

Local Coverage Determination (LCD): Stereotactic Body Radiation Therapy (L34224)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern American Samoa Guam Hawaii Northern Mariana Islands Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	

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LCD Information

Document Information

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L34224

Original Effective Date
For services performed on or after 10/01/2015

Original ICD-9 LCD ID
[L33490](#)

Revision Effective Date
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LCD Title
Stereotactic Body Radiation Therapy

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N/A

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CMS National Coverage Policy Title XVIII of the Social Security Act, §1862(a)(1)(A). 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, §1833(e). Prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act, §1862(a)(1)(D), Investigational or Experimental.

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §90, X-ray, Radium and Radioactive Isotope Therapy.

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapters 13, §§13.7.1, 13.11,E,3.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Stereotactic body radiation therapy (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.

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.

All SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization. To minimize intra-treatment tumor motion associated with respiration or other motion, some form of motion control or "gating" may be used.

SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance.

Since the goal of SBRT is to intensify 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.

This LCD addresses only CPT codes 77373, 77435, G0339 and G0340. All other acceptable uses of CPT codes 77373 and 77435 are described in the companion LCD, Stereotactic Radiosurgery.

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 IMRT). Only one delivery code is to be billed.

Indications for SBRT for lung, liver, kidney, adrenal gland, pancreas or prostate neoplasms:

This A/B MAC covers primary and metastatic tumors of the **lung, liver, kidney, adrenal gland, or pancreas** when and only when each of the following criteria are met, and each specifically documented in the medical record:

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 discreet 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. Typically, such a patient would have also been a potential candidate for alternate forms of intense local therapy applied for the same purpose (e.g. surgical resection, radiofrequency ablation, cryotherapy, etc).
2. Other forms of radiotherapy, including but not limited to external beam and IMRT, cannot be as safely or effectively utilized, and
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 or are otherwise not feasible.
5. Other forms of focal therapy, including but not limited to radiofrequency ablation and cryotherapy, cannot be as safely or effectively utilized.

The clinical experience with SBRT for carcinoma of the prostate is of short term duration relative to the natural history of prostate cancer. Published peer reviewed studies of the success and complication rates are still small and of short or medium term duration. Prominent specialty societies and academicians suggest SBRT is still investigational, while others who currently use the equipment feel SBRT has some selected advantages. We will cover SBRT for prostate cancer only when:

1. Other forms of first line therapy are not available or feasible since other forms have known long term success and complication rates; and
2. All of the criteria listed above are documented in the medical record; **or**
3. The patient is enrolled in an approved clinical study listed in ClinicalTrials.Gov.

Other neoplasms:

Lesions of bone, breast, uterus, ovary and other internal organs not listed above are not covered for primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities, but may be appropriate for SBRT in the setting of recurrence after conventional radiation modalities.

Malignant lesions of the Head & Neck or paranasal sinuses may be appropriate for SBRT following other conventional radiation modalities to complete initial definitive therapy.

Other Indications for SBRT:

Except as above, any lesion with a documented necessity to treat using a high dose per fraction of radiation. When using high radiation doses per fraction, high precision is required to avoid surrounding normal tissue exposure.

Lesions which have received previous radiotherapy or are immediately adjacent to previously irradiated fields, where the additional precision of stereotactic radiotherapy is required to avoid unacceptable tissue radiation will be covered when other conditions of coverage are met (see Limitations below) and this necessity is documented in the medical record.

Limitations:

Coverage will be denied for each of the following:

1. Treatment unlikely to result in clinical cancer control and/or functional improvement.
2. Patients with wide-spread cerebral or extra-cranial metastases

3. Patients with poor performance status (Karnofsky Performance Status **less than 40**), - see Karnofsky Performance Status below.

Karnofsky Performance Scale (Perez and Brady, 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

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

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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.

99999 Not Applicable

CPT/HCPCS Codes

Group 1 Paragraph: Note: Uses of 77373 and 77435 are addressed in both this LCD and in the Stereotactic Radiosurgery LCD.

CPT Codes

Group 1 Codes:

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 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS

Group 2 Paragraph: HCPCS Codes

Group 2 Codes:

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
 INTRA-FRACTION LOCALIZATION AND TRACKING OF TARGET OR PATIENT MOTION DURING DELIVERY OF
 G6017 RADIATION THERAPY (EG,3D POSITIONAL TRACKING, GATING, 3D SURFACE TRACKING), EACH FRACTION OF TREATMENT

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: These are the **only** covered ICD-10-CM codes that support medical necessity under this LCD:

Group 1 Codes:

ICD-10 Codes	Description
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C30.0	Malignant neoplasm of nasal cavity
C30.1	Malignant neoplasm of middle ear
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C31.2	Malignant neoplasm of frontal sinus
C31.3	Malignant neoplasm of sphenoid sinus
C31.8	Malignant neoplasm of overlapping sites of accessory sinuses
C33	Malignant neoplasm of trachea
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
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
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung

ICD-10 Codes	Description
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.7*	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.89*	Secondary malignant neoplasm of other digestive organs
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.31	Secondary malignant neoplasm of brain
C79.32*	Secondary malignant neoplasm of cerebral meninges
C79.49*	Secondary malignant neoplasm of other parts of nervous system
C79.51*	Secondary malignant neoplasm of bone
C79.52*	Secondary malignant neoplasm of bone marrow
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.89*	Secondary malignant neoplasm of other specified sites
D09.3*	Carcinoma in situ of thyroid and other endocrine glands
D09.8*	Carcinoma in situ of other specified sites
D35.6	Benign neoplasm of aortic body and other paraganglia
D40.0	Neoplasm of uncertain behavior of prostate
D44.6	Neoplasm of uncertain behavior of carotid body
D44.7	Neoplasm of uncertain behavior of aortic body and other paraganglia
T66.XXXA	Radiation sickness, unspecified, initial encounter

Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation: ** ICD-10-CM C78.7 and C78.89 are limited to secondary malignant neoplasms of pancreas and may not be used for other diagnoses.

* ICD-10-CM codes C79.32, C79.49, C79.51, C79.52, C79.89, D09.3 and D09.8 are all limited to use for lesions occurring either above the neck or in the spine.

* ICD-10-CM T66.XXXA may only be used where prior radiation therapy to the site is the governing factor necessitating SBRT in lieu of other radiotherapy. An ICD-10-CM code for the anatomic diagnosis must also be used.

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: All diagnoses not listed in ICD-10-CM Codes That Support Medical Necessity above.

Group 1 Codes: N/A

ICD-10 Additional Information

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General Information

Associated Information

Documentation Requirements

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The patient's record must support the necessity and frequency of treatment. 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 must evaluate the clinical and technical aspects of the treatment, and document this evaluation as well as the resulting management decisions.

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.

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.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Utilization Requirement

CPT 77435 will be paid **only once per course of treatment** of SBRT.

CPT 77373 will be paid **only once per day of treatment regardless of the number of sessions or lesions.**

Sources of Information and Basis for Decision
Medical Consultants

Contractor Medical Directors

American Society of Therapeutic Radiation and Oncology and American College of Radiology (ACR) Radiation Oncology Carrier Advisory Committee "Model" Policy and multiple supplemental recommendations, discussions and draft reviews.

American Association of Neurological Surgeons/Congress of Neurological Surgeons and American Society for Therapeutic Radiology and Oncology and American College of Radiology: multiple discussions, recommendations and draft reviews.

Perez CA, Brady LW, Halperin EC, Schmidt-Ullrich RK. eds. *Principles and Practice of Radiation Oncology*. New York, NY : Lippincott-Raven; 4th ed. 2003.

Kavanagh BD, Timmerman RD, eds *Stereotactic Body Radiation Therapy*. Philadelphia: Lippincott Williams & Wilkins; 2005.

Chang BK, Timmerman RD. Stereotactic Body Radiation Therapy: A Comprehensive Review. *Am J Clin Oncol*. Dec 2007;30(6):637-44.

Timmerman RD, Kavanagh BD, Cho LC, Papiez L, Xing L. Stereotactic Body Radiation Therapy in Multiple Organ Sites. *J Clin Oncol*. Mar 2007;25(8):947-52.

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Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2015	R3		

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2015	R2	Removed: CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §160.4. from CMS National Coverage Policy section. The LCD is revised to clarify coverage for adrenal indications and to add diagnosis codes: C74.01, C74.02, C74.11, C74.12, C74.91, C74.92, C79.71, C79.72.	<ul style="list-style-type: none"> Other (CMS retired NCD §160.4.) Creation of Uniform LCDs Within a MAC Jurisdiction
10/01/2015	R1	CPT code 0197T is replaced with G6017 effective 01/01/2015 due to annual CPT/HCPCS code updates.	<ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes

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Associated Documents

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

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Keywords

- SBRT
- stereotactic
- radiation
- therapy

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