FUTURE PROPOSED/DRAFT Local Coverage Determination (LCD): Radiology: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (DL32973)

[ PROPOSED/DRAFT ]

Please note: This is a Proposed/Draft policy. Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Please note: Future Effective Date.

Contractor Information

Contractor Name
Cahaba Government Benefit Administrators®, LLC opens in new window
Contractor Number 10102
Contractor Type MAC - Part B

Proposed/Draft LCD Information

Document Information

Primary Geographic Jurisdiction opens in new window
Alabama

Oversight Region
Region IV

Projected Determination Effective Date
For services performed on or after 04/01/2013

Original Determination Ending Date
ANTICIPATED 07/22/2013

Revision Effective Date

Revision Ending Date

AMA CPT/ADA CDT Copyright Statement
CMS National Coverage Policy

- Title XVIII of the Social Security Act, Section 1833 (e). This section states that no payment shall be made to any provider for any claims that lack the necessary information to process the claim.
- 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 reasonable and necessary, i.e., reasonable and necessary are those tests used in the diagnosis and management of illness or injury or to improve the function of a malformed body part.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(D). Investigational or Experimental.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 90.
- Medicare Program Integrity Manual (Pub. 100-08).

Coverage Indications Limitations and/or Medical Necessity

**Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT) (for Cranial Lesions Only)**
SRS/SBRT (for cranial lesions only) 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. (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.)

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.

SRS 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. 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.

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.)

Regardless of the number of sessions, all SRS procedures include the following components:
1. Position stabilization (attachment of a frame or frameless)

2. Imaging for localization (CT, MRI, angiography, PET, etc.)

3. Computer assisted tumor localization (i.e. "Image Guidance")

4. Treatment planning – number of isocenters; number, placement and length of arcs or angles; number of beams; beam size and weight, etc.

5. Isodose distributions, dosage prescription and calculation

6. Setup and accuracy verification testing

7. Simulation of prescribed arcs or fixed portals

8. Radiation treatment delivery

Radiation oncologists and neurosurgeons have separate CPT billing codes for SRS. CPT Codes 61781-61783, 61796-61800 and 63620 and 63621 are reported for the work attributed to the neurosurgeon. These codes are mutually exclusive with the radiation oncology CPT codes 77432 and 77435; therefore, the same physician should not bill for both of these codes.

A radiation oncologist may bill the SRS management code 77432 [stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)] for single fraction intracranial SRS and only once per treatment course when, and only when, fully participating in the management of the procedure. CPT code 77432 will be paid only once per course of treatment for cranial lesions regardless of the number of lesions. When SRS is administered in more than one but not more than five fractions to the brain, or in one through five fractions to the spine, the radiation oncologist should instead bill the Stereotactic Body Radiation Therapy (SBRT) code 77435 to cover patient management during the course of therapy. CPT code 77435 will be paid only once per course of therapy regardless of the number of sessions, lesions or days of treatment. The radiation oncologist may not bill 77432 and 77435 for the same course of therapy. In addition to the management codes, a radiation oncologist may bill other appropriate radiation oncology (77xxx) codes for services performed prior to the delivery of SRS as indicated by the pattern of care and other Medicare policies.

No one physician may bill both the neurosurgical CPT codes 61781-61783, 61796-61800, 63620 or 63621 and the radiation oncology (77xxx) codes. The physician(s) billing these codes must be physically present during the entire process of defining the target volume and structures at risk. If either the radiation oncologist or the neurosurgeon does not fully participate in the patient’s care, that physician must take care to indicate this change by using the appropriate –52, 54, 55, or 56 modifier. As the services are collegial in nature with different specialties providing individual components of the treatment, surgical assistants will not be reimbursed.

The technical charges used by hospital-based and outpatient facilities for SRS delivery are described by the CPT codes listed below. 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 IMRT). Only one delivery code is to be billed.

Other radiation oncology professional and technical services required prior to the delivery of SRS are coded separately and may be appropriately billed by the radiation oncologist, when necessary.

**Indications**
1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions less than 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.


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, with a 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).

7. Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

**Limitations**

SRS is not considered reasonable and 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. In patients with more than three (3) primary or metastatic lesions, SRS is inappropriate and consideration should be given to whole brain irradiation.

4. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.

5. 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.

6. For essential tremor, coverage should be limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery. Coverage should further be limited to unilateral thalamotomy.

**Stereotactic Body Radiation Therapy (SBRT) (not for cranial lesions)**
Background

**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 extracranial sites as opposed to stereotactic radiosurgery (SRS), which is used to treat intracranial 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 confirm 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.

SBRT may be delivered in one to five sessions (fractions). 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.

**SBRT addresses only the CPT codes for SBRT treatment management (77435), and SBRT treatment delivery (77373, G0339, and G0340).**

Indications
1. 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.

   A. 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;
   B. Other forms of radiotherapy, including but not limited to external beam and IMRT, cannot be safely or effectively utilized;
   C. The tumor burden can be completely targeted with acceptable risk to critical normal structures; and
   D. 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.

2. SBRT may be covered for low or intermediate risk prostate cancer when the patient is:

   A. enrolled in an IRB-approved clinical trial which meets the ‘standards of scientific integrity and relevance to the Medicare population’ described in IOM 100-03, National Coverage Determinations, Chapter 1, Section 20.32 B.3.a-k;
     
      or

   B. enrolled in a national or regional 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).

   Whether in a clinical trial or in a national or regional registry, the information about the trial or registry must be included in the clinical record / progress notes.

3. 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 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.

**Limitations**

1. 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.

2. SBRT is not considered reasonable and necessary under the circumstances:

   A. Treatment 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. Patients with poor performance status (Karnofsky Performance Status less than 40 or ECOG Status of 3 or worse) - see Karnofsky Performance Status and ECOG Status below.

**Karnofsky Performance Status Scale**

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 is not imminent.
20: Very sick; hospitalization is necessary; active supportive treatment is necessary.
10: Moribund, fatal processes progressing rapidly.
0: Dead


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: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
Grade 5: Dead


Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT) (for cranial lesions only)
77371  Srs multisource
77372  Srs linear based
77373  Sbrt delivery

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Stereotactic radiation trmt
77435 Sbrt management
G0173 Linear acc stereo radsur com
G0251 Linear acc based stero radio
G0339 Robot lin-radsurg com, first

**Stereotactic Body Radiation Therapy (SBRT) (not for cranial lesions)** CPT 77373, G0339 and G0340 will pay only once per day of treatment regardless of the number of sessions or lesions. CPT 77435 will pay only once per course of therapy
77373 Sbrt delivery
77435 Sbrt management
G0339 Robot lin-radsurg com, first
G0340 Robt lin-radsurg fractx 2-5

ICD-9 Codes that Support Medical Necessity
There are numerous reasonable and necessary conditions that might warrant the use of these procedures but which are too many to list. However, an appropriate ICD-9-CM diagnosis must be submitted with each claim and failure to do so may result in denial or delay in claim processing.

ICD-9 codes must be coded to the highest level of specificity. Consult the 'Official ICD-9-CM Guidelines for Coding and Reporting' in the current ICD-9-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

XX000* Not Applicable
N/A

Diagnoses that Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity
See narrative above for "ICD-9 Codes that Support Medical Necessity".
XX000* Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

General Information
[ PROPOSED/DRAFT ] [ FUTURE ]

Documentation Requirements
1. All coverage criteria must be clearly documented in the patient's medical record and made available to Medicare upon request.

2. 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.

3. Basic dosimetry calculations (CPT code 77300) greater than one per isocenter when multiple isocenters are necessary, require documentation of medical necessity in the medical record.

4. Treatment devices, complex (CPT code 77334) is limited to one unit for each collimator in a linear accelerator system or one for each helmet in a cobalt-60 system. More than three require documentation of medical necessity in the medical record.
5. When SBRT is used for treatment of low or intermediate risk prostate cancer, whether in a clinical trial or in a national or regional registry, the information about the trial or registry must be included in the clinical record / progress notes.

6. Documentation must support CMS ‘signature requirements’ as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

Appendices N/A

Utilization Guidelines

1. 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.

2. SBRT for primary tumors of and tumors metastatic to the lung, liver, kidney, adrenal gland, or pancreas is usually performed by an appropriately trained radiation oncologist. The addition of a general surgeon or urologist (to the performing radiation oncologist) performing and billing SBRT delivery and management codes for these tumors is not medically necessary.

3. Services exceeding the above utilization parameters may be subject to medical review or auto-adjudication

Sources of Information and Basis for Decision

- Consultations with the representatives to the Carrier Advisory Committee and other Medicare Contractors
- Other Medicare Contractor's Local Coverage Determinations.

Advisory Committee Meeting Notes Date of Open Meeting:

10/30/2012

Dates of Carrier Advisory Committee (CAC) Meetings:

10/30/2012 (Alabama)
11/01/2012 (Tennessee)

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11/16/2012 (Georgia)

This local coverage determination (LCD) does not reflect the sole opinion of the contractor or contractor medical director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which include representatives from physician specialties; representatives from the Medical Associations for the above states; and other Association Representatives.

Start Date of Comment Period 11/16/2012  End Date of Comment Period 12/31/2012
Start Date of Notice Period 02/15/2013

Revision History Number
Revision History Explanation What’s New Posted Date: January 2013
Newsline Published Date: February 2013
Effective Date: April 1, 2013

This new LCD has been finalized. Following the Notice Period, this LCD will become effective April 1, 2013.

Reason for Change Other

Related Documents
This LCD has no Related Documents.

LCD Attachments

Proposed Contact
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Updated on 10/04/2012 with effective dates N/A
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