome measures included tumor control, patient survival and complications. Actuarial analysis showed local tumor control 2 years post-treatment was 78% for patients who underwent treatment with 45 Gy vs. 96% for patients who underwent treatment with 60 Gy. At 2 years post treatment, overall survival was 62% and cause-specific-survival was 85%. Based on their results, researchers found SBRT to be safe and effective for NSCLC.

A 2010 Report from the American Society for Therapeutic Radiology and Oncology (Buyyounouski, et al.) reviewed available data and found “In the medically inoperable setting, we conclude that SBRT is an accepted treatment option for stage I/II NSCLC. In the operable setting, we conclude more study and longer follow-up are necessary to ensure that results are equivalent to those of surgery. Ideally, medically operable patients with stage I lung cancer would likely receive SBRT on a structured investigative protocol.”

Brown et al. (2008) published a retrospective study evaluating SRS for lung metastases. 35 patients underwent SRS for 69 pulmonary metastases. Tumors had to be less than 5cm. Measured outcomes included tumor control, patient survival, and complications. At final follow-up, local control was achieved in 48 tumors (70%), and 77%
of patients were alive. Death due to progressive disease or complications occurred in 8 patients and 4 were lost to follow up. Results suggest that SRS can be safe and effective for tumors that have metastasized to the lung. Brown et al. (2009, 2011) published additional studies with some patient overlap, showing SRS can be safe and effective for peripheral stage I NSCLC.

Prostate Cancer: Most studies published evaluating the use of SBRT for prostate cancer focus on patients with low and intermediate risk, organ-confined disease. There is an increasing body of evidence to support the use of SBRT for patients with this form of the disease. Boike et al. (2011) published a phase I study of dose escalation of SBRT in the treatment of localized prostate cancer. Patients enrolled had a 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 cm³, and American Urological Association (AUA) score less than or equal to 15. Dose-limiting toxicity was defined as grade 3 or worse. QOL surveys were completed at defined intervals. Groups of 15 patients received 45 Gy, 47.5 Gy, and 50 Gy in five fractions (45 total patients). The median follow-up is 30 months (range, 3 to 36 months), 18 months (range, 0 to 30 months), and 12 months (range, 3 to 18 months) for the 45 Gy, 47.5 Gy, and 50 Gy groups, respectively. For all patients, GI grade ≥ 2 and grade ≥ 3 toxicity occurred in 18% and 2%, respectively, and GU grade ≥ 2 and grade ≥ 3 toxicity occurred in 31% and 4%, respectively. Mean AUA scores increased significantly from baseline in the 47.5-Gy dose level (P = .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. Based on these results, the authors concluded that dose escalation to 50 Gy was achieved without DLT.

2014 Prostate Cancer Treatment Guidelines from the National Comprehensive Cancer Network state, “The relatively slow proliferation rate of prostate cancer is reflected in a Low α/β ratio, 85 most commonly reported between 1 and 4. These values are similar to that for the rectal mucosa. Since the α/β ratio for prostate cancer is similar to or lower than the surrounding tissues responsible for most of the toxicity reported with RT, appropriately designed radiation treatment fields and schedules using hypofractionated regimens should result in similar cancer control rates without an increased risk of late toxicity. Stereotactic body radiotherapy (SBRT) delivers highly conformal, high-dose radiation in 5 or fewer treatment fractions, which are safe to administer only with precise delivery. Single institution series with median follow-up as long as 5 years report that biochemical progression-free survival is 90%-100% and early toxicity (bladder, rectal, and quality of life) is similar to other standard radiation techniques. Longer follow-up and prospective multi-institutional data are required to evaluate longer-term results, especially since late toxicity theoretically could be worse in hypofractionated regimens compared to conventional fractionation (1.8-2.0 Gy per fraction).”

King et al. (2012) published long-term results of SBRT for low-risk prostate cancer. 67 patients with clinically localized low-risk prostate cancer were treated. Treatment consisted of 36.25 Gy in 5 fractions using SBRT with the CyberKnife as the delivery technology. No patient received hormone therapy. Patient self-reported bladder and rectal toxicities were graded on the Radiation Therapy Oncology Group scale (RTOG). Median follow up was 2.7 years. Results showed there were no grade 4 toxicities. Urinary incontinence, complete obstruction, or persistent hematuria was not observed. Rectal Grade 3, 2, and 1 toxicities were seen in 0, 2% (1 patient), and 12.5% (7 patients), respectively. Authors concluded significant late bladder and rectal toxicities from SBRT for prostate cancer are infrequent. PSA relapse-free survival compares favorably with other definitive treatments. The current evidence supports consideration of stereotactic body radiotherapy among the therapeutic options for localized prostate cancer. King et al. (2013) also released results on health-related quality of life for patients with localized prostate cancer treated with SBRT. Patient self-reported QOL was prospectively measured among 864 patients from phase 2 clinical trials of SBRT for localized prostate cancer. Data from the Expanded Prostate Cancer Index Composite (EPIC) instrument were obtained at baseline and at regular intervals up to 6 years. Median follow-up was 3 years and 194 patients remained evaluable at 5 years. Results found a transient decline in the urinary and bowel domains was observed within the first 3 months after SBRT which returned to baseline status or better within 6 months and remained so beyond 5 years. The same pattern was observed among patients with good versus poor baseline function and was independent of the degree of early toxicities.

Researchers felt the long-term results demonstrated that prostate SBRT is well tolerated and has little lasting impact on health-related QOL. A transient and modest decline in urinary and bowel QOL during the first few
same lesion with the first SBRT. Intrahepatic recurrence other than the lesion with the 1st SBRT, and one patient underwent re-irradiation for the radiation therapy and brachytherapy. Late urinary symptom flares were observed but the majority resolved with benign PSA bounces were common. Late GI and GU toxicity rates were comparable to conventionally fractionated years following treatment.

Conservative management. A high percentage of men who were potent prior to treatment remained potent two years following treatment. A study of 100 patients who underwent SBRT for localized prostate cancer found the treatment provided promising outcomes in localized disease with good PSA response, minimal toxicity and patient inconvenience (Bolzicco et al, 2013). Oliai et al. (2013) discussed use of dose-escalated SBRT for treatment of low-intermediate- and high-risk patients with localized prostate cancer. Their results found the treatment exhibited favorable efficacy with acceptable toxicity. 100 patients with localized prostate cancer were treated at Georgetown University (Chen et al., 2013). Chen et al. found SBRT for clinically localized prostate cancer was well tolerated, with an early biochemical response similar to other radiation therapy treatments. Results showed benign PSA bounces were common. Late GI and GU toxicity rates were comparable to conventionally fractionated radiation therapy and brachytherapy. Late urinary symptom flares were observed but the majority resolved with conservative management. A high percentage of men who were potent prior to treatment remained potent two years following treatment.

Hepatocellular carcinoma (HCC): Jang et al (2015) conducted a retrospective review to determine the feasibility and efficacy of repeated SBRT in 28 patients with inoperable recurrent HCC. 96% underwent repeated SBRT for intrahepatic recurrence other than the lesion with the 1st SBRT, and one patient underwent re-irradiation for the same lesion with the first SBRT. The median follow-up duration was 11 months. The median interval between the first and the repeated SBRT was 11 months. The 2-year local failure-free and overall survival rates were 77% and 42%. Three patients experienced deteriorating of CTP score by greater than or equal to 2 within 3 months of SBRT without disease progression. The total mean normal liver dose was the most significant predictor for hepatic deterioration after the repeated SBRT. The authors concluded that repeated SBRT can be safely and effectively administered to patients with inoperable recurrent HCC, and the results suggest that this technique might be considered a salvage treatment. A further well-controlled large-scale study and longer follow-up are needed to determine the optimal dose-volume constraints and characterize late complications.

Kimura et al (2015) evaluated the efficacy and safety of SBRT in 65 patients with small HCC who were ineligible for resection or ablation therapies. The 2-year overall survival, progression-free survival and local control rates were 76.0%, 40.0% and 100%. At 6-12 months after SBRT, grade 3 or higher toxicities was observed in 15 patients. The incidence of grade 3 or higher toxicities was higher in CTP class B than in class A. The authors
concluded that SBRT is effective and relatively safe for patients with small HCC who are ineligible for resection or ablation therapies. 

Klein et al (2015) evaluated the QoL in 222 patients with HCC, liver metastases, or intrahepatic cholangiocarcinoma following SBRT to the liver. Appetite loss and fatigue measured by the QLQ-C30 clinically and statistically worsened by 1 month after treatment but recovered by 3 months. At 3 and 12 months after treatment, the FACT-Hep score had improved relative to baseline in 13%/19%, worsened in 36%/27%, and remained stable in 51%/54%. Using the QLQ-C30 Global Health score, QoL improved in 16%/23%, worsened in 34%/39%, and remained stable in 50%/38% at 3 and 12 months. Median survival was 17.0 months. Higher baseline scores on both FACT-Hep and QLQ-C30 Global Health were associated with improved survival. The authors concluded that liver SBRT temporarily worsens appetite and fatigue, but not overall QoL. SBRT is well tolerated and warrants comparison against other liver-directed therapies.

Wahl et al (2014) compared outcomes between SBRT and RFA in 184 patients with unresectable HCC. Mean SBRT dose was 41 Gy, delivered in 3-5 fractions 2-3 times weekly. With a median follow-up of 12.6 months, one and two year FFLP rates for all SBRT-tumors were 93.0% and 93.0% vs 86.2% and 84.3% for RFA. Ablation was unsuccessful in 8% RFA cases with evidence of residual tumor at first imaging follow-up; 7 of these tumors were re-ablated and not counted as local failures. For SBRT, tumor size did not predict for FFLP. For RFA, tumors ≥ 2.0 cm had significantly worse FFLP compared to tumors < 2.0 cm. For tumors ≥ 2.0 cm, there was a trend towards improved FFLP for SBRT compared to RFA. One year overall survival was similar for patients treated with SBRT or RFA. The authors concluded that SBRT is a safe and effective alternative to RFA for treatment of HCC and potentially provides improved local control in tumors larger than 2 cm.

Schaffer et al (2014) compared the outcomes of a pooled cohort of 217 patients treated with SBRT for either colorectal cancer metastases, HCC, or biliary tract cancer. The 1 year local control was 76% for colorectal cancer metastases, 92% for HCC, and 83% for biliary tract cancer. The 1 year overall survival was 86% for colorectal cancer metastases, 66% for HCC, and 61% for biliary tract cancer. The authors concluded that local control for liver SBRT is inferior for colorectal cancer metastases and biliary tract cancers compared to HCC. However, overall survival was superior for colorectal cancer metastases compared with HCC and biliary tract cancer.

Que et al (2014) evaluated the safety and efficacy of Cyberknife SBRT in 22 patients with unresectable huge HCC unsuitable of other treatment options. After a median follow-up of 11.5 months, the objective response rate was achieved in 86.3% of patients. The 1-year local control rate was 55.56% and the 1-year overall survival was 50% and median survival was 11 months. The dose of SBRT and the Child-Pugh stage were both significant factors of survival. The authors concluded that the study showed SBRT can be delivered safely to huge HCC and achieve substantial tumor regression and survival. SBRT should be used as a salvage treatment.

Sanuki et al (2014) retrospectively examined the outcomes for 185 patients who were treated with SBRT for HCC. Mean follow-up was 24 months. The 3-year local control was 91% and overall survival was 70%. Acute toxicities ≥ grade 3 were observed in 13% of patients. The authors concluded that SBRT for HCC was safe.

Pancreatic cancer: Moningi et al (2015) conducted a review of 88 patients who received SBRT to treat locally advanced (LAPC) and borderline resectable (BRPC) pancreatic cancer (PCA). The median follow-up from date of diagnosis for LAPC and BRPC patients was 14.5 and 10.3 months. Median overall survival from date of diagnosis was 18.4 months (LAPC, 18.4 mo; BRPC, 14.4 mo). Acute toxicity was minimal with only three patients experiencing acute grade ≥3 toxicity. Late grade ≥2 gastrointestinal toxicity was seen in five patients. The authors concluded that chemotherapy followed by SBRT in patients with LAPC and BRPC resulted in minimal acute and late toxicity. A large proportion of patients underwent surgical resection despite limited radiographic response to therapy. Further refinements in the integration of chemotherapy, SBRT, and surgery might offer additional advancements toward optimizing patient outcomes.

Znatchkova et al (2015) evaluated the efficacy and safety of SBRT for pancreatic cancer in 8 patients who have been denied alternative treatments. All 8 patients had a course of SBRT under the control of the visualization (IGRT) using VMAT technique (RapidArc) on electron accelerator Varian Clinac 2300iX, multileaf collimator Milenium 120 and dynamic wedge filters, 6 MeV photon energy. 5 of 8 patients are alive. Median follow-up was 8.5 months. Two patients achieved tumor progression. In one patient complete response was observed, in two patients -stable disease, in three - partial response. Local control is 75%. 3 of 8 patients died from further disease progression and metastatic process. The authors concluded that the proposed method of fractionation in SBRT is effective, has medium toxicity and can be used in patients with inoperable pancreatic cancer.

Comito et al (2015) assessed the safety and efficacy of SBRT in 62 patients affected by inoperable locally advanced pancreatic adenocarcinoma and local recurrence after surgery. Median follow-up was 12 months.
Nineteen patients were alive at the time of analysis. Median follow-up was 17 months the living patients. In patients with inoperable locally advanced disease, FFLP was 90% at 1 year. Median progression free-survival was 8 months. Median overall survival was 13 months, with 1-year overall survival rate of 51%. In those patients with local recurrence after surgery, FFLP was 85% at median follow-up. Median progression free-survival was 9 months. Median overall survival was 19 months, with 1-year overall survival rate of 53%. In all the cases, toxicity rates were satisfactory with no patients who experienced acute grade 3 toxicity or greater. The authors concluded that SBRT is a safe and effective treatment to improve local control in patients with unresectable locally advanced or recurrence pancreatic adenocarcinoma, in absence of grade 3 toxicity or greater. Results suggest that SBRT may be a promising therapeutic option in the multi-modality treatment of these patients.

Dagolou et al (2015) explored the role of SBRT for reirradiation of recurrent pancreas cancer in 30 patients. Median follow-up was 11 months and median overall survival was 14 months. The 1 and 2 year local control was 78%. 10% of patients had grade III acute toxicity for pain, bleeding and vomiting. 7% had grade III long-term bowel obstructions. The authors conclude that SBRT for reirradiation of locally recurrent pancreas cancer after prior radiation offers reasonable local control, modest survival and acceptable toxicity.

Li et al (2015) retrospectively reviewed the data for 17 patients with metastatic pancreatic cancer who were treated with SBRT. The authors found that SBRT can improve the quality of life and local control rate with small toxicity and acceptable complications.

Lin et al (2015) compared SBRT with IMRT for patients with locally advanced unresectable pancreatic cancer (LAUPC) with respect to survival rate, local control rate, and toxicity-related dose distribution. 20 patients received SBRT and 21 patients received IMRT. The median follow-up was 16 months. Median survival rate was 13 months for IMRT and 20 months for SBRT. The 1-year overall survival rates were 70.7% for IMRT and 80% for SBRT. There was no difference in overall survival between groups. SBRT showed significantly better local control compared to IMRT. The authors concluded that SBRT improved local control for LAUPC patients and similar toxicity compared with IMRT.

3. Professional/Governmental Agencies:

FDA: A number of SRS and SBRT devices have received FDA approval and clearance.

CMS: No NCD for SRS

International Radiosurgery Association Practice Guidelines:
http://www.irsa.org/guidelines.html

American Academy of Neurology Practice Guidelines:
http://www.neurology.org/cgi/reprint/71/15/1183.pdf

Codes:

**SRS of the head:**
CPT and HCPCS:
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); one 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
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
77432 - Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)
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

Medically Necessary ICD-10 diagnoses for SRS of the head:

**Stereotactic Body Radiation Therapy:**
CPT and HCPCS:
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
77373 – Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
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
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

Medically Necessary ICD-10 diagnoses for SBRT:

**References:**


56. NCCN Prostate Cancer Treatment Guideline:


69. Que, JY., Lin, LC., Lin, KL., Lin, YW., Yang, CC. The efficacy of stereotactic body radiation therapy on huge hepatocellular carcinoma unsuitable for other local modalities. Radiat Oncol. 2014; 9(1).


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