#### MEDICAL POLICY

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

- If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
- If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

#### POLICY STATEMENT:

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

I. Stereotactic radiosurgery has been medically proven to be effective and therefore **medically appropriate** for the following indications:
   
   A. Benign conditions:
      1. Arteriovenous malformations (less than 4 cm in diameter);
      2. Acoustic neuromas;
      3. Pituitary adenomas;
      4. Nonresectable, residual, or recurrent meningiomas;
      5. Craniopharyngiomas;
      6. Glomus jugulare tumor;
      7. Hemangioblastoma;
      8. Pineocytoma;
      9. Schwannoma;
     10. Cavernous malformations.
   
   B. Primary tumors of the brain and spinal cord *that have been previously irradiated*.
   
   C. Primary spinal tumor with compression or intractable pain.
   
   D. Brain metastases under the following conditions:
      1. Initial treatment:
         a. Any number of lesions to be treated with no lesion greater than 3 cm; and
         b. Patient has a good performance status; and
         c. Systemic disease is limited and under control (or good options for systemic treatment are available); and
         d. The total volume of treated lesions should be considered safe to deliver SRS.
      2. Previous whole brain irradiation (WBRT):
         a. Patient has a good performance status; and
         b. Systemic disease is under control.
      3. No previous WBRT:
         a. Recurrence with 1-3 lesions; and
         b. More than 6 months has elapsed since RT; and
         c. Patient has a good performance status; and
         d. Systemic disease is under control.
      4. An SRS boost is medically necessary in those patients with a single lesion when WBRT is being delivered.
E. The following indications when refractory to medical management and/or invasive neurosurgical treatment:
   1. Trigeminal neuralgia;
   2. Movement disorders (e.g., epilepsy, Parkinson’s disease, essential tremor, or familial tremor classifications with major systemic disease.

II. Stereotactic body radiation therapy (SBRT) has been medically proven to be effective and therefore medically appropriate for the following indications:
   A. Recurrent or residual nasopharyngeal, carcinoma at primary site when radiation therapy treatments such as three-dimensional conformal or IMRT cannot be utilized;
   B. Spinal or vertebral body tumors (metastatic or primary) in patients who have received prior radiation therapy;
   C. Inoperable stage I or II Non-small cell lung cancer (NSCLC);
   D. Pancreas; resectable; prior to surgery; or
   E. Any of the following neoplasms presenting with 1 to 3 metastases in the synchronous setting when local control is expected and treatment of the metastases may result in an increased disease-free interval and possible survival:
      1. For an individual with non-small cell lung cancer who:
         a. has had or who will undergo curative treatment of the primary tumor (based on T and N stage) and
      2. For an individual with colorectal cancer who:
         a. has had or who will undergo curative treatment of the primary tumor and
         b. whose metastases are in the lung or liver and
         c. for whom surgical resection is not possible.
   F. Any of the following neoplasms where the primary tumor was previously controlled and metachronous metastases have presented under all of the following circumstances:
      1. Clinical presentation of 1 to 3 metastases of the adrenal gland, lung, liver, or bone when the following criteria are met:
         a. histology is non-small cell lung, colon, breast, sarcoma, renal cell or melanoma;
         b. disease free interval of greater than one (1) year from the initial diagnosis;
         c. primary tumor received curative therapy and is controlled;
         d. no prior evidence of metastatic disease (cranial or extracranial); or
      2. Locally recurrent radioresistant pathologies of melanoma, soft tissue sarcoma, and renal cell carcinoma that are within or immediately adjacent to an area that has received radiation treatments and who treatment is expected to result in long-term control and/or result in symptom improvement and/or functional improvement.
   G. Prostate cancer; clinically localized disease when used as definitive treatment;
      1. Stage less than T3A; and
      2. Gleason Score (GS) less than 8; and
      3. Prostate Specific Antigen (PSA) less than 20; and
      4. Negative bone scan in the last 6 months (bone scans not recommended for patients with low risk prostate cancer – PSA less than 10 and GS less than 7 and stage 1c/2a).

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

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

Refer to Corporate Medical Policy #6.01.11 regarding Proton Beam Radiation.
Refer to Corporate Medical Policy #6.01.24 regarding Intensity Modulated Radiation Therapy (IMRT).

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

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

POLICY GUIDELINES:

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

DESCRIPTION:

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

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

RATIONALE:

The addition of stereotactic radiosurgery as a treatment regimen for intracranial masses less than 4 cm in diameter (e.g., gliomas, brain metastases, and meningiomas) has improved health outcomes by providing local tumor control and increasing survival rates. Radiosurgery in patients with lesions over 4 cm is associated with increased complications (e.g., radionecrosis, CNS toxicity) and lowers probability of reaching effective radiation doses.

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

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

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

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

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

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

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

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

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

**CODES:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
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*Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*

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

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

**CPT:** 31626 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with placement of fiducial markers, single or multiple
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31627</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure(s))</td>
</tr>
<tr>
<td>32553</td>
<td>Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple</td>
</tr>
<tr>
<td>49411</td>
<td>Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple</td>
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<tr>
<td>49412</td>
<td>Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), open, intra-abdominal, intrapelvic, and/or retroperitoneum, including image guidance, if performed, single or multiple (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>77371</td>
<td>Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s), consisting of one session; multi-source cobalt 60 based linear accelerator based</td>
</tr>
<tr>
<td>77372</td>
<td>Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions</td>
</tr>
<tr>
<td>77373</td>
<td>Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)</td>
</tr>
<tr>
<td>77435</td>
<td>Stereotactic body radiation therapy, treatment management, pretreatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions</td>
</tr>
<tr>
<td>61796</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 small cranial lesion</td>
</tr>
<tr>
<td>61797</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesions, simple</td>
</tr>
<tr>
<td>61798</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion</td>
</tr>
<tr>
<td>61799</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex</td>
</tr>
<tr>
<td>61800</td>
<td>Application of stereotactic headframe for stereotactic radiosurgery</td>
</tr>
<tr>
<td>63620</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion</td>
</tr>
<tr>
<td>63621</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion</td>
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</tbody>
</table>

**HCPCS:** Medically appropriate for diagnosis codes listed below:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0339</td>
<td>Image guided robotic linear accelerator base stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment</td>
</tr>
</tbody>
</table>
G0340  Image guided robotic linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment

ICD9:
155.0  Malignant neoplasm of liver, primary
155.1  Malignant neoplasm of intrahepatic bile ducts
155.2  Malignant neoplasm not specified as primary or secondary
162.2  Malignant neoplasm of main bronchus
162.3  Malignant neoplasm of upper lobe, bronchus or lung
162.4  Malignant neoplasm of middle lobe, bronchus or lung
162.5  Malignant neoplasm of lower lobe, bronchus or lung
162.8  Malignant neoplasm of other parts of bronchus or lung
162.9  Malignant neoplasm of bronchus and lung, unspecified
170.0  Malignant neoplasm of bones of skull and face, except mandible
170.2  Malignant neoplasm of vertebral column, excluding sacrum and coccyx
185.0  Malignant neoplasm of prostate
189.0  Malignant neoplasm of kidney, except pelvis
189.1  Malignant neoplasm of renal pelvis
191.0-191.9  Malignant neoplasm of brain (code range)
192.1  Malignant neoplasm of cerebral meninges
192.2  Malignant neoplasm of spinal cord
192.3  Malignant neoplasm of spinal meninges
194.3  Malignant neoplasm of pituitary gland and craniopharyngeal duct
194.4  Malignant neoplasm of pineal gland
197.7  Secondary malignant neoplasm of liver, specified as secondary
198.0  Secondary malignant neoplasm of kidney
198.3  Secondary malignant neoplasm of brain and spinal cord
225.0  Benign neoplasm of brain
225.1  Benign neoplasm of cranial nerves (include acoustic neuromas)
225.2  Benign neoplasm of cerebral meninges
225.3  Benign neoplasm of spinal cord
225.4  Benign neoplasm of spinal meninges
227.3  Benign neoplasm of pituitary gland
227.4  Benign neoplasm of pineal gland
<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
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</thead>
<tbody>
<tr>
<td>228.02</td>
<td>Hemangioma of intracranial structures</td>
</tr>
<tr>
<td>237.0</td>
<td>Neoplasm of pituitary gland and craniopharyngeal duct</td>
</tr>
<tr>
<td>230.8</td>
<td>Carcinoma in situ of liver and biliary system</td>
</tr>
<tr>
<td>235.3</td>
<td>Neoplasm of uncertain behavior of liver and biliary passages</td>
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<tr>
<td>237.1</td>
<td>Neoplasm of uncertain behavior of pineal gland</td>
</tr>
<tr>
<td>237.5</td>
<td>Neoplasm of uncertain behavior of brain and spinal cord</td>
</tr>
<tr>
<td>237.6</td>
<td>Neoplasm of uncertain behavior of meninges</td>
</tr>
<tr>
<td>350.1</td>
<td>Trigeminal neuralgia</td>
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<tr>
<td>742.9</td>
<td>Unspecified congenital anomaly of brain, spinal cord, and nervous system</td>
</tr>
<tr>
<td>747.81</td>
<td>Anomalies of cerebrovascular system includes arteriovenous malformations</td>
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<tr>
<td>747.82</td>
<td>Congenital spinal vessel anomaly</td>
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<tr>
<td>ICD10:</td>
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<tr>
<td>C22.0-C22.9</td>
<td>Malignant neoplasm of liver and intrahepatic bile ducts (code range)</td>
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<tr>
<td>C34.00-C34.92</td>
<td>Malignant neoplasm of bronchus and lung (code range)</td>
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<tr>
<td>C41.0</td>
<td>Malignant neoplasm of bones of skull and face</td>
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<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
</tr>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate</td>
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<tr>
<td>C64.1-C64.9</td>
<td>Malignant neoplasm of kidney, except renal pelvis (code range)</td>
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<tr>
<td>C65.1-C65.9</td>
<td>Malignant neoplasm of renal pelvis (code range)</td>
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<td>C70.0-C70.9</td>
<td>Malignant neoplasm of meninges (code range)</td>
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<tr>
<td>C71.0-C71.9</td>
<td>Malignant neoplasm of brain (code range)</td>
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<tr>
<td>C72.0-C72.1</td>
<td>Malignant neoplasm of spinal cord and cauda equine (code range)</td>
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<td>C75.1-C75.3</td>
<td>Malignant neoplasm of other endocrine glands and related structures (code range)</td>
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<td>C78.7</td>
<td>Secondary malignant neoplasm of liver and intrahepatic bile duct</td>
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<tr>
<td>C79.00-C79.02</td>
<td>Secondary malignant neoplasm of kidney and renal pelvis (code range)</td>
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<td>C79.31</td>
<td>Secondary malignant neoplasm of brain</td>
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<td>D01.5</td>
<td>Carcinoma in situ of liver, gallbladder and bile ducts</td>
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<td>D18.02</td>
<td>Hemangioma of intracranial structures</td>
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<tr>
<td>D32.0-D32.9</td>
<td>Benign neoplasm of meninges (code range)</td>
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<tr>
<td>D33.0-D33.4</td>
<td>Benign neoplasm of brain and other parts of central nervous system (code range)</td>
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<tr>
<td>D52.2-D52.4</td>
<td>Benign neoplasm of other and unspecified endocrine glands (code range)</td>
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<tr>
<td>D37.6</td>
<td>Neoplasm of uncertain behavior of liver, gallbladder and bile ducts</td>
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<tr>
<td>D42.0-D42.9</td>
<td>Neoplasm of uncertain behavior of meninges (code range)</td>
</tr>
<tr>
<td>D43.0-D43.4</td>
<td>Neoplasm of uncertain behavior of brain and central nervous system (code range)</td>
</tr>
</tbody>
</table>
D44.3-D44.5  Neoplasm of uncertain behavior of pituitary gland and craniopharyngeal duct (code range)
G50.0       Trigeminal neuralgia
Q04.9       Congenital malformation of brain, unspecified
Q06.9       Congenital malformation of spinal cord, unspecified
Q07.9       Congenital malformation of nervous system, unspecified
Q27.9       Congenital malformation of peripheral vascular system, unspecified
Q28.2       Arteriovenous malformation of cerebral vessels
Q28.3       Other malformations of cerebral vessels

REFERENCES:


*Proprietary Information of Excellus Health Plan, Inc.*


**KEY WORDS:**

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

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a Local Coverage Determination (LCD) for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35076&ContrId=298&ver=19&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AggAAAAQAAAAAA%3d%3d&