Stereotactic Radiosurgery and Proton Beam Therapy

Overview

Stereotactic radiosurgery (SRS) is a highly precise form of radiation therapy initially used to treat tumors and other abnormalities of the brain (intracranial). When used to treat other parts of the body (extracranial), the procedure is referred to as stereotactic body radiotherapy (SBRT).

Fractionated stereotactic radiotherapy is the term utilized when multiple SRS treatments are administered (typically 2–5).

Despite its name, SRS is a non-surgical procedure that delivers precisely-targeted radiation at much higher doses than traditional radiation therapy while sparing healthy adjacent tissue.

SRS and SBRT technologies

1. Three-dimensional (3D) imaging and localization techniques that determine the exact coordinates of the target within the body.
2. Systems to immobilize and carefully position the patient.
3. Highly focused gamma-ray or x-ray beams that converge on a tumor or abnormality.
4. Image-guided radiation therapy (IGRT), which uses medical imaging to confirm the location of a tumor immediately before, and in some cases during the delivery of radiation to further improve the precision and accuracy of the treatment.

Radiation modalities for SRS and SBRT:

1. Gamma Knife — for intracranial indications; consists of multiple beams of highly focused gamma rays converging in three dimensions.
2. The treatment involves four phases: placement of a head frame, imaging of the tumor location, computerized dose planning and radiation delivery.
3. Linear accelerator (LINAC) — for either intracranial or extracranial indications; consists of high-energy x-ray photons or electrons that are delivered to the brain or to outside the brain (extracranially) as with SBRT.
The LINAC involves the same four phases of the Gamma Knife, but unlike the Gamma Knife, which remains motionless during the procedure, part of the LINAC, a gantry, rotates around the patient delivering radiation beams from different angles. (Note: The CyberKnife, a LINAC technology, utilizes a robotic arm that moves around the patient under image-guidance)

Compared to the Gamma Knife, the LINAC is able to use a larger x-ray beam, which enables it to treat larger tumors more uniformly. It can also be used for single-session or fractionated radiotherapy using a relocatable frame; an advantage for large tumors or particularly critical locations.

4. **Proton beam therapy (PBT)** — uses a special machine called a cyclotron or a synchrotron to generate and accelerate protons (atoms that carry a positive charge).

The protons leave the machine and are steered by magnets toward the tumor; releasing most of their energy when they hit the tumor (delivering no exit dose beyond the tumor boundary, unlike photons). The result is that the radiation dose may conform to the tumor better with less damage occurring to healthy tissue; thus potentially enabling the administration of larger doses while minimizing unwanted side effects.

PBT may be considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the member. Examples include:

i. The target volume is in close proximity to ≥ 1 more critical structure and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s)

ii. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to lessen the risk of excessive early or late normal tissue toxicity

iii. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity

iv. The same (or an immediately adjacent area) has been previously irradiated and the dose distribution within must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue

Treatment with PBT is limited within the United States and not available in the state of New York.

**Guideline**

I. Single or multiple-session (fractionated) SRS/SRBT, utilizing any FDA-approved Gamma Knife or LINAC technology, is considered medically necessary for any of the following conditions:

   A. **Nonmalignant cranial/spinal/central nervous system (CNS) tumors/lesions**
      1. Arteriovenous (AV)/cavernous malformations
      2. Acoustic neuroma
      3. Craniopharyngioma
      4. Glomus tumor
      5. Hemangioblastoma
      6. Meningioma
      7. Pineocytoma
      8. Pituitary adenoma
      9. Schwannomas
      10. Spinal tumors — inoperable primary with compression or intractable pain

   B. **Malignant primary tumors/lesions**
      1. Prostate cancer:
         v. Low-, intermediate-, and high-risk prostate cancer
vi. Negative bone scan within the last 6 months, where applicable

2. CNS (includes spinal tumors); initial or recurrence treatment (see Limitations/Exclusions for gliomas)
   Note: Boost treatment may be considered on a case-by-case basis for larger cranial or spinal lesions (such as sarcomas, chondrosarcomas, chordomas and nasopharyngeal or paranasal sinus malignancies) that have been treated initially with external beam radiation therapy or surgery. This restriction is not applicable to Medicare members per Local Coverage Determination, Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

3. Uveal melanoma

4. Non-small cell lung cancer (NSCLC) — medically inoperable Stage 1 or 2

5. Malignant primary tumors of the adrenal gland, kidney, liver and pancreas
   Note regarding pancreatic cancer: Stereotactic body radiation therapy (using up to 5 radiation treatment fractions) will be considered on a case-by-case basis for Commercial and Medicaid members, as consistent with eviCore, for:
   i. Pre-operative (neoadjuvant resectable or borderline resectable) cases following a minimum of 2 cycles of chemotherapy and restaging in which there is no evidence of tumor progression
   ii. Definitive treatment for medically inoperable or locally advanced cases following a minimum of 2 cycles of chemotherapy and restaging in which there is no evidence of tumor progression and the disease volume can be entirely encompassed in the radiation treatment volume.
   iii. Postoperative (adjuvant) cases in which there is residual gross disease or positive microscopic margins that can be entirely encompassed in the radiation treatment volume

C. Malignant metastatic tumors/lesions
   1. Brain
      i. Initial treatment is medically necessary when the following conditions are met:
         • Lesion no > 5 cm
         • Karnofsky Performance Status (KPS) > 70
         • Primary histology is not germ cell, small cell, or lymphoma
         • Systemic disease is under control or good options for systemic treatment are available
         • All lesions can be treated in a single treatment plan in a single fraction (for SRS) or up to 5 fractions (for fractionated SRS)
           Note that all lesions present on imaging must be targeted as a single episode of care. If this cannot be accomplished in a maximum of 5 fractions, each fraction must be billed as 3D conformational or intensity modulated radiation therapy (IMRT), depending on the planning, as the definition of SRS is not met.
      ii. In a member who has received prior SRS, retreatment with SRS is medically necessary when the following conditions are met:
         • 1–5 new lesions (no > 5 cm) are present with evidence of controlled systemic disease
         • KPS score > 70
         • Primary histology is not germ cell, small cell, or lymphoma
         • Member has not been treated with > 2 episodes of radiosurgery in past 9 months
         • All lesions can be treated in a single treatment plan with a single fraction (for SRS) or up to 5 fractions (for fractionated SRS). Note that all lesions present on imaging must be targeted as a single episode of care. If this cannot be accomplished in a maximum of 5 fractions, each fraction must be billed as 3D conformational or IMRT, depending on the planning, as the definition of SRS is not met
      iii. In a member who has received prior whole-body radiation therapy (WBRT), SRS may be medically necessary if the member’s KPS is > 70, systemic disease is under control, and life expectancy is > 6 months
      iv. Post-operative SRS is considered not medically necessary
2. Member with NSCLC (who will undergo curative treatment of primary tumor) and presents with 1–3 metastases in the synchronous setting

3. Spinal tumors — recurrent metastatic for members who have undergone prior surgery and conventional radiation therapy
   Note: Prior surgery or conventional radiation therapy is not a prerequisite for Medicare members per Local Coverage Determination. Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

4. Member with colorectal cancer (who will undergo curative treatment of primary tumor) and presents with 1–3 metastases in the lung or liver in the synchronous setting and for whom surgical resection is not possible

5. Member presenting with 1–3 adrenal gland, lung, liver or bone metastases in the metachronous setting when all the following criteria are met:
   i. Histology is NSCLC, colon, breast, sarcoma, renal cell or melanoma
   ii. Disease free interval of > 1 year from the initial diagnosis
   iii. Primary tumor received curative therapy and is controlled
   iv. No prior evidence of metastatic disease (cranial or extracranial)

6. Medicare members (only) presenting with 1–3 kidney or pancreas metastases in the metachronous setting

D. Tumors of any type arising in areas of overlap with previously irradiated regions (where there is likely to be obvious clinical benefit)

E. SRS is medically necessary for any of the following diseases that are refractory to medical treatment and/or invasive neurosurgical treatment
   1. Epilepsy
   2. Parkinson’s disease
   3. Essential tremor
   4. Familial tremor classifications with major systemic disease
   5. Trigeminal neuralgia

Authorization for this class of diseases will only be granted once all standard treatments have proven to be ineffective. Substantiating documentation must accompany request. Discussion with a Medical Director may also be required.

II. Proton beam therapy (PBT) (Subsection “B” for Medicare)

A. Commercial and Medicaid members

Treatment of the following tumors is considered medically necessary:
   1. Chondrosarcomas and chordomas of the skull base; localized and in postoperative setting
   2. Uveal Melanomas when preferential compared to brachytherapy
   3. Localized unresectable hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma
      Note: Documentation substantiating the medical necessity of PBT, versus alternate techniques (e.g., 3DCRT, intensity modulated radiation therapy [IMRT], ablative, transarterial or SBRT techniques in the curative setting, etc.), must be submitted to the plan.
   4. Stage IIA seminoma
   5. Malignancies requiring Craniospinal Irradiation (CSI)

PBT for the following indications will be reviewed on a case-by-case basis:
   1. Locally advanced Breast Cancer when treating the internal mammary nodes
   2. Primary CNS cancer
3. Esophageal cancer
4. Head and neck cancer (excluding T1-T2N0M0 laryngeal cancer)
5. Remaining cases of unresectable hepatocellular carcinoma and intrahepatic cholangiocarcinoma**
6. Hodgkin’s Lymphoma
7. Non-Hodgkin’s Lymphoma
8. Stage IIIIB Non-Small Cell Lung Cancer
9. Pancreatic cancer
10. Prostate cancer (Unoperated)
11. Retroperitoneal Sarcoma
12. Thymomas and Thymic Carcinoma

Due to insufficient evidence, PBT is considered experimental, investigational and/or unproven for all other tumors including adjuvant or salvage treatment of prostate cancer (i.e., after prostatectomy).

B. Medicare members (See also National Government Services Local Coverage Determination [LCD]: Proton Beam Therapy)

Treatment is considered medically necessary for the tumors listed in Group 1 when ≥ 1 of the following is applicable:

1. The target volume is in close proximity to ≥ 1 more critical structure and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s)
2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to lessen the risk of excessive early or late normal tissue toxicity
3. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity
4. The same (or an immediately adjacent area) has been previously irradiated and the dose distribution within must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue

GROUP 1
1. Ocular tumors, including intraocular melanomas
2. Tumors that approach or are located at the base of skull, including but not limited to:
   i. Chordoma
   ii. Chondrosarcomas
   iii. Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
3. Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations
4. Primary hepatocellular cancer treated in a hypofractionated regimen
5. Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
6. Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
7. Pituitary neoplasm
8. Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck
9. Malignant lesions of the paranasal sinus, and other accessory sinuses
10. Unresectable retroperitoneal sarcoma.

**GROUP 2**
Coverage of the following tumors is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature:

1. Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
2. Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
3. Breast cancers
4. Unresectable pancreatic and adrenal tumors
5. Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
6. Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
7. Prostate cancer, without distant metastases
8. Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
9. Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

**Prostate Cancer**
Coverage and payments of proton beam therapy for prostate cancer will require both:

1. Physician documentation of member selection criteria (i.e., stage and other factors per NCCN guidelines)
2. Documentation and verification that member was informed of range of therapy choices including risks and benefits.

**Limitations/Exclusions**

**A.** Proton beam therapy is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value. Case-by-case consideration will be given for special situations [See diagnostic coding below]

**B.** Stereotactic radiosurgery is regarded as investigational and not medically necessary for the following indications:

1. Gliomas (case by case consideration for inoperable malignant gliomas that have received prior radiation treatment)
2. Chronic pain syndromes
3. Extracranial lesions/tumors (other than those depicted above)
4. SBRT for palliation is not considered medically necessary
5. Psychoneurosis

**Revision History**

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<th>Date</th>
<th>Description</th>
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<tr>
<td>4/12/19</td>
<td>Added Commercial and Medicaid coverage of PBT for malignancies requiring craniospinal irradiation (CSI). Added Commercial and Medicaid PBT coverage consideration language for unresectable HCC and intrahepatic cholangiocarcinoma. Added PBT case-by-case review language for Commercial and Medicaid members specific to: Locally advanced breast cancer when treating the internal mammary nodes, primary CNS cancer, esophageal cancer, head and neck cancer (excluding T1-T2NOM0 laryngeal cancer), remaining cases of unresectable HCC and intrahepatic cholangiocarcinoma,</td>
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10/12/18
Added covered indications for malignant primary tumors of the adrenal gland, kidney, liver and pancreas.
Added covered indication for Medicare members (only) presenting with 1–3 kidney or pancreas metastases in the metachronous setting.

1/12/17
Brain metastasis criteria modified for SRS to include Karnofsky scoring, specify lesion size characteristics and communicate utilization parameters. Neurologic diseases added as covered indications.

12/1/16
Prostate cancer criteria modified for SRBT to include high-risk members.

9/9/2016
For proton beam therapy, separated criteria per line of business. Added Stage IIA seminoma indication for Commercial and Medicaid members; added Group 1 and Group 2 indications for Medicare members. For stereotactic radiosurgery; specific to Medicare members, clarified that prior surgery or conventional radiation therapy is not required in certain instances.

3/11/2016
Added case-by-case language for boost treatment of larger cranial or spinal lesions within the section pertaining to malignant primary tumors/lesions.

### Applicable Procedure Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>61796</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion</td>
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<tr>
<td>61797</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>61798</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion</td>
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<tr>
<td>61799</td>
<td>Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)</td>
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<tr>
<td>61800</td>
<td>Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)</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 (List separately in addition to code for primary procedure)</td>
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<tr>
<td>77371</td>
<td>Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based</td>
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<tr>
<td>77372</td>
<td>Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based</td>
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<tr>
<td>77373</td>
<td>Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions</td>
</tr>
<tr>
<td>77432</td>
<td>Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)</td>
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<tr>
<td>77435</td>
<td>Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions</td>
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<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
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<td>77522</td>
<td>Proton treatment delivery; simple, with compensation</td>
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<tr>
<td>77523</td>
<td>Proton treatment delivery; intermediate</td>
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<td>Proton treatment delivery; complex</td>
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<td>Tissue marker, implantable, any type, each</td>
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<tr>
<td>A4650</td>
<td>Implantable radiation dosimeter, each</td>
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<tr>
<td>G0339</td>
<td>Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment</td>
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</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

S0830: Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

**Applicable ICD-10 Diagnosis Codes**

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<tr>
<td>C00.0</td>
<td>Malignant neoplasm of external upper lip</td>
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## Stereotactic Radiosurgery and Proton Beam Therapy

Last review: Apr. 12, 2019

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### Proton Beam

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<tr>
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Proton Beam

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### Gamma Knife, LINAC

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### Gamma Knife, LINAC

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### References

Specialty-matched clinical peer review.