Local Coverage Determination (LCD): Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
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LCD Information

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CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those

services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, Section 1862(a)(1)(D). This section allows coverage and payment for only those services that are not investigational or experimental.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

Medicare Benefit Policy Manual, Publication 100-2, Chapter 15, Section 90: X-ray, Radium, and Radioactive Isotope Therapy.

Medicare Program Integrity Manual, Publication 100-08, Chapter 13.7.1 and Chapter 13.11, E, 3.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT) (for Cranial Lesions Only) is a method of delivering high doses of ionizing radiation to small intracranial targets. In SRS, highly focused convergent beams are delivered to the target while adjacent structures are spared due to a rapid dose fall-off. SRS relies on stereotactic guidance and many SRS systems use a positioning frame to restrict head movement. Treatments may be delivered between 1-5 sessions. SRS typically is performed in a single session, 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. **(If more than one session is required, the SBRT codes must be used.)**

SRS 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. To assure quality of patient care, the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist. (For a subset of tumors involving the skull base, the multidisciplinary team may also include a head and neck surgeon with training in stereotactic radiosurgery.)

Regardless of the number of sessions, all SRS procedures include the following components:
1. Planning
2. Position stabilization (attachment of a frame or frameless)
3. Imaging for localization (CT, MRI, angiography, PET, etc.)
4. Computer assisted tumor localization (i.e. “Image Guidance”)
5. Treatment planning – number of isocenters, number, placement and length of arcs or angles, number of beams, beam size and weight, etc.
6. Isodose distributions, dosage prescription and calculation
7. Setup and accuracy verification testing
8. Simulation of prescribed arcs or fixed portals
9. Radiation treatment delivery

Indications for SRS/SBRT (for Cranial Lesions only):

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 bony structures.
3. Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.
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. 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).
6. 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 other wise 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).
7. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
8. Unilateral thalamotomy using stereotactic radiosurgery may be used to treat limb tremor in Essential Tremor that is refractory to medical management using at least two drugs but is not currently recommended by the Guidelines of the American Academy of Neurology.

Limitations for SRS/SBRT (for Cranial Lesions only):

SRS is not considered medically necessary under 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)- see Karnofsky and ECOG Performance Status scales below.
5. Cobalt-60 pallidotomy is non-covered.
6. Basic dosimetry calculations are limited to one (1) unit for each arc in a linear accelerator system and one (1) unit for each shot in Cobalt-60 system with a maximum of ten (10) units.
7. Complex treatment devices is limited to one unit for each collimator in a linear accelerator system or one for each helmet in a cobalt-60 system. If the total number of units exceeds six (6) or the number of isocenters plus three (3) when multiple isocenters are necessary, a detailed explanation of medical necessity must be documented in the medical record. (See Documentation Guidelines.)

Stereotactic Body Radiation Therapy (SBRT)

SBRT is a treatment that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation, thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues. SBRT is used to treat extra-cranial sites as opposed to stereotactic radiosurgery (SRS) which is used to treat intra-cranial and spinal targets.

The adjective “stereotactic” describes a procedure during which a target lesion is localized relative to a known three dimensional reference system that allows for a high degree of anatomic accuracy and precision. Examples of devices used in SBRT for stereotactic guidance may include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV) x-rays, and CT-imaging-based systems used to confirmed the location of a tumor immediately prior to treatment.

Treatment of extra-cranial sites requires accounting for internal organ motion as well as for patient motion. Thus,

reliable immobilization or repositioning systems must often be combined with devices capable of decreasing organ motion or accounting for organ motion e.g. respiratory gating. Additionally, all SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization prior to delivery of each fraction. The ASTRO/ACR Practice Guidelines for SBRT outline the responsibilities and training requirements for personnel involved in the administration of SBRT.

SBRT may be delivered in one to five sessions (fractions). Each fraction requires an identical degree of precision, localization and image guidance. 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 and is not to be billed using these codes. 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.

When billing for SBRT *delivery,* it is not appropriate to bill more than one treatment delivery code on the same day of service, even though some types of delivery may have elements of several modalities (for example, a stereotactic approach with intensity-modulated static beams or arcs.) Also, *only one,* delivery code is to be billed even if multiple lesions are treated on the same day.

Indications for Stereotactic Body Radiation Therapy (SBRT):

SBRT is indicated for primary tumors of and tumors metastatic to the **lung, liver, kidney, adrenal gland, or pancreas as well as for pelvic and head and neck tumors that have recurred after primary irradiation** when and only when each of the following criteria are met, and each specifically documented in the medical record. Multiple ICD-10 codes fit this description and they are not listed in detail here.

1. The patient's general medical condition (notably, the performance status) justifies aggressive treatment to a primary cancer or, for the case of metastatic disease, justifies aggressive local therapy to one or more discrete deposits of cancer within the context of efforts to achieve total clearance or clinically beneficial reduction in the patient's overall burden of systemic disease.
2. Other forms of radiotherapy, including but not limited to external beam and IMRT, cannot be safely or effectively utilized.
3. The tumor burden can be completely targeted with acceptable risk to critical normal structures.
4. If the tumor histology is germ cell or lymphoma, effective chemotherapy regimens have been exhausted and external beam radiation is ineffective or inappropriate for the patient as fully explained in the medical record.

Other Neoplasms:

- For patients with tumors of any type arising in or near previously irradiated regions, SBRT may be appropriate when a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues. Also, in other cases where a high dose per fraction treatment is indicated SBRT may be appropriate. The necessity should be documented in the medical record.
  Coverage may be considered at the Redetermination (Appeal) level on an individual basis for lesions when documentation clearly supports the necessity for high radiation dose per fraction and the necessity to avoid surrounding tissue exposure.
  Low or intermediate risk prostate cancer may be covered when the patient is enrolled in an IRB-approved clinical trial and which clinical trial meets the "standards of scientific integrity and relevance to the Medicare population" described in IOM 100-03, National Coverage Determinations Manual, Chap 1, Part 1, section 20.32, B3a-k (with l-m desirable). Similarly, enrollment in a clinical registry compliant with the principles established in AHRQ's "Registries for Evaluating Patient Outcomes: A User's Guide", such as the Registry for Prostate Cancer Radiosurgery (RPCR), may qualify the treatment for coverage.

Limitations for Stereotactic Body Radiation Therapy (SBRT):

- Primary treatment of lesions of bone, breast, uterus, ovary, and other internal organs not listed earlier in this LCD as covered is non-covered. The literature does not support an outcome advantage over other conventional radiation modalities. However, SBRT treatment in the setting of recurrence after conventional radiation modalities have been utilized may be covered.
  SBRT is not considered medically necessary under the following circumstances for any condition:
  1. Treatment 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. Patients with poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse).
  Karnofsky Performance Status Scale (Perez and Brady, p225)
  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
  Karnofsky DA, Burchenal JH. (1949). "The Clinical Evaluation of Chemotherapeutic Agents in Cancer." In: MacLeod CM (Ed), Evaluation of Chemotherapeutic Agents. Columbia Univ Press. Page 196.
  ECOG Performance Status Scale
  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: Completed disabled. Cannot carry on any self-care. Totally confined to bed or chair.
  Grade 5: Dead
  Eastern Cooperative Oncology Group, Robert Comis M.D., Group Chair.
  *As published in Am. J. Clin. Oncol.: *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 5:649-655, 1982.*

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

General Information

Associated Information

Except where other requirements are explicitly written in this LCD, Noridian requires the exact degree of documentation described in the most recent edition of the ASTRO/ACR Guide to Radiation Oncology Coding.

The patient's record must support the necessity and frequency of treatment. The medical record must clearly indicate the critical nature of the anatomy or other circumstances necessitating the services. Medical records should include not only the standard history and physical but also the patient's functional status and a description of current performance status (Karnofsky Performance Status). See Karnofsky Performance Status listed under Indications and Limitation of Coverage and/or Medical Necessity above.

Documentation should include the date and the current treatment dose. A radiation oncologist and a neurosurgeon must evaluate the clinical aspects of the treatment, and document and sign this evaluation as well as the resulting management decisions.

For basic radiation dosimetry calculations and complex treatment devices: Documentation must specify factors, such as, multiple isocenters, irregularity of target volume(s), proximity of critical structures or other reasons which justify the units of service for dosimetry or treatment devices.

All documentation must be available upon request of the Medicare contractor.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

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Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R8	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R7	As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Revisions Due To Code Removal
10/01/2018	R6	09.07.18: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. The following ICD-10 code was deleted from the ICD-10 Codes that Support Medical Necessity field: G51.3 was deleted from Group 1. The following ICD-10 Codes were added to the ICD-10 Codes that Support Medical Necessity field: G51.31; G51.32;G51.33. This revision is due to the Annual ICD-10 Code Update and becomes effective October 1, 2018.	• Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
07/01/2016	R5	(10/23/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. LCD is revised to correct HTML coding conversion error of bullet points (.) appearing as question marks (?).	• Other (MCD programming changes.)
07/01/2016	R4	LCD is revised to add G25.0 to Group 1 ICD-10 codes. Coverage Indications, Limitations and/or Medical Necessity were revised to include, "8. Unilateral thalamotomy using stereotactic radiosurgery may be used to treat limb tremor in Essential Tremor that is refractory to medical management using at least two drugs but is not currently recommended by the Guidelines of the American Academy of Neurology" and Sources of Information and Basis for Decision was updated to include, " 8. Zesiewicz TA, Elble R, Louis ED, et al., Practice Parameter: Therapies for essential tremor, Report of the Quality Standards Subcommittee of the American Academy of Neurology, Neurology 2005; 64; 2008-2020, 2005." This LCD, effective 07/01/2016, combines JFA L34136 into the JFB LCD so that both JFA and JFB contract numbers will have the same MCD LCD number.	• Reconsideration Request
10/01/2015	R3	Coverage Indications, Limitations and/or Medical Necessity above were revised to remove the clinical trial requirement for patients with greater than 3 primary or metastatic brain lesions. Removed: CMS Manual System, Pub. 100-03,	• Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §160.4. from CMS National Coverage Policy section.	
10/01/2015	R2	This LCD is revised to remove the paragraph, "When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review." from the Associated Information field.	• Other (Removed the paragraph, "When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review.")
10/01/2015	R1	The following CPT/HCPCS codes were deleted due to CPT/HCPCS annual updates: G0173 and G0251 from Group 1 and G0251 from Group 2, effective 01/01/2015.	• Revisions Due To CPT/HCPCS Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57461 - Billing and Coding: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

Related National Coverage Documents

N/A

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