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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
- With non-neoplastic intracranial 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 intracranial 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; 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 |
<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| 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:  
• 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  
• Surgery  
• Combinations of other forms of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
• Overall survival  
• Symptoms  
• Treatment-related morbidity |
| Individuals:  
• With primary spinal or vertebral body tumors who have received prior spinal radiotherapy | Interventions of interest are:  
• Stereotactic radiotherapy | 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 primary or metastatic tumor of the liver that is considered inoperable | Interventions of interest are:  
• Stereotactic body radiotherapy | Comparators of interest are:  
• Other forms of radiotherapy  
• Surgery  
• Combinations of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
• Overall survival  
• Symptoms  
• Treatment-related morbidity |
| Individuals:  
• With pancreatic adenocarcinoma | Interventions of interest are:  
• Stereotactic body radiotherapy | Comparators of interest are:  
• Other forms of radiotherapy  
• Surgery  
• Combinations of radiotherapy, surgery, or chemotherapy | Relevant outcomes include:  
• Overall survival  
• Symptoms  
• Treatment-related morbidity |
Populations | Interventions | Comparators | Outcomes
---|---|---|---
**Individuals:**
- With primary or metastatic renal cell carcinoma who are not good surgical candidates
**Interventions of interest are:**
- Stereotactic body radiotherapy
**Comparators of interest are:**
- Other forms of radiotherapy
- Surgery
- Combinations of radiotherapy, surgery, or chemotherapy
**Relevant outcomes include:**
- Overall survival
- Symptoms
- Treatment-related morbidity

**Individuals:**
- With oligometastases involving adrenal glands
**Interventions of interest are:**
- Stereotactic body radiotherapy
**Comparators of interest are:**
- Other forms of radiotherapy
- Surgery
- Combinations of radiotherapy, surgery, or chemotherapy
**Relevant outcomes include:**
- Overall survival
- Symptoms
- Treatment-related morbidity

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 who have non-neoplastic intracranial conditions (e.g., arteriovenous malformations, trigeminal neuralgia), non-neoplastic neurologic conditions (e.g., epilepsy, tremor and movement disorders, chronic pain), benign neoplastic intracranial lesion(s) (e.g., acoustic neuromas, pituitary adenoma, meningiomas, cranio- pharyngioma, glomus jugulare tumors), and malignant neoplastic intracranial lesion(s) (e.g., gliomas, astrocytomas), or uveal melanoma who receive SRS, the evidence includes randomized controlled trials (RCTs), nonrandomized retrospective cohort studies, and observational studies or case series. Relevant outcomes are overall survival (OS), symptoms, and treatment-related morbidity. General limitations of the body of evidence include a lack of trials that directly compare SRS with comparators, patient heterogeneity within and between studies, and failure to use standardized methods to collect and report outcomes (benefits and harms). There are several contextual factors to consider, such as SRS offers a noninvasive, highly precise radiotherapy alternative to surgery (particularly important for patients unable to undergo resection due to the presence of underlying comorbidities), intracranial lesions often are difficult to access surgically (and may be associated with a high-risk for devastating adverse sequelae), intracranial lesions typically are located adjacent to vital organs and structures that are highly susceptible to radiation toxicities, and the accuracy and precision of SRS in this context make this technique a viable alternative to standard, nonconformal external-beam radiotherapy. Finally, given the rarity of many of the conditions under review, direct comparative trials are unlikely.

The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for patients with:

- arteriovenous malformations;
- trigeminal neuralgia refractory to medical management;
- acoustic neuromas;
- pituitary adenomas;
- nonresectable residual or recurrent meningiomas;
- malignant neoplastic intracranial lesion(s) (e.g., gliomas, astrocytomas).

For individuals with epilepsy (primary or secondary tumor-related), the evidence for the use of SRS as a treatment for epilepsy includes case reports in primary epileptic disorders and case reports for tumor-related epilepsy. Relevant outcomes are symptoms and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with mesial temporal lobe epilepsy refractory to medical management, the published evidence for the use of SRS includes a pilot prospective noncomparative intervention and a single RCT comparing SRS to anterior temporal lobectomy (ATL). Relevant outcomes are symptoms and treatment-related morbidity. The RCT did not meet participant accrual targets and, thus, did not demonstrate noninferiority of SRS to ATL. Seizure remission rates between 25 and 36 months were reported on 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 published evidence for SRS in mesial temporal lobe epilepsy is insufficient. However, in 2018, clinical expert opinion input reported the less invasive nature of SRS with acceptable seizure remission rates over time may be appropriate for the specific subpopulation of patients with mesial temporal epilepsy refractory to medical management when the standard alternative treatments are not an option. Thus, for this specific subpopulation, SRS would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful improvement in the net health outcome.

For individuals with tremor and movement disorder, the evidence related to the use of SRS includes uncontrolled cohort studies, many of which reported outcomes from the treatment of tremor of varying etiologies. There is a retrospective analysis of a single-center experience. Relevant outcomes are symptoms and treatment-related morbidity. 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. Clinical expert opinion input reported systematic reviews of retrospective studies that reported a reduction in tremors after SRS but confirmed that alternative approaches to thalamotomy are appropriate. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic pain syndromes refractory to standard medical and psychological treatments, the evidence includes a systematic review of noncomparative studies. Relevant outcomes are symptoms and treatment-related morbidity. Clinical expert opinion input reported that intracranial SRS for treatment of chronic pain (other than associated with trigeminal neuralgia) was not an appropriate alternative to other surgical interventions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals in the subgroup of uncommon benign neoplastic intracranial lesions (acoustic neuroma, pituitary adenoma, craniopharyngioma, 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 are 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 and the published evidence is insufficient to
determine the effects of the technology on health outcomes. However, in 2018, clinical expert opinion input continues to support an individualized approach to the use of SRS for these tumors with the recognition that outcomes are affected by factors such as the location of the tumor and type of SRS used (hypofractionated, fractionated or single-session treatment). Thus, for the subpopulation of patients with uncommon benign neoplastic intracranial tumors (acoustic neuroma, pituitary adenoma craniopharyngioma, and glomus jugulare tumors), SRS would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful improvement in net health outcome.

For individuals with uveal melanoma, evidence for use of SRS is limited to case series. Relevant outcomes are overall survival, 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. In 2018, clinical expert opinion input reported that the use of SRS to treat uveal melanoma could provide patients with low-risk disease (based on tumor size using the Collaborative Ocular Melanoma Study (COMS) definition of small and medium) an option to avoid or postpone enucleation with preservation of some visual acuity and functional abilities. Thus, for individuals with uveal melanoma, SRS would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful improvement in 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 overall survival, 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 (reduce pain) in patients with spinal (vertebral) tumors. In addition, in 2018, clinical expert opinion input reported that SBRT is an important treatment option for patients whose spinal tumors have had prior radiotherapy because of the ability to spare the spinal cord and escalate tumor dose. Thus, for individuals with primary or metastatic spinal or vertebral body tumors in patients who have received prior spinal radiotherapy, SBRT would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful improvement in net health outcome.

For individuals with primary hepatocellular carcinoma (HCC), there are no RCTs reported on the use of SBRT for HCC. Relevant outcomes are overall survival, 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 one 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 (larger than three 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. Overall, the evidence from published literature is insufficient to determine the effect on net health outcomes. However, clinical expert opinion input confirmed the lack of RCTs and reported on nonrandomized observational studies that support the use of SBRT as an alternative locoregional treatment for patients with inoperable primary hepatocellular carcinoma or metastatic lesions. Clinical input also referred to national guidelines that have rendered the same recommendation. Thus, for this specific subpopulation including primary or metastatic tumor of the liver that is considered inoperable, SBRT would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful improvement in net health outcome.
For individuals with pancreatic adenocarcinoma combined chemoradiotherapy plays a significant role in the treatment of locally advanced pancreatic cancer. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. Noncomparative observational and retrospective studies of SBRT have reported increased patient survival compared with historical data. Acute, grade 3 toxicities have been reported. Limited clinical expert opinion input reported that the use of SBRT for inoperable pancreatic adenocarcinoma also referred to guideline-based recommendations for use in localized disease. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 overall survival, symptoms, and treatment-related morbidity. Generally, high rates of local control have been reported for primary RCC. Adverse effects include nephron loss and kidney shrinkage, however, avoidance of nephrectomy in patients with hypertension or solitary kidney may be desirable. RCC is considered to be relatively radioresistant. The published evidence is insufficient to determine that the impact of the technology results in an improvement in the net health outcome. Limited clinical expert opinion input reported that SBRT may be appropriate for patients with primary renal cell carcinoma who are not good surgical candidates and, for relapsed or stage IV disease referred to guideline-based recommendations. Thus, for this specific subpopulation, SBRT would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful 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 adrenal glands, consists of relatively small, noncomparative studies that confirm clinically important rates of local control. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. 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 a meaningful improvement in the net health outcome. Limited clinical expert opinion input reported that given the emergence of highly effective systemic therapies; SBRT used to treat oligoprogression maintains the patient on the same line of systemic therapy, delaying the need for another line of therapy that is likely to be less effective. Clinical input also reported that SBRT may represent the singular option for some patients with oligometastatic disease that includes one or both adrenal glands in patients who are poor surgical and RFA candidates. Thus, for this specific subpopulation, SBRT would provide a clinically meaningful improvement in net health outcome. The evidence is sufficient to determine the impact of the technology results in a meaningful 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);
• uveal melanoma.

Stereotactic body radiotherapy may be considered medically necessary for the following indications:
• primary spinal or vertebral body tumors in patients who have received prior spinal radiotherapy;
• 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 adrenal glands.

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 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. The use of charged particle (proton or helium ion) radiotherapies is addressed in the Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions Protocol.

**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 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.

6. 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 paranasal sinus malignancies).

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 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).
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 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 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 (primary), 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).
   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).

**MEDICARE ADVANTAGE POLICY GUIDELINES**

Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treat-
ment within an extremely accelerated time frame, any course of radiation treatment extending beyond five frac-
tions 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 seden-
tary nature, e.g., light house work, office work.
Grade 2: Ambulatory and capable of all self-care but unable to carry out and 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**

**CONFORMAL RADIOTHERAPY**

SRS and 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 one 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 more than five) over a course of days, referred to as fractionated radiotherapy.

Platforms available for SRS and SBRT are distinguished by their source of radiation; they include gamma radia-
tion 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 assess-
ment that encompasses all potential uses is beyond the scope of this protocol. Thus, a brief introduction follows
for common applications of SRS and SBRT for which published evidence has been identified in database searches.

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 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.

RELATED PROTOCOLS

Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
Intensity-Modulated Radiotherapy: Abdomen and Pelvis
Intensity-Modulated Radiotherapy: Central Nervous System Tumors
Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas

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


60. 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):61-66. PMID 21332664


