

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 185	Date: August 21, 2015
	Change Request 9246

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 2, 2015. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that Medicare covers lung cancer screening with low dose computed tomography (LDCT) if all eligibility requirements listed in the National Coverage Determination(NCD) are met.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: February 5, 2015

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 4, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	1/part4/210.14/Lung Cancer Screening with Low Dose Computed Tomography (LDCT)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically

authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 185	Date: August 21, 2015	Change Request: 9246
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SUBJECT: Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

EFFECTIVE DATE: February 5, 2015

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 4, 2016

I. GENERAL INFORMATION

A. Background: Pursuant to §1861(ddd) of the Social Security Act, the Centers for Medicare and Medicaid Services (CMS) may add coverage of "additional preventive services" through the Medicare National Coverage Determinations (NCD) process. The "additional preventive services" must meet all of the following criteria: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and, (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

The CMS reviewed the evidence for lung cancer screening with low dose computed tomography (LDCT) and determined that the criteria listed above were met, enabling CMS to cover this "additional preventive service" under Medicare Part B. Effective February 5, 2015, Medicare covers lung cancer screening with LDCT if all eligibility requirements listed in the NCD are met.

B. Policy: Effective February 5, 2015, CMS has determined that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT), as an additional preventive service benefit under the Medicare program if all eligibility criteria described in the NCD are met.

For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following eligibility criteria:

Age 55 – 77 years;

Asymptomatic (no signs or symptoms of lung cancer);

Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);

Current smoker or one who has quit smoking within the last 15 years; and

Receives a written order for lung cancer screening with LDCT that meets the requirements described in the NCD. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary's medical records, and must contain the following information:

Beneficiary date of birth;

Actual pack – year smoking history (number);

Current smoking status, and for former smokers, the number of years since quitting smoking;

Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and

National Provider Identifier (NPI) of the ordering practitioner.

Before the first lung cancer LDCT screening, the beneficiary must receive a lung cancer screening counseling and shared decision making visit, and if appropriate, receive the written order for his/her first lung cancer LDCT screen during such visit. Written orders for subsequent annual LDCT screens may be furnished during any appropriate visit with a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist) as described in the NCD.

This NCD also establishes data collection requirements and specific coverage eligibility criteria for radiologists and radiology imaging facilities for purposes of Medicare coverage of lung cancer screening with LDCT.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
9246 - 03.1	Effective for dates of service on and after February 5, 2015, contractors shall pay claims for lung cancer screening with LDCT as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 210.14, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, Section 220.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9246 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification	X	X			

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
	from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing Part B) , Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Supplier Claims Processing) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Part A Institutional Claims Processing) , Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

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(Rev.185, 08-21-15)

210.14 – Lung Cancer Screening with Low Dose Computed Tomography (LDCT)

210.14 – Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (Effective February 5, 2015)

(Rev.185, Issue: 08-21-15, Effective: 02-05-15, Implementation: 01-04-16)

A. General

Lung cancer is the third most common cancer and the leading cause of cancer deaths in the United States. Cancer of the lung and bronchus accounted for over 150,000 deaths in 2013, with a median age at death of 72 years. Computed tomography (CT) is an imaging procedure that uses specialized x-ray equipment to create detailed pictures of areas inside the body. Low dose computed tomography (LDCT) is a chest CT scan performed at settings to minimize radiation exposure compared to a standard chest CT. Screening for lung cancer with LDCT is not currently covered under the Medicare program.

Under §1861(ddd) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of “additional preventive services” through the Medicare national coverage determination (NCD) process if certain statutory requirements are met: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

B. Nationally Covered Indications

Effective for claims with dates of service on or after February 5, 2015, CMS has determined that the evidence is sufficient to add coverage under Medicare Part B a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with LDCT, as an additional preventive service benefit under the Medicare program only if all of the following eligibility criteria are met.

Beneficiary Eligibility Criteria

For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following eligibility criteria:

- Age 55 – 77 years;*
- Asymptomatic (no signs or symptoms of lung cancer);*
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);*
- Current smoker or one who has quit smoking within the last 15 years; and*
- Receive a written order for lung cancer screening with LDCT. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary’s medical records, and must contain the following information:*
 - Beneficiary date of birth;*
 - Actual pack – year smoking history (number);*
 - Current smoking status, and for former smokers, the number of years since quitting smoking;*
 - Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and*

- *National Provider Identifier (NPI) of the ordering practitioner.*

Counseling and Shared Decision Making Visit

Before the beneficiary's first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision making visit that meets all of the following criteria, and is appropriately documented in the beneficiary's medical records:

- *Must be furnished by a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Social Security Act), and*
- *Must include all of the following elements:*
 - *Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;*
 - *Shared decision making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;*
 - *Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;*
 - *Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and*
 - *If appropriate, the furnishing of a written order for lung cancer screening with LDCT.*

Written Orders for Subsequent Annual Lung Cancer Screenings with LDCT

For subsequent annual lung cancer LDCT screenings, the beneficiary must receive a written order for lung cancer LDCT screening. The written order may be furnished during any appropriate visit with a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Social Security Act).

If a physician or qualified non-physician practitioner elects to provide a lung cancer screening counseling and shared decision making visit before a subsequent annual lung cancer LDCT screening, the visit must meet all of the criteria described above for a counseling and shared decision making visit.

Reading Radiologist Eligibility Criteria

For purposes of Medicare coverage of lung cancer screening with LDCT, the reading radiologist must meet all of the following eligibility criteria:

- *Board certification or board eligibility with the American Board of Radiology or equivalent organization;*
- *Documented training in diagnostic radiology and radiation safety;*

- *Involvement in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years;*
- *Documented participation in continuing medical education in accordance with current American College of Radiology standards; and*
- *Furnish lung cancer screening with LDCT in a radiology imaging facility that meets the radiology imaging facility eligibility criteria described below.*

Radiology Imaging Facility Eligibility Criteria

For purposes of Medicare coverage, lung cancer screening with LDCT must be furnished in a radiology imaging facility that meets all of the following eligibility criteria:

- *Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy (milligray) for standard size patients (defined to be 5’ 7” and approximately 155 pounds) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients;*
- *Utilizes a standardized lung nodule identification, classification and reporting system;*
- *Makes available smoking cessation interventions for current smokers; and*
- *Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved registry must include, at minimum, all of the following elements:*

<i>Data Type</i>	<i>Minimum Required Data Elements</i>
<i>Facility</i>	<i>Identifier</i>
<i>Radiologist (reading)</i>	<i>National Provider Identifier (NPI)</i>
<i>Patient</i>	<i>Identifier</i>
<i>Ordering Practitioner</i>	<i>National Provider Identifier (NPI)</i>
<i>CT scanner</i>	<i>Manufacturer, Model.</i>
<i>Indication</i>	<i>Lung cancer LDCT screening – absence of signs or symptoms of lung cancer</i>
<i>System</i>	<i>Lung nodule identification, classification and reporting system</i>
<i>Smoking history</i>	<i>Current status (current, former, never). If former smoker, years since quitting. Pack-years as reported by the ordering practitioner. For current smokers, smoking cessation interventions available.</i>
<i>Effective radiation dose</i>	<i>CT Dose Index (CTDIvol).</i>
<i>Screening</i>	<i>Screen date Initial screen or subsequent screen</i>

Information regarding CMS-approved registries is posted on the CMS website at: <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html>.

C. Nationally Non-Covered Indications

Unless specifically covered in this NCD, any other NCD, in statute or regulations, preventive services are non-covered by Medicare.

D. Other

Medicare coinsurance and Part B deductible are waived for this preventive service.

(This NCD last reviewed February 2015.)