

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11388	Date: April 29, 2022
	Change Request 12691

SUBJECT: National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

I. SUMMARY OF CHANGES: The purpose of this change request is to inform interested parties that effective February 10, 2022, CMS is expanding beneficiary eligibility for screening for lung cancer with LDCT.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (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 10, 2022

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

IMPLEMENTATION DATE: October 3, 2022

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
R	1/210/14/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

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I. GENERAL INFORMATION

A. Background: 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 130,000 deaths in 2021 (more than the total number of estimated deaths from colon, breast and prostate cancer combined) with a median age at death of 72 years. Screening is aimed at early detection of non-small cell lung cancer. The only recommended screening test for lung cancer is low dose computed tomography (LDCT). It is a unique CT scan technique that combines special x-ray equipment with sophisticated computers to produce multiple, cross-sectional images or pictures of the inside of the body.

B. Policy: Effective February 10, 2022, CMS is expanding beneficiary eligibility for screening for lung cancer with LDCT to closely align with the USPSTF recommendation. CMS is lowering the minimum age for screening from 55 to 50 years and reducing the smoking history from at least 30 pack-years to at least 20 pack-years. The policy simplifies requirements for the counseling and shared decision-making visit, removes the restriction that it must be furnished by a physician or non-physician practitioner, reduces the eligibility criteria for the reading radiologist, and reduces the radiology imaging facility eligibility criteria (including removes the requirement that facilities participate in a registry).

Note: As a result of the revised eligibility criteria for this NCD, CMS is replacing the current text of Section 210.14 of the NCD Manual, Publication (Pub.) 100-03, Chapter 1, Part 4, and section 220, chapter 18 of the Claims Processing Manual, Pub. 100-04.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12691 - 03.1	Effective for claims with dates of service on and after February 10, 2022, contractors shall pay claims for lung cancer screening with LDCT as described in Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 210.14, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, Section 220.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12691 - 03.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

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): Lisa Davis, lisa.davis@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, patricia.brocato-simmons@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, Wanda.belle@cms.hhs.gov (Coverage and Analysis) , William Ruiz, william.ruiz@cms.hhs.gov (Institutional Claims) , Wendy Knarr, wendy.knarr@cms.hhs.gov (Supplier Claims) , Kimberly Long, Kimberly.Long@cms.hhs.gov (Coverage and Analysis) , Thomas Dorsey, thomas.dorsey@cms.hhs.gov (Practitioner Claims)

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

210.14 – Lung Cancer Screening with Low Dose Computed Tomography (LDCT) *(Rev.11388; Issued:04-29-22; (Effective: 02-10-22; Implementation:10-03-22)*

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 130,000 deaths in 2021 (more than the total number of estimated deaths from colon, breast and prostate cancer combined) 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. 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 10, 2022, CMS has determined that the evidence is sufficient to cover, 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

Beneficiaries must meet all of the following eligibility criteria:

- Age 50 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 20 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 an order for lung cancer screening with LDCT.

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:

- Determination of beneficiary eligibility;
- Shared decision-making, including the use of one or more decision aids;
- Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment; and,
- 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.

Reading Radiologist Eligibility Criteria

The reading radiologist must have board certification or board eligibility with the American Board of Radiology or equivalent organization.

Radiology Imaging Facility Eligibility Criteria

Lung cancer screening with LDCT must be furnished in a radiology imaging facility that utilizes a standardized lung nodule identification, classification, and reporting system.

C. Nationally Non-Covered Indications

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

D. Other

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

(This NCD last reviewed February 2022.)