Stereotactic Radiosurgery
Clinical Coverage Criteria

Overview

The adjective “Stereotactic” describes a procedure during which a target lesion is localized relative to a fixed three dimensional reference system, such as a rigid head frame affixed to a patient, fixed bony landmarks, a system of implanted fiducial markers, or other similar system. This type of localization procedure allows physicians to perform image-guided procedures with a high degree of anatomic accuracy and precision.

Stereotactic Radiosurgery (SRS) is a distinct discipline that utilizes externally generated ionizing radiation in certain cases to inactivate or eradicate a defined target(s) in the head or spine without the need to make an incision. The target is defined by high-resolution stereotactic imaging. To assure quality of patient care the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist. SRS is typically performed in a single session (multiple fractions may be necessary when lesions are near critical structures), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system, but can be performed in a limited number of sessions, up to a maximum of five. Technologies that are used to perform SRS include linear accelerators, particle beam accelerators, and multisource Cobalt 60 units. In order to enhance precision, various devices may incorporate robotics and real time imaging.

Stereotactic body radiation therapy (SBRT) couples this anatomic accuracy and reproducibility with very high doses of highly precise, externally generated, ionizing radiation, thereby maximizing the ablative effect on the target(s) while minimizing collateral damage to adjacent tissues. SBRT is used to treat extra-cranial sites as opposed to SRS which is used to treat intra-cranial and spinal targets, and may be delivered in one to five sessions (fractions). SBRT requires computer-assisted, three-dimensional planning and delivery with stereotactic and convergent-beam technologies, including, but not limited to, multiple convergent cobalt sources (e.g. Gamma Knife®), protons, multiple, coplanar or non-coplanar photon arcs or angles (e.g. XKnife®), fixed photon arcs or image-directed robotic devices (e.g. CyberKnife®) that meet the criteria.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for stereotactic radiosurgery. National Government Services, Inc. has an LCD for Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076) and an LCA Billing and Coding: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (A56874) (MCD search 02/10/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Prior authorization is required.

Fallon Health Clinical Coverage Criteria
Fallon Health follows National Government Services, Inc. LCD for Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076) for all plan members.

LCD link: **Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076)**
LCA link: **Billing and Coding: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (A56874)**

Indications for SRS/SBRT (for Cranial and Spinal Lesions):
1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions < 5 cm.
2. Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent boney structures.
3. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.Cranial arteriovenous malformations and hemangiomas.
4. Cranial arteriovenous malformations, cavernous malformations, and hemangiomas
5. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy.
6. Unilateral thalamotomy by SRS for Parkinson's disease, essential tremor, drug-induced tremor and other specified forms of tremor; limited to patients who:
    a. Cannot be controlled with medication,
    b. Have major systemic disease or coagulopathy, and
    c. Are unwilling or unsuited for open surgery.
7. 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).
8. Metastatic brain or spine lesions, with stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, OR an Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the

lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.
9. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
10. Choroidal and other ocular melanomas.

SRS/SBRT is not considered medically necessary for the following circumstances:
1. Treatment for anything other than a severe symptom or serious threat to life or critical functions.
2. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
3. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
4. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3) greater than 3)).
5. Cobalt-60 pallidotomy is not covered.

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

SBRT is considered not medically necessary for the following circumstances:
1. Primary treatment of lesions of bone, breast, uterus, ovary, and other internal organs not listed above as covered is not considered medically necessary.
2. SBRT is not considered 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 3 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).
    e. Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT. SBRT is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment.

Karnofsky Performance Scale (Perez et al, p 225)
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

Eastern Cooperative Oncology Group (ECOG) Status Scale (Oken et al., 1982)
Grade 0: Fully active, able to carry on all pre-disease performance without restriction.
Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work.
Grade 2: Ambulatory and capable of all self-care but unable to carry out 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

Exclusions

- Cobalt-60 pallidotomy is not covered.
- Stereotactic radiosurgery is experimental for the treatment of functional disorders (other than trigeminal neuralgia), including chronic pain.
- Stereotactic cingulotomy as a treatment of psychiatric conditions is experimental and not covered.
- Bilateral thalamotomy is considered experimental and investigational.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Radiation oncologists and neurosurgeons have separate CPT billing codes for SRS. The comprehensive CPT code 61796, 61797, 61798, 61799, 61800, 63620 and 63621 may be billed by the neurosurgeon, as one member of the team, when and only when this physician is (a) present, (b) medically necessary and (c) fully participating, in the coded course of the procedure. The medical record must clearly indicate the critical nature of the anatomy or other circumstances necessitating the services encompassed by this code.

A radiation oncologist may bill the SRS management code 77432 for single fraction SRS (and only once per treatment course) when and only when fully participating in the management of the procedure. When SRS is administered in more than one but not more than 5 fractions, the radiation oncologist may instead bill the SBRT code 77435 to cover patient management during that course of therapy; the radiation oncologist may not bill 77432 and 77435 for the same course of therapy. In addition, a radiation oncologist may bill other appropriate radiation oncology (77xxx) codes when full participation in the coded procedure(s) is appropriately documented, as directed in Medicare policies.

No one physician may bill both the neurosurgical codes 61796-61800, 63620 or 63621 and the radiation oncology codes 77371-77435.

Code	Description
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
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
61800	Application of stereotactic headframe for stereotactic radiosurgery
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 1 session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
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 5 sessions per course of treatment

References

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Policy history

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Approval(s):	Technology Assessment Committee: 05/27/2020 (policy origination)
	02/10/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.