

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
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada

LCD Information

Document Information

LCD ID

L34224

LCD Title

Stereotactic Body Radiation Therapy

Proposed LCD in Comment Period

N/A

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 12/01/2019

Revision Ending Date

N/A

Retirement Date

N/A

Source Proposed LCD

N/A

Notice Period Start Date

N/A

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Notice Period End Date

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.

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.

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.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation Requirements

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.

Sources of Information

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.

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R4	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p> <p>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.</p>	<ul style="list-style-type: none">Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2015	R3	Removed: CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §160.4. from CMS National Coverage Policy section.	<ul style="list-style-type: none"> Other (CMS retired NCD §160.4.)
10/01/2015	R2	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"> 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

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57471 - Billing and Coding: Stereotactic Body Radiation Therapy

Related National Coverage Documents

N/A

Public Version(s)

Updated on 10/30/2019 with effective dates 12/01/2019 - N/A

Updated on 04/17/2015 with effective dates 10/01/2015 - 11/30/2019

Updated on 02/05/2015 with effective dates 10/01/2015 - N/A

Updated on 12/11/2014 with effective dates 10/01/2015 - N/A

Updated on 03/31/2014 with effective dates 10/01/2015 - N/A

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- G0340
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