

Proposed National Coverage Determination for Lung Cancer Screening with Low Dose Computed Tomography (LDCT) CAG-00439R

Decision Summary:

The Centers for Medicare & Medicaid Services (CMS) is reconsidering the national coverage determination established in section 210.14 of the Medicare National Coverage Determinations manual and proposed that the evidence is sufficient to expand the eligibility criteria for Medicare beneficiaries receiving low dose computed tomography (LDCT) when the following criteria are met:

Beneficiary 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

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

- Board certification or board eligibility with the American Board of Radiology or equivalent organization; and

- Documented participation in continuing medical education in accordance with current American College of Radiology standards.

The above proposal 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 removes the radiology imaging facility eligibility criteria (including removing the requirement that facilities participate in a registry).

CMS Analysis

For this reconsideration of the NCD on lung cancer screening with low dose CT, CMS focused on three questions:

- 1) *Is the evidence sufficient to determine that screening for lung cancer with low dose computed tomography is recommended with a grade of A or B by the United States Preventive Services Task Force?*
- 2) *Is the evidence sufficient to determine that screening for lung cancer with low-dose computed tomography is reasonable and necessary for the prevention or early detection of illness or disability?*
- 3) *Is the evidence sufficient to determine that screening for lung cancer with low-dose computed tomography is appropriate for Medicare beneficiaries?*

Given the burden of lung cancer on the United States population, a suitable screening test for lung cancer has been sought for many years. Lung cancer screening has been recommended by the USPSTF with a grade B recommendation for certain individuals. Based on CMS's review of the available evidence, including clinical guidelines and public comments, they find that the evidence is sufficient to conclude that broadening the eligibility criteria for lung cancer screening with low dose CT is reasonable and necessary for the prevention or early detection of illness or disability and appropriate for Medicare beneficiaries under conditions established in this NCD. These conditions are supported by the evidence reviewed, including conditions in the randomized controlled clinical trials and evidence-based multi-society, multi-disciplinary recommendations. The results of ongoing trials will provide additional evidence. CMS believes that specific beneficiary and practitioner eligibility requirements are necessary to ensure that the benefits of screening outweigh harms in the Medicare population, consistent with the various randomized controlled clinical trials. Lung cancer screening with low dose CT has not been implemented broadly in any population to date.

Lowering Starting Age From 55 years to 50 years

The 2021 USPSTF recommendation on lung cancer screening recommends that people start screening at age 50, rather than age 55 years. To determine whether to lower the starting age for low dose CT screening from 55 years to 50 years, CMS assessed the human clinical evidence (NELSON, LUSI, and MILD) study results on low dose CT screening and its impact on lung cancer mortality among persons age 50 to 54 years. CMS found that the human clinical evidence is sufficient to conclude that lung cancer screening with low dose CT is reasonable and necessary for the prevention or early detection of illness or disability, for Medicare beneficiaries with the specific eligibility criterion for starting low dose CT screening at age 50 years. This approach to broadening the starting age for lung cancer screening from 55 to 50 years is consistent with the USPSTF grade B recommendation.

Changing Stopping Age From 77 years to 80 years

The current 2021 USPSTF lung cancer screening statement recommends a stopping age for screening of 80 years. This stopping age is the same as the 2013 USPSTF recommendation of stopping screening at age 80 years. However, the 2015 NCD on Screening for Lung Cancer with LDCT had the stopping age for screening at 77 years because there were no trial data or evidence on adults over 77 years. For this reconsideration, CMS assessed the recently updated trial data published from 2014 to the present for evidence of the effect of screening with low dose CT among persons age 77 years to 80 years. CMS determined overall, there are no lung cancer screening trial data or evidence on adults over 77 years. There is insufficient evidence to determine if these patients over 77 years would benefit from low-dose CT screening for lung cancer. There is no relevant published human clinical study literature regarding the use of low dose CT in persons age 77- to 80-years-old. The study results do not show sufficient evidence to change the eligibility criterion for the age to stop lung cancer screening with low dose CT. Thus, evidence is not sufficient to conclude that lung cancer screening is reasonable and necessary for Medicare beneficiaries with the specific eligibility criterion for the stopping age of 80 years. The Medicare beneficiary eligibility criterion for stopping age will not be changed and will remain at 77 years old.

In our joint society letter, we recommend CMS eliminate the upper age cutoff, as decisions to cease screening should be individualized and based on the overall health status of the patient. It is important that lung cancer screening is recommended to individuals who are designated as high-risk (as already set by USPSTF as age 50 years, smoking 20 pack-years, etc.) and who are candidates for definitive treatment. A balancing of risks and benefits of treatment for lung cancer is an individualized decision between a patient and their health care provider and should not be subject to arbitrary oversight especially given the evolving trends highlighting the importance of personalized medicine.

Lowering Pack-Year Smoking History From 30 Pack-Years to 20 Pack-Years

The 2021 USPSTF lung cancer screening statement recommends annual lung cancer screening with low dose CT for adults who have a 20 pack-year smoking history. The current updated 2021 USPSTF recommendation reduces the pack-years of smoking history that makes someone eligible for screening from 30 pack-years to 20 pack-years. Thus, the pack-year eligibility criterion was lowered from 30 pack-years in the previous 2013 USPSTF recommendation. CMS found that the empiric evidence is sufficient to conclude that lung cancer screening with low-dose CT is reasonable and necessary for the prevention or early detection of illness or disability, for Medicare beneficiaries with the specific eligibility criterion for a smoking history of 20 or more pack-years. This approach to broadening the smoking history from 30 pack-years to 20 or more pack-years is consistent with the USPSTF grade B recommendation.

Maintaining Quit Smoking History at Quitting Within Past 15 Years

In 2021, the USPSTF recommends annual lung cancer screening with low-dose CT in adults who have quit within the past 15 years. Like the 2013 USPSTF recommendation, screening should be discontinued once a person has not smoked for 15 years. CMS received public comments during the first public comment period for the decision memo requesting removal of the eligibility criterion for the quit smoking history. CMS assessed whether the clinical studies had data on quit smoking history for former smokers who quit within the past 15 years to confirm the effectiveness of the current recommendation. Overall, there are no lung cancer screening trial data or evidence on adults quitting smoking beyond 15 years ago. Only one study, the NLST study, shows that the quitting smoking history eligibility criterion for persons who had quit within the past 15 years significantly reduces lung cancer mortality among those receiving low dose CT. There is no relevant published human clinical study literature regarding the use of low dose CT in persons who quit smoking beyond 15 years ago. CMS found empiric evidence is sufficient to conclude that screening for lung cancer with low dose CT is reasonable and necessary for Medicare beneficiaries with the specific eligibility criterion for the quit smoking history of quitting smoking within the past 15 years. However, CMS found the human clinical evidence is not sufficient to conclude that screening for lung cancer with low dose CT is reasonable and necessary for Medicare beneficiaries with the specific eligibility criterion for the quit smoking history of quitting smoking more than 15 years ago. The Medicare beneficiary eligibility criterion for quitting smoking will not be changed and will remain at quitting smoking within the past 15 years. This recommended screening population for quitting smoking within the past 15 years does align with the 2021 USPSTF recommendation statement on low-dose CT screening.

In our joint comment letter, we implore CMS to simplify eligibility requirements and further promote screening; we urge CMS to remove the 15-year smoking cessation quit date. Patients that meet eligibility criteria should continue screening unless they develop a health problem that substantially limits life expectancy or the ability or willingness to have curative intent lung cancer treatment.

Counseling and Shared Decision-Making

Due to the complexities of lung cancer screening with LDCT including specific patient selection criteria, benefits, harms, and adherence, we continue to support the need for shared decision-making. However, CMS believes that the requirements should be modified to reflect a service that is no longer considered new. Professional societies and provider groups have noted that providers have gained considerable experience and expertise and believe flexibility will reduce the burden. CMS proposed to remove specificity regarding the type of provider who must furnish the counseling and shared decision-making and remove some specificity around documentation of the information on the beneficiary eligibility criteria. Specifically, CMS does not believe there is an evidentiary reason to continue to limit the shared decision-making visit to physician and non-physician practitioners. They note that this expansion can allow for this service to be furnished “incident to” a physician’s professional service. Removing the specification for the type of practitioner should expand the individuals that can conduct shared decision-making to other health care practitioners, such as health educators and others beyond physicians or non-physician practitioners. This proposed change may broaden access to LDCT screening.

Additionally, based on the organizations’ guidelines on shared decision-making tools, CMS proposes that lung cancer screening with low dose CT is appropriate for Medicare beneficiaries who meet the other eligibility criteria and who participate in shared decision-making when the provider uses at least one decision aid. CMS believes that removing the restriction for the type of practitioner who can furnish the counseling and shared decision-making visit, removing the specificity of redundant documentation requirements, and eliminating the excessive requirement for a written order will reduce administrative burden and facilitate improved access to lung cancer screening with LDCT.

Substantial concerns remain among medical professional societies, physician groups, screening centers, patient communities, and other stakeholders that the counseling and SDM criteria as written in the NCD are an unintended yet major barrier to lung cancer screening. The joint societies encourage CMS to revisit the “Counseling and Shared Decision Making (SDM)” NCD criteria and eliminate the current language and requirements to ensure it does not act as a barrier to screening uptake. While the informed discussion is important and medically appropriate, CMS should consider mirroring the USPSTF approach with an emphasis on informed discussion importance. Patient/provider discussions regarding informed consent are important across all cancer screenings and are done so without an NCD requirement. While informed discussion with patients should be encouraged and utilized, CMS should eliminate the NCD requirement for SDM entirely, as the complex requirements act as a barrier to screening and especially since CMS does require SDM for coverage of other cancer screening, including screening mammography or colon cancer screening.

Smoking Cessation

CMS proposed to retain the furnishing of information on smoking cessation or smoking abstinence during the counseling and shared decision-making visit, based on the guidelines published by the societal organizations. Many guideline organizations discuss smoking cessation as an important part of low-dose CT screening. For annual lung cancer screening with low dose CT in adults, the 2021 USPSTF recommendation has that if a person currently smokes, they should receive smoking cessation interventions. CMS found none of the organizations specify the facility setting within which smoking cessation intervention should occur, thus, CMS proposed removing the smoking cessation intervention requirement from the radiology imaging facility eligibility criteria. CMS indicates that health care providers should provide information about smoking cessation or cigarette smoking abstinence within the context of a shared decision-making visit, instead of a radiology imaging facility. Based on the organizations' guidelines on smoking cessation for low dose CT screening, they propose to retain the eligibility criterion that lung cancer screening with low dose CT is appropriate for Medicare beneficiaries who meet the other eligibility criteria and who have furnished information about tobacco cessation interventions if current smoker, or maintaining cigarette smoking abstinence if former smoker, during the shared decision-making visit. CMS proposed that it is not appropriate for Medicare beneficiaries to receive smoking cessation interventions for current smokers within the setting of a radiology imaging facility and that this eligibility criterion be removed from the radiology imaging facility eligibility criteria.

MACs should be instructed to cover LDCT LCS performed in IDTFs and all facilities from the date of the initial NCD (Feb. 2015). MACs should be advised the therapeutic exam or intervention is part of the counseling and Shared Decision-Making visit for lung cancer screening HCPCS code G0296 and separate and distinct from the LDCT LCS imaging test 71271 (formerly G0297). As such, we affirm that LDCT LCS is a covered benefit in all facilities, including IDTFs where the LDCT CT exam is performed and interpreted. Given the prolonged MAC denial and misinterpretations of the NCD, it may be helpful and necessary for CMS to inform and instruct MACs that LDCT LCS is considered a non-invasive imaging test. It is analogous to other non-invasive annual imaging screening tests in diagnostic radiology which are appropriately performed in the IDTF setting.

Written Order

CMS proposed to modify the criterion for a written order by removing the word "written" and removing the data elements that are required as part of the order. CMS considers orders for lung cancer screening with LDCT as standard practice and no longer believes it is necessary to specify each data element on the order. While it is important and necessary for a facility to receive an order for the appropriate Medicare beneficiary to have a low dose CT scan to screen for lung cancer, the order does not have to be written since it is more likely that an order is transmitted electronically with the use of an electronic health record system. Additionally, the information CMS previously specified is available in the medical record such as smoking history

and years since quitting smoking. CMS asserts another reason for removing the detailed data elements is because CMS is proposing to remove the low dose CT lung cancer screening registry requirement and many of these elements were required as part of the registry data submission.

Written Orders for Subsequent Annual Lung Cancer Screenings with Low Dose CT

CMS proposed to remove the requirement for written orders for subsequent annual lung cancer screening with low dose CT. They believe that specifying the order be “written” is outdated and that orders for subsequent annual lung cancer screening with LDCT are standard practice and are no longer necessary as part of the NCD.

Reading Radiologist Training and Eligibility Criteria

CMS proposed to modify the reading radiologist eligibility criteria by removing the training documentation requirement, the 300 chest CT acquisitions in 3 years requirement, and the radiology facility eligibility criteria. CMS will retain the eligibility criterion that the reading radiologist must be board certified or board eligible with the American Board of Radiology or equivalent organization to maintain the standards of the American Board of Radiology. Because maintenance of board certification in diagnostic radiology incorporates documented training in diagnostic radiology and radiation safety, CMS proposed to remove the eligibility criterion that the reading radiologist has documented training in diagnostic radiology and radiation safety, which should reduce the documentation paperwork burden on the provider.

Additionally, none of the guideline organizations mention a need for the reading radiologist for CT scans to be involved in a specific number of chest computed tomography readings. CMS proposed to remove the eligibility criterion that the reading radiologist be involved in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years, which should reduce unnecessary requirements for the provider.

CMS will retain the eligibility criterion that the reading radiologist must have documented participation in continuing medical education in accordance with current American College of Radiology standards. Lastly, CMS proposed to remove the reading radiologist eligibility criterion for furnishing lung cancer screening with low dose CT in a radiology imaging facility that meets the radiology imaging facility eligibility criteria because they are proposing to remove the radiology imaging facility eligibility criteria, which should reduce the burden of work on the provider.

Low Dose CT Lung Cancer Screening Imaging Facilities, Low Dose CT Lung Cancer Screening Registry, and Radiation Dose

CMS proposed to remove the radiology imaging facility eligibility criteria. Lung cancer screening with LDCT is now a mature technology that no longer requires the criteria established early in its inception.

We recommend CMS reconsider its proposal to remove the radiology imaging facility eligibility criteria and instead seek modifications. The ACR is committed to both increasing our work with screening facilities and radiologists to provide education on lung cancer screening performance by using their registry data to perform quality audits with a goal of quality improvements, and to using the national practice data to inform the development of performance benchmarks made possible by registry data, which took 15-20 years to develop for breast cancer screening in the absence of such data.

Low Dose CT Lung Cancer Screening Imaging Facilities: Radiation Dose

CMS proposed removing the radiology imaging facility eligibility criteria for volumetric CT dose index by the number of milligrays, based on recently published guidelines. Several multi-society multi-disciplinary guideline organizations (American College of Chest Physicians, National Comprehensive Cancer Network including major professional medical societies such as the American College of Radiology, have comments on radiation dosage. Additionally, the guidelines appear to support the effort to standardize the protocol for administering the low dose CT scan, including the radiation dosing, indicating a maturing technology. Thus, CMS proposed removing the radiology imaging facility eligibility criteria for volumetric CT dose index by the number of milligrays, which is likely to reduce the burden of documentation paperwork on providers and institutions.

An awareness of the potential for radiation-related harm can help programs thoughtfully plan ways to minimize this risk through proper patient selection, the performance of the CT scan, tracking of the radiation dose being administered, and appropriate management of screen-detected findings.

Low Dose CT Lung Cancer Screening Imaging Facilities: Lung Nodule Reporting System

CMS proposed removing the radiology imaging facility eligibility criteria for utilizing a standardized lung nodule identification, classification, and reporting system, based on guidelines published by multi-society multi-disciplinary stakeholders. Several multi-society guideline organizations have commented on utilizing a standardized lung nodule identification, classification, and reporting system that focuses primarily on the reporting system developed by the American College of Radiology. The 2021 USPSTF recommendation reports that to standardize low dose CT screening and the evaluation and management of abnormal lung nodule findings, the USPSTF endorses the use of the American College of Radiology Lung Imaging

Reporting and Data System (Lung-RADS) classification system for lung cancer screening with low dose CT in adults. Given that societal organizations with extensive expertise in low dose CT scans have opined about the use of a lung nodule reporting and management system, we propose removing the radiology imaging facility eligibility criteria for utilizing a standardized lung nodule identification, classification, and reporting system, which is likely to reduce the burden of documentation paperwork on providers.

We recommend keeping the eligibility criteria for utilizing a standardized lung nodule identification, classification, and reporting system. Lung-RADS is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations, reduce confusion in lung cancer screening CT interpretations, and facilitate outcome monitoring. As lung cancer screening programs screen more patients this will be more critical. Society guidelines are being updated to reflect current practices and experience of screening programs.

Low Dose CT Lung Cancer Screening Imaging Facilities: Smoking Cessation

As noted in the above section on smoking cessation that has the rationale for modifying the radiology imaging facility eligibility criteria, CMS proposed that health care providers should provide information about smoking cessation or cigarette smoking abstinence within the context of a shared decision-making visit, instead of a radiology imaging facility providing an intervention. This modification should simplify and streamline the patient workflow for lung cancer screening at the radiology imaging facility.

Low Dose CT Lung Cancer Screening Registry

CMS proposed removing the radiology imaging facility eligibility criteria for collecting and submitting data to a CMS-approved low dose CT lung cancer screening registry along with the minimum required data elements. From the 2015 decision memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT), “[t]he primary purpose for requiring the submission of data to the registry is to document compliance with the coverage criteria that are not evidenced on the health care claim. Furthermore, based on the public comments and the evidence reviewed, CMS strongly believes that the registry will serve as an aid to those seeking to study the clinical benefits of this screening” (CAG-00439N; CMS, 2015). CMS examined three studies used the American College of Radiology Lung Cancer Screening Registry to ascertain how the rates of low dose CT utilization were affected by Medicaid expansion, the association between the geographic distribution of lung cancer screening facilities and the rate of screening eligible individuals, and most importantly, that lung cancer screening remains heavily underutilized despite the positive USPSTF guideline recommendation since 2013. CMS believes the results of the three studies fulfill the purpose of the low dose CT lung cancer screening registry which is to study the clinical benefit of low dose CT screening.

Several societal organizations provided comments on whether there is a need for a low-dose CT lung cancer screening registry. Many of the guideline organizations do not comment on a low

dose CT lung cancer screening registry, however, the American Thoracic Society (ATS) and American College of Chest Physicians (CHEST) policy statements discuss the registry requirement, but only in the context of the 2015 CMS requirement. Given that three published studies use the Lung Cancer Screening Registry administered by the American College of Radiology and the most recent 2021 USPSTF recommendation statement has changed to have no comment on the need for a lung cancer registry, CMS proposed removing the radiology imaging facility eligibility criteria for collecting and submitting data to a CMS-approved low dose CT lung cancer screening registry. They propose these changes will likely reduce the burden of administrative paperwork on providers and institutions.

ACR recommends registry reporting remain an option for lung cancer screening programs. This information helps practices and program coordinators establish best practices and a high-quality lung cancer screening program that is sustainable. These criteria serve as a major national infrastructure for facilities and radiologists to collect, submit and review their data with benchmark data from other practices. Without an alternative structure for quality, there is concern that discontinuing it at this time could set back quality efforts in screening as practices build and grow further to increase the number of patients being screened. LCS quality activities and efforts over the years have relied on registry data and have served as a central resource and reference for LCS research and quality measures.

Health Disparities

Lung cancer incidences are more common in men than women and are highest in African American men (NCI, 2021). Regarding the issues underlying health disparities in lung cancer screening, In 2021 the USPSTF reported that “African American/Black (Black) men have a higher incidence of lung cancer than White men, and Black women have a lower incidence than White women. These differences are likely related to differences in smoking exposure (i.e., prevalence of smoking) and related exposure to carcinogens in cigarettes. The differences may also be related to other social risk factors. More specifically on smoking and race and gender disparities, the authors of the American Thoracic Society (ATS) statement reported that “incidence and mortality rates vary by race, ethnicity, and sex. African American and Native Hawaiian individuals have the highest incidence, and white individuals have midlevel incidence, whereas Hispanic and Asian individuals have the lowest rates. These differences in incidence are more evident by sex at low levels of smoking exposure and younger ages. Recent data demonstrate that lung cancer cases in African American individuals were less likely to be eligible under USPSTF screening guidelines than lung cancer cases in white individuals, primarily because of fewer pack-years smoked.

This Medicare coverage update could help ease lung cancer outcomes disparities — particularly among women, Black men, and those in rural areas.

Strategies to Address Health Disparities

Disparities in lung cancer incidence, diagnosis, treatment, and mortality are well documented. There is concern that disparities in the implementation of and access to lung cancer screening (LCS) will further widen existing gaps in lung cancer care and mortality among racial and ethnic minorities, individuals of low socioeconomic status (SES), and uninsured or underinsured populations. The American Thoracic Society statement on healthcare disparities concludes that socially and economically disadvantaged populations are among the most vulnerable populations at risk for poor lung cancer outcomes. Significant disparities across the continuum of LCS implementation—not getting screened for tobacco use, not meeting eligibility criteria, not having access to quality screening and tobacco treatment, and lack of insurance, among many—threaten to worsen disparities in lung cancer.

CMS encourages shared decision-making between patients and practitioners that is culturally sensitive and understandable by those with lower literacy and numeracy and by those of different cultural backgrounds; and if appropriate, participation in a lung cancer screening program. CMS also encourages the use of tobacco cessation and abstinence programs that address differences in cultural beliefs, language, and literacy.

Modification of Eligibility Criteria for Age and Smoking History

The available evidence, including the health disparity study results and the societal organization's clinical guideline statements, suggest that the CMS proposal to revise the lung cancer screening eligibility criteria by lowering the starting age to 50 years and reducing the smoking history to 20 pack-years may help to partially ameliorate gender and race/ethnicity related health disparities in eligibility for lung cancer screening.

APPENDIX B: Medicare National Coverage Determinations Manual

Draft

CMS is seeking public comments on the proposed language that they would include in the Medicare National Coverage Determinations Manual. This proposed language does not reflect public comments that will be received on the proposed decision memorandum, which may be revised in response to those comments.

Table of Contents (Rev.)

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

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 xx/xx/xx, 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 For purposes of Medicare coverage of lung cancer screening with LDCT, 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

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; and

Documented participation in continuing medical education in accordance with current American College of Radiology standards.

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 xx/xx/xx.)