

Stereotactic Radiosurgery and Proton Beam Therapy

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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:

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

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:
 - i. Low-, intermediate-, and high-risk prostate cancer
 - ii. 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

C. Malignant metastatic tumors/lesions

1. Brain— solitary or multiple (initial or recurrence treatment; for recurrence treatment, member must have good performance status and not have active systemic disease) and include members with reasonable systemic options
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)

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

E. Trigeminal neuralgia refractory to medical management

II. Proton beam therapy (PBT)

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 cancers when preferential to radiofrequency ablation or SBRT
4. Stage IIA seminoma

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

1. 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 [\(See diagnostic coding below\)](#)
2. Stereotactic radiosurgery is regarded as investigational and not medically necessary for the following indications:
 - a. Gliomas (case by case consideration for inoperable malignant gliomas that have received prior radiation treatment)
 - b. Chronic pain syndromes
 - c. Extracranial lesions/tumors (other than those depicted above)
 - d. Pancreatic adenocarcinoma (case by case consideration [using up to 5 radiation treatment fractions]) as follows:
 - 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 volumeSBRT for palliation is not considered medically necessary
 - e. Psychoneurosis
 - f. Neurologic diseases/disorders

Note: Case-by-case consideration will be given for the following indications. Authorization will only be granted once all standard treatments have proven to be ineffective/refractory to medical treatment and/ or neurosurgery:

- i. Epilepsy
- ii. Movement disorders (e.g., Parkinson's, essential tremor, familial tremor classifications with major systemic disease)

Revision History

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

61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)
61800	Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex
A4648	Tissue marker, implantable, any type, each
A4650	Implantable radiation dosimeter, each
G0339	Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment
G0340	Image guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment
S8030	Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

Applicable ICD-10 Diagnosis Codes

Protein Beam — Commercial and Medicaid*

C22.0	Liver cell carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type

*For Medicare diagnostic coding; see [National Government Services Local Coverage Determination \[LCD\]: Proton Beam Therapy](#)

Gamma Knife, LINAC

C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C61	Malignant neoplasm of prostate
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C70.0	Malignant neoplasm of cerebral meninges
C70.1	Malignant neoplasm of spinal meninges
C70.9	Malignant neoplasm of meninges, unspecified
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles

Gamma Knife, LINAC	
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.20	Malignant neoplasm of unspecified olfactory nerve
C72.21	Malignant neoplasm of right olfactory nerve
C72.22	Malignant neoplasm of left olfactory nerve
C72.30	Malignant neoplasm of unspecified optic nerve
C72.31	Malignant neoplasm of right optic nerve
C72.32	Malignant neoplasm of left optic nerve
C72.40	Malignant neoplasm of unspecified acoustic nerve
C72.41	Malignant neoplasm of right acoustic nerve
C72.42	Malignant neoplasm of left acoustic nerve
C72.50	Malignant neoplasm of unspecified cranial nerve
C72.59	Malignant neoplasm of other cranial nerves
C72.9	Malignant neoplasm of central nervous system, unspecified
C75.1	Malignant neoplasm of pituitary gland
C75.2	Malignant neoplasm of craniopharyngeal duct
C75.3	Malignant neoplasm of pineal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
D02.20	Carcinoma in situ of unspecified bronchus and lung
D02.21	Carcinoma in situ of right bronchus and lung
D02.22	Carcinoma in situ of left bronchus and lung
D16.4	Benign neoplasm of bones of skull and face
D18.02	Hemangioma of intracranial structures
D32.0	Benign neoplasm of cerebral meninges
D32.1	Benign neoplasm of spinal meninges
D32.9	Benign neoplasm of meninges, unspecified
D33.0	Benign neoplasm of brain, supratentorial
D33.1	Benign neoplasm of brain, infratentorial
D33.2	Benign neoplasm of brain, unspecified
D33.3	Benign neoplasm of cranial nerves

Gamma Knife, LINAC	
D33.7	Benign neoplasm of other specified parts of central nervous system
D33.9	Benign neoplasm of central nervous system, unspecified
D35.2	Benign neoplasm of pituitary gland
D35.3	Benign neoplasm of craniopharyngeal duct
D35.4	Benign neoplasm of pineal gland
D42.0	Neoplasm of uncertain behavior of cerebral meninges
D42.1	Neoplasm of uncertain behavior of spinal meninges
D42.9	Neoplasm of uncertain behavior of meninges, unspecified
D43.0	Neoplasm of uncertain behavior of brain, supratentorial
D43.1	Neoplasm of uncertain behavior of brain, infratentorial
D43.2	Neoplasm of uncertain behavior of brain, unspecified
D43.4	Neoplasm of uncertain behavior of spinal cord
D49.6	Neoplasm of unspecified behavior of brain
D49.7	Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system
G50.0	Trigeminal neuralgia
Q28.0	Arteriovenous malformation of precerebral vessels
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

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