Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy
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:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization is required for stereotactic radiosurgery and stereotactic body radiotherapy.

Medicare Advantage

Fallon Health complies with CMS’s national coverage determinations (NCDs), local coverage

determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for stereotactic radiosurgery or stereotactic body radiotherapy. Medicare does not have an NCD for stereotactic radiosurgery or stereotactic body radiotherapy. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area has an LCD for Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076), Revision Effective Date: For services performed on or after 04/01/2020 (Medicare Coverage Database search 07/23/2024).

Coverage criteria for stereotactic radiosurgery and stereotactic body radiotherapy are fully established by Medicare.

Link: National Government Services, Inc. LCD **Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076)**

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for stereotactic radiosurgery or stereotactic body radiotherapy (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

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.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care and MassHealth ACO members.

Stereotactic Radiosurgery (SRS)

Fallon Health considers SRS medically necessary for the following indications:

1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions.
2. Primary and secondary tumors involving the brain parenchyma, meninges/dura, or any immediately adjacent boney structures such as the cranial vault or skull base.
3. Benign brain tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.
4. Arteriovenous malformations and cavernous malformations.
5. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy, movement disorders such as Parkinson's disease and essential tremor, and hypothalamic hamartomas.
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. Metastatic brain lesions, independent of number of lesions, if other positive clinical indications exist, e.g., stable systemic disease, Karnofsky Performance Status 40 or greater (and expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, or Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (and expected to return to 2 or less with treatment).
8. Relapse in a previously irradiated cranial field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
9. Uveal or ocular melanoma.

Stereotactic radiosurgery is considered not medically necessary under the following circumstances:

1. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
2. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
3. Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3).
4. For essential tremor, coverage is limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for invasive surgical procedure. Coverage should further be limited to unilateral thalamotomy.

Stereotactic Body Radiation Therapy (SBRT)

Fallon Health considers SBRT medically necessary for the following indications:

1. Primary malignant tumors of the lung, liver, kidney, adrenal gland, pancreas, bone, and prostate, and primary malignant and benign tumors of the spine and spinal cord. The patient's general medical condition (namely, the performance status) must justify aggressive, curative treatment to a primary, non-metastatic tumor and be specifically documented in the medical record.
2. Secondary, or metastatic, tumors and recurrent tumors or any tumor arising within or near previously irradiated volumes when at least one of the following criteria is met and specifically documented in the medical record:
    a. The patient's general medical condition (namely, the performance status) justifies aggressive local therapy to one or more deposits of metastatic cancer in an effort either to achieve total disease clearance in the setting of oligometastatic disease or to reduce the patient's overall burden of systemic disease for a specifically defined clinical benefit.
    b. Recurrent disease requiring palliation, or any tumor cannot be treated as effectively or safely by other radiotherapy methods due to proximity of previously irradiated volumes

and a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues.

3. Spinal metastases - SBRT has been demonstrated to achieve durable tumor control when treating lesions in vertebral bodies or the paraspinous region, where extra care must be taken to avoid excess irradiation of the spinal cord when tumor-ablative doses are administered. There is an important clinical distinction between the status of patients described above and a patient with widely metastatic disease for whom palliation is the major objective. In one setting, a patient with limited metastatic disease and good performance status is treated with the intention of eradicating all known active disease or greatly reducing the total disease burden in a manner that can extend progression-free survival. For such a patient, SBRT can be a reasonable therapeutic intervention. However, for uncomplicated, previously untreated bone metastases in a patient with widespread progressive disease in the spine or elsewhere and where the prognosis is unfavorable, it is generally appropriate to use a less technically complex form of palliative radiation therapy rather than SBRT.

SBRT is considered not medically necessary under the following circumstances:

1. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
2. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
3. The patient has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse).

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 for the treatment of 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.

If either the radiation oncologist or neurosurgeon does not fully participate in the patient's care, that physician must take care to indicate this change by use of the appropriate -54 modifier (followed by any appropriate -55 modifier) on the procedure(s) submitted.

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

The key components of a SBRT procedure are target delineation, treatment planning, and treatment delivery.

According to the CPT codes, SRS treatment is delivered to a cranial lesion or spinal lesion consisting of one session (CPT codes: 77371, 77372, 77432, 63620); while SBRT has two applicable codes (77373 and 77435) with treatment delivery not to exceed five fractions within the body.

There are no specific codes for clinical treatment planning and simulation for SRS or SBRT. However, because of the complexity of SRS and SBRT and the need for three-dimensional conformal or IMRT dosimetric treatment planning, CPT code 77263, 77295 or 77301 are usually appropriate for SRS/SBRT cases. Use of IMRT planning is based on the delivery system and medical necessity.

Add-on CPT code 77293 may be reasonable for SRBT cases in which target movement during respiration must be accounted for during treatment planning in conjunction with CPT 77295 or 77301.

There are no SRS or SBRT specific codes for medical radiation physics, dosimetry, treatment devices and special services. CPT 77300, 77334, and 77338 may be used with SRS and SBRT as appropriate.

CPT code 77373 (SBRT treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) includes the possibility of treating multiple sites of disease in 1 treatment course. Therefore, if the sum of the treatment days for all of the sites treated during a single course of therapy exceeds 5; it is not appropriate to charge CPT code 77373 for SBRT delivery.

For all spinal radiosurgery (1 to 5 fractions), use CPT code 77435 once for the entire course of treatment.

HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) and other edits.

Neurosurgeon Coding for Stereotactic Radiosurgery

The following codes may be reported by the neurosurgeon for involvement in the procedure.

Code	Description
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 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); 1complex 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); 1spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (list separately in addition to code for primary procedure)

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy for Cranial Lesions

The following codes may be reported by the radiation oncologist for involvement in the procedure.

Code	Description
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

Stereotactic Body Radiotherapy

The following codes may be reported by the radiation oncologist for involvement in the procedure.

Code	Description
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or

	more lesions, including image guidance, entire course not to exceed 5 fractions
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
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

1. National Government Services, Inc. Local Coverage Determination (LCD) for Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (L35076). Original Effective Date 10/01/2015. Revision Effective Date 04/01/2020. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed 07/22/2024.
2. National Government Services, Inc. LCD Reference Article. Billing and Coding: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (A56874). Original Effective Date 08/22/2019. Revision Effective Date 10/01/2023. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed 07/22/2024.
3. Perez CA. Brady LW, Halperin EC, Schmidt-Ullrich RK. eds. Principles and Practice of Radiation Oncology. New York, NY: Lippincott-Raven; 4th ed. 2003.
4. Delamarter RB, Zigler J. Five-year Reoperation Rates, Cervical Total Disc Replacement versus Fusion, Results of a Prospective Randomized Clinical Trial. *Spine (Phila Pa 1976).* 2013; 38(9):711-7.
5. Solberg TD, Balter JM, Benedict SH, et. al. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy: Executive summary. *Practical Radiation Oncology.* 2012;2(1):2-9.
6. Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carone,P.P. Toxicity and Response Criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655.
7. ASTRO. Model Policies. Stereotactic Radiosurgery (SRS). June 2022. Available at: https://www.astro.org/daily-practice/reimbursement/model-policies. Accessed 07/22/2023.
8. ASTRO. Model Policies. Stereotactic Body Radiation Therapy (SBRT). Updated June 2020. Available at: https://www.astro.org/daily-practice/reimbursement/model-policies. Accessed 07/22/2024.
9. American College of Radiology (ACR) and the American Radium Society (ARS). ACR-ARS Practice Parameter for the Performance of Brain Stereotactic Radiosurgery. Revised 2021. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/StereoBrain.pdf. Accessed 07/22/2024.
10. ACR and ARS. ACR–ARS Practice Parameter for the Performance of Stereotactic Body Radiation Therapy. Revised 2024. Effective July 1, 2024. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/SBRT-RO.pdf. Accessed 07/22/2024.
11. ACR and the American Association of Physicists in Medicine (AAPM). ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Stereotactic Body Radiation Therapy (SBRT). Revised 2024. Effective July 1, 2024. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/SBRT-TS.pdf. Accessed 07/22/2024.

Policy history

Origination date: 06/01/2020

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), 07/23/2024 (annual review; updated Medicare regulatory language in Policy section, added coverage for stereotactic radiosurgery for uveal or ocular melanoma, updated Coding and References).

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.