Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOLS

Intensity-Modulated Radiotherapy: Abdomen and Pelvis
Intensity-Modulated Radiotherapy: Central Nervous System Tumors
Intensity-Modulated Radiotherapy of the Breast and Lung
Intensity-Modulated Radiotherapy of the Prostate
Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas

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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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| Individuals:  
  • With non-neoplastic intra-cranial conditions (e.g., arteriovenous malformations) | Interventions of interest are:  
  • Stereotactic radiosurgery | Comparators of interest are:  
  • Medical therapy | Relevant outcomes include:  
  • Overall survival  
  • Symptoms  
  • Treatment-related morbidity |
| Individuals:  
  • With non-neoplastic intra-cranial conditions (e.g., trigeminal neuralgia refractory to medical management) | Interventions of interest are:  
  • Stereotactic radiosurgery | Comparators of interest are:  
  • Medical therapy | Relevant outcomes include:  
  • Overall survival  
  • Symptoms  
  • Treatment-related morbidity |
| Individuals:  
  • With non-neoplastic neurologic disorders (e.g., epilepsy primary or secondary tumor-related) | Interventions of interest are:  
  • Stereotactic radiosurgery | Comparators of interest are:  
  • Surgery  
  • Medical therapy | Relevant outcomes include:  
  • Symptoms  
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| Individuals:  
- With non-neoplastic neurologic disorders: mesial temporal epilepsy refractory to medical management | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Surgery  
- Medical therapy | Relevant outcomes include:  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With non-neoplastic neurologic disorders: tremor and movement disorders | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Medical therapy | Relevant outcomes include:  
- Overall survival  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With non-neoplastic neurologic disorders: (e.g., chronic pain) | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Medical or surgical therapy | Relevant outcomes include:  
- Overall survival  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With benign neoplastic intracranial lesion(s) (e.g., acoustic neuromas, pituitary adenoma, nonresectable residual or recurrent meningiomas) | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Other forms of radiotherapy  
- Surgery  
- Combinations of other forms of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
- Overall survival  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With benign neoplastic intracranial lesion(s) (craniopharyngioma, glomus jugulare tumors) | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Other forms of radiotherapy  
- Surgery  
- Combinations of other forms of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
- Overall survival  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With malignant neoplastic intracranial lesion(s) (e.g., gliomas, astrocytomas) | Interventions of interest are:  
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| Individuals:  
- With malignant neoplastic intracranial lesion(s) (e.g., brain metastases) | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Other forms of radiotherapy  
- Surgery  
- Combinations of other forms of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
- Overall survival  
- Symptoms  
- Treatment-related morbidity |
| Individuals:  
- With uveal melanoma | Interventions of interest are:  
- Stereotactic radiosurgery | Comparators of interest are:  
- Other forms of radiotherapy  
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<td>2. Individuals: • With stage T1 or T2A non-small cell lung cancer who are not candidates for surgical resection</td>
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<td>3. Individuals: • With primary or metastatic tumor of the liver that is considered inoperable</td>
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<td>4. Individuals: • With primary prostate carcinoma</td>
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<td>5. Individuals: • With pancreatic adenocarcinoma</td>
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<td>6. Individuals: • With primary or metastatic renal cell carcinoma who are not good surgical candidates</td>
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<td>7. Individuals: • With oligometastases involving lung, adrenal glands, or bone (other than spine or vertebral body)</td>
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DESCRIPTION

Stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) are 3-dimensional conformal radiotherapy methods that deliver highly focused, convergent radiotherapy beams on a target that is defined with 3-dimensional imaging techniques with the ability to spare adjacent radiosensitive structures. SRS primarily refers to such radiotherapy applied to intracranial lesions. SBRT refers to therapy generally applied to other areas of the body. Both techniques differ from conventional external-beam radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over multiple sessions.

SUMMARY OF EVIDENCE

STEREOTACTIC RADIOSURGERY

For individuals with non-neoplastic intracranial conditions (e.g., arteriovenous malformations [AVMs]), the evidence includes noncomparative cohort studies, systematic reviews, and a single randomized controlled trial (RCT). Relevant outcomes are symptoms, treatment-related morbidity, and overall survival (OS). Observational studies have reported relatively high rates (40% to 70%) of complete obliteration of AVM after SRS. An RCT that compared medical therapy with various interventions in the treatment for AVM showed no significant improvement in outcomes; however, given that the interventional studies included a variety of therapies, it is difficult to assess whether a particular component of the intervention has or lacks benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with non-neoplastic intracranial conditions (e.g., trigeminal neuralgia refractory to medical management), the evidence includes systematic reviews and case series. Relevant outcomes are symptoms, treatment-related morbidity, and OS. A case series identified improvements in pain related to trigeminal neuralgia after treatment with SRS. Comparative studies that evaluated the use of SRS compared with alternative treatments for trigeminal neuralgia were reviewed in a systematic review without meta-analysis and were judged to be of poor quality. Only 1 study specifically addressed the use of radiosurgery, and it was stopped before accrual was completed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with epilepsy refractory to medical management, the evidence on the use of SRS as a treatment for epilepsy includes a systematic review, a single RCT, and case reports in primary epileptic disorders and for tumor-related epilepsy. Relevant outcomes are symptoms, treatment-related morbidity, and quality of life (QOL). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For mesial temporal lobe epilepsy, a systematic review of data from 13 studies and a single RCT comparing SRS to anterior temporal lobectomy (ATL) comprise the majority of data. Relevant outcomes include symptoms, treatment-related morbidity, and QOL. In the RCT, remission rates were reported for a total of 58 patients (31 in SRS arm and 27 in ATL arm). Seizure remission rates suggest that ATL (78%) has an advantage over SRS (52%) in terms of proportion with seizure remission. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with tremor and movement disorder, the evidence related to the use of SRS includes a systematic review and nonrandomized observational studies, many of which reported outcomes from the treatment of tremors of varying etiologies. Relevant outcomes include OS, symptoms, treatment-related morbidity, and QOL. Most studies report improvements in standardized tremor scores, although few studies used a blinded evaluation of tremor score, allowing for bias in assessment. No studies comparing SRS with alternative methods of treatment or a control group were identified. Limited long-term follow-up is available, making the long-term risk-benefit ratio of an invasive therapy uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals with chronic pain syndromes refractory to standard medical and psychological treatments, the evidence includes a systematic review of noncomparative studies. Relevant outcomes include OS, symptoms, and treatment-related morbidity. Although clinical success was reported in varying percentages of patients dependent upon the radiation target and pain etiology, the data are primarily from a period of time before the common use of other treatments for patients with chronic pain syndromes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals in the subgroup of uncommon benign neoplastic intracranial lesions (acoustic neuroma, pituitary adenoma, craniopharyngioma, nonresectable residual or recurrent meningiomas, and glomus jugulare tumors) the published evidence for the use of SRS remains limited to systematic reviews of nonrandomized observational studies, other nonrandomized observational studies, and case series. Relevant outcomes include OS, symptoms, and treatment-related morbidity. These reports would suggest that long-term outcomes of fractionated radiosurgery for these benign neoplasms are associated with good local control and, acceptable treatment-related side effects. The likelihood of high-quality systematically acquired evidence is low due to the rarity of the conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with malignant neoplastic intracranial conditions (i.e., gliomas, astrocytomas), the evidence on the use of SRS includes a single systematic review and meta-analysis of case series with ≥5 patients and heterogeneous observational studies. Relevant outcomes are symptoms, treatment-related morbidity, and OS. Observational studies have demonstrated local control using SRS in combination with chemotherapy to treat gliomas in the primary and recurrent setting. These tumors are very aggressive and there are limited treatment options. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with malignant neoplastic intracranial conditions (i.e., brain metastases), the evidence includes systematic reviews, RCTs, and nonrandomized observational studies. Relevant outcomes are symptoms, treatment-related morbidity, and OS. The existing evidence body indicates that SRS improves outcomes in the treatment of brain metastases. Stereotactic radiosurgery appears to be feasible for treatment of larger numbers (e.g., >10) of brain metastases, and outcomes after SRS treatment do not appear to be worse for patients with larger numbers of metastases, at least for patients with ≤10 metastases. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with uveal melanoma, evidence for use of SRS is limited to a meta-analysis of case series and individual case series. Relevant outcomes include OS, symptoms, and treatment-related morbidity. The published literature is insufficient to demonstrate improved outcomes with SRS over other accepted radiation modalities in the treatment of uveal melanoma. The condition is rare with poor clinical outcomes and treatment options. There are currently no active clinical trials to evaluate SRS to treat uveal melanoma and, therefore, there are limited prospects for accumulating additional high-quality data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Stereotactic Body Radiotherapy

For individuals with primary and metastatic spinal or vertebral body tumors who have received prior radiotherapy who are treated with SBRT, the observational literature primarily addresses metastases that recur after prior radiotherapy. Relevant outcomes are OS, progression-free survival (PFS), disease-free survival (DFS), symptoms, and treatment-related morbidity. Repeat administration of conventional radiation therapy increases the risk of treatment-related myelopathies. Nonrandomized study results are sufficient to determine that SBRT improves outcomes (reduces pain) in patients with spinal (vertebral) tumors. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.
For individuals with stage T1 or T2A non-small cell lung cancer (NSCLC) there is no direct comparative evidence for the use of SBRT compared to surgical resection in patients with stage T1 and T2A cancer without nodal or distant disease. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Although no direct comparative evidence is available, evidence suggests that survival rates may be similar for SBRT and surgical resection for patients with stage T1 and T2A NSCLC tumor (not >5 cm in diameter) who show no nodal or distant disease and who are not candidates for surgical resection because of comorbid conditions. Additionally, SBRT was associated with improved survival and a reduced risk of adverse events as compared to conventional radiotherapy in inoperable NSCLC. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with primary hepatocellular carcinoma (HCC), there are no RCTs reported on the use of SBRT for HCC treatment. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Studies have used heterogeneous treatment schedules, treatment planning techniques, patient populations, and outcome measures. The optimal dose and fractionation scheme are unknown. Although promising local control rates of 71% to 100% at 1 year have been reported, there is only retrospective study reporting on the use of SBRT in conjunction with or as an alternative to established treatment modalities, including systemic therapy, radiofrequency ablation, and transarterial chemoembolization. Similar short-term lesion-control rates have been reported for metastatic liver disease. Palliative treatment, including for larger lesions (>3 cm), has also been reported. The use of SBRT, either alone or in conjunction with other liver-directed therapies, is emerging as a bridge to transplant. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with primary prostate carcinoma, the evidence on the use of SBRT consists of systematic reviews of prospective and retrospective studies, a phase 2, randomized study, single-arm assessments of acute and late toxicity, and early prostate-specific antigen outcome data retrospectively compared with historical controls. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Studies have shown promising initial results on the use of SBRT in prostate cancer with seemingly low toxicity rates. One comparative study of intensity-modulated radiotherapy and SBRT suggested higher gastrointestinal and genitourinary complication rates after SBRT; while this study had a large number of patients and attempted to control for bias using matching on observed variables, it was subject to limitations deriving outcome measures from claims data. In the randomized ORIOLE study, SBRT was associated with a significant improvement in disease progression and median PFS as compared to observation in men with recurrent hormone-sensitive prostate cancer and 1 to 3 metastases with a similar toxicity profile. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with pancreatic adenocarcinoma, the evidence for the use of SBRT consists of systematic reviews, retrospective, comparative studies, and noncomparative studies. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Combined chemoradiotherapy plays a significant role in the treatment of locally advanced pancreatic cancer whereas re-resection demonstrates improved median OS outcomes for isolated local recurrence. Noncomparative observational and retrospective studies of SBRT have reported increased patient survival compared with historical data. Acute, grade 3 toxicities have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with renal cell carcinoma (RCC), the evidence for the use of SBRT consists of small case series, a systematic review of case series, and retrospective reviews. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. Combined chemoradiotherapy plays a significant role in the treatment of locally advanced pancreatic cancer whereas re-resection demonstrates improved median OS outcomes for isolated local recurrence. Noncomparative observational and retrospective studies of SBRT have reported increased patient survival compared with historical data. Acute, grade 3 toxicities have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
established treatment modalities for RCC. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with oligometastatic disease, the evidence for the use of SBRT for the management of oligometastases at multiple sites, including the lungs, adrenal glands, and bones (other than spine or vertebral body) primarily consists of relatively small, noncomparative studies that confirm clinically important rates of local control and 1 RCT. Relevant outcomes are OS, PFS, DFS, symptoms, and treatment-related morbidity. In the randomized SABR-COMET trial that compared SBRT versus standard of care palliative treatment in patients with oligometastatic cancers, results revealed a significantly improved median OS in the SBRT group with grade 2 or worse adverse events occurring more frequently, including 3 treatment-related deaths versus 0 in the control group. In a subsequent publication of long-term results of the SABR-COMET trial, the 5-year OS rate was significantly improved with SBRT with no new grade 2 to 5 adverse events reported. Systemic therapy is most frequently the preferred therapy for patients with metastatic disease of these selected tumor types. The published evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY
Stereotactic radiosurgery using a gamma ray or linear accelerator unit may be considered medically necessary for the following indications:

- arteriovenous malformations;
- trigeminal neuralgia refractory to medical management;
- mesial temporal lobe epilepsy refractory to medical management when standard alternative surgery is not an option;
- acoustic neuromas;
- pituitary adenomas;
- non-resectable, residual, or recurrent meningiomas;
- craniopharyngiomas;
- glomus jugulare tumors;
- malignant neoplastic intracranial lesion(s) (e.g., gliomas, astrocytomas);
- solitary or multiple brain metastases in patients having good performance status and no active systemic disease (defined as extracranial disease that is stable or in remission) (see Policy Guidelines section);
- uveal melanoma.

Stereotactic body radiotherapy may be considered medically necessary for the following indications:

- primary or metastatic spinal or vertebral body tumors in patients who have received prior spinal radiotherapy;
- spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, sarcoma);
- patients with stage T1 or T2a non-small-cell lung cancer (not less than five cm) showing no nodal or distant disease and who are not candidates for surgical resection;
- primary or metastatic tumors of the liver as an alternative locoregional treatment for patients with inoperable primary or metastatic lesions;
• primary renal cell carcinoma in patients who are not good surgical candidates or metastatic renal cell carcinoma;
• oligometastases involving lung, adrenal glands and, bone (other than spine or vertebral body).

When stereotactic radiosurgery or stereotactic body radiotherapy are performed using fractionation (defined in the Policy Guidelines) for the medically necessary indications described above, it may be considered medically necessary.

Stereotactic radiosurgery is investigational for other applications including, but not limited to, the treatment of functional disorders (other than trigeminal neuralgia), including chronic pain and tremor.

Stereotactic body radiotherapy is investigational for prostate cancer, pancreatic adenocarcinoma, and other conditions except as outlined in the policy statements above.

POLICY GUIDELINES

RADIATION SOURCE

This protocol addresses the use of SRS and SRBT delivered by gamma ray or high-energy photons generated by a linear accelerator (LINAC) unit.

Number of Lesions

A TEC Assessment (1995) on SRS for multiple brain metastases found that evidence was sufficient to show that radiosurgery improved health outcome for up to three metastases in the presence of good performance status and no active systemic disease. While evidence continues to demonstrate the importance of good performance status and absence of active systemic disease, it appears that the number of metastases may not be as predictive of outcome. Thus, patients with more than three metastases who otherwise have good performance status and no evidence of active systemic disease may still benefit from SRS.

Many patients with brain metastases can either receive whole-brain radiotherapy along with SRS, or whole-brain radiotherapy may be delayed for use as salvage therapy for recurrent intracranial disease.

Fractionation

Fractionated SRS refers to SRS or SBRT performed more than once on a specific site.

SRS is most often single-fraction treatment; however, multiple fractions may be necessary when lesions are near critical structures.

SBRT is commonly delivered over three to five fractions.

MEDICARE ADVANTAGE

Medically necessary indications for SRS/SBRT (for Cranial and Spinal Lesions only):
1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions <5 cm.
2. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures.
3. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.
5. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy. As a boost treatment for larger cranial or spinal lesions that have been treated initially with external beam radiation therapy or surgery (e.g., sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or para-nasal sinus malignancies).

6. Metastatic brain or spine lesions, with stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, OR an Eastern Cooperative Oncology Group (ECOG) Performance Status of three or less (or expected to return to two or less with treatment). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.

7. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

Limitations for SRS/SBRT (for Cranial and Spinal Lesions). SRS is considered not medically necessary under the following circumstances:
1. Treatment for anything other than a severe symptom or serious threat to life or critical functions.
2. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
3. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
4. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than three) (see Medicare Advantage Policy Guidelines). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.
5. Cobalt-60 pallidotomy.

Medically necessary indications for Stereotactic Body Radiation Therapy (SBRT):
1. SBRT is indicated for primary tumors and tumors metastatic to the lung, liver, kidney, adrenal gland, or pancreas.
2. SBRT is indicated for treatment of pelvic and head and neck tumors that have recurred after primary irradiation.
3. SBRT is indicated for patients with clinically localized, low- to intermediate-risk prostate cancer.
4. SBRT treatment, of any body site or internal organ, is indicated for treatment of recurrence in or near previously irradiated regions when a high level of precision and accuracy or a high dose per fraction is indicated to minimize the risk of injury to surrounding normal tissues and treatment with conventional methods is not appropriate or safe for the particular patient (medical records must describe the specific circumstances).

Limitations for Stereotactic Body Radiation Therapy (SBRT);
1. Primary treatment of lesions of bone, breast, uterus, ovary, and other internal organs not listed in the policy statements above is considered not medically necessary.
2. SBRT is considered not medically necessary under the following circumstances for any condition:
   a. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
   b. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
c. The patient has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of three or worse). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.

d. Recurrent (other than pelvic and head and neck tumors) or metastatic disease could be treated by conventional methods (record must describe why other radiation therapy measures are not appropriate or safe for the particular patient).

e. Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT. SBRT is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment.

MEDICARE ADVANTAGE POLICY GUIDELINES

Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT. SBRT is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment.

KARNOFSKY PERFORMANCE STATUS SCALE

100 Normal; no complaints, no evidence of disease
90 Able to carry on normal activity; minor signs or symptoms of disease
80 Normal activity with effort; some signs or symptoms of disease
70 Cares for self; unable to carry on normal activity or to do active work
60 Requires occasional assistance but is able to care for most needs
50 Requires considerable assistance and frequent medical care
40 Disabled; requires special care and assistance
30 Severely disabled; hospitalization is indicated although death not imminent
20 Very sick; hospitalization necessary; active supportive treatment is necessary
10 Moribund, fatal processes progressing rapidly
0 Dead

ECOG PERFORMANCE STATUS SCALE

Grade 0: Fully active, able to carry on all pre-disease performance without restriction.
Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
Grade 2: Ambulatory and capable of all self-care but unable to carry out work activities. Up and about more than 50% of waking hours.
Grade 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
Grade 5: Dead
BACKGROUND

Stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) are techniques that use highly focused, conformal radiation beams to treat both neoplastic and non-neoplastic conditions. Although SRS and SBRT may be completed with 1 session (single-fraction), SRS typically refers to a single-session procedure to ablate the target lesion. However, either technique may require additional sessions (typically not >5) over a course of days, referred to as fractionated radiotherapy.

Platforms available for SRS and SBRT are distinguished by their source of radiation; these platforms include gamma radiation from cobalt 60 sources; high-energy photons from linear accelerator (LINAC) systems; and particle beams (e.g., protons). Particle beam therapy is not covered in this protocol.

SRS and SBRT have been used for a range of malignant and nonmalignant conditions. A comprehensive assessment that encompasses all potential uses is beyond the scope of this protocol.

REGULATORY STATUS

Several devices that use cobalt 60 radiation (gamma-ray devices) for SRS have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The most commonly used gamma-ray device, approved in 1999, is the Gamma Knife® (Elekta; product code IWB), which is a fixed device used only for intracranial lesions. Gamma-ray emitting devices that use cobalt 60 degradation are also regulated through the U.S. Nuclear Regulatory Commission.

A number of LINAC movable platforms that generate high-energy photons have been cleared for marketing by the FDA through the 510(k) process. Examples include the Novalis Tx® (Novalis); the TrueBeam STx (Varian Medical Systems; approved 2012; FDA product code IYE); and the CyberKnife® Robotic Radiosurgery System (Accuray; approved 1998; FDA product code MUJ). LINAC-based devices may be used for intracranial and extracranial lesions.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

64. Roos D. What is the randomised evidence for surgery and stereotactic radiosurgery for patients with solitary (or few) brain metastases?. Int J Evid Based Healthc. Mar 2011;9(1):61-6. PMID 21332664


204. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): STEREOTACTIC Radiation Therapy: STEREOTACTIC RADIOSURGERY (SRS) and STEREOTACTIC Body Radiation Therapy (SBRT) (L35076), Revision Effective Date For services performed on or after 04/01/2020.