

Screening for Lung Cancer with Low Dose Computed Tomography Final Decision Memo

Detailed Summary

On Feb. 10, the Centers for Medicare & Medicaid Services (CMS) released its final coverage decision memorandum which updates the national coverage determination (NCD) to expand coverage for lung cancer screening with low-dose computed tomography (LDCT) to improve health outcomes for Medicare beneficiaries with lung cancer. CMS initiated two 30-day public comment periods and issued a proposed decision memorandum on Nov. 17, 2022. In the final decision memorandum, CMS has responded to over 200 comments received during the public comment period.

The coverage 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). The finalized policy is effective Feb. 10. Medicare will cover lung cancer screening with LDCT if all eligibility requirements listed in the NCD are met.

CMS has determined that the evidence is sufficient to expand the eligibility criteria for Medicare beneficiaries receiving LDCT when the criteria below are met:

Summary of Changes

Topic	Proposed Coverage Decision (Nov. 17, 2021)	Final Coverage Decision (Feb. 10, 2022)
Beneficiary Eligibility Criteria	<ul style="list-style-type: none"> 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. 	No changes policy finalized as proposed.
Counseling and Shared Decision-Making Visit	<p>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:</p> <ul style="list-style-type: none"> Determination of beneficiary eligibility; 	<p>No changes policy finalized as proposed.</p> <p>Note: CMS finalized it will remove the restriction that the counseling and shared decision-making visit must be furnished by a physician or non-physician practitioner. This change allows for this service to be furnished</p>

	<ul style="list-style-type: none"> • 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. 	<p>by auxiliary personnel “incident to” a physician’s professional service.</p>
<p>Reading Radiologist Eligibility Criteria</p>	<p>For purposes of Medicare coverage of lung cancer screening with LDCT, the reading radiologist must meet the following eligibility criteria:</p> <ul style="list-style-type: none"> • 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® (ACR®) standards. 	<p>CMS removed the requirement for the reading radiologist to document participation in continuing medical education.</p>
<p>Radiology Imaging Facility Eligibility Criteria</p>	<p>CMS proposed to remove the radiology imaging facility eligibility criteria (including radiation dose, lung nodule reporting system, smoking cessation interventions, and CMS-approved registry data submission)</p>	<p>CMS did not finalize its proposal to remove the requirements for utilization of a standardized lung nodule identification, classification, and reporting system. All other changes were finalized as proposed.</p> <p>Note: Despite CMS’ decision to no longer require registry data submission, the ACR Lung Cancer Screening registry will remain in operation to support quality improvement and excellence in lung cancer screening.</p>

Timeline of Recent Activities

Date	Actions Taken
May 18, 2021	CMS initiates this national coverage analysis. A 30-day public comment period begins.
June 17, 2021	First public comment period ends. CMS receives 170 comments.
Nov. 17, 2021	Proposed Decision Memorandum posted. 30-day public comment period begins.
Dec. 17, 2021	Second public comment period ends. CMS receives 49 public comments.

Synopsis of Public Comments

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.

CMS finalized its proposed decision to expand lung cancer screening with LDCT for Medicare beneficiaries. Most of the public comments received supported revising the NCD to expand beneficiary eligibility by reducing the starting screening age from 55 to 50 and lowering the pack tobacco smoking history from 30 to 20 years. This expansion will expand access to at-risk populations; specifically, females, African Americans, and underserved populations. This also enables expansion for screening in persons who have enrolled in Medicare early due to disability or End Stage-year Renal Disease (ESRD).

Upper age limit

CMS received comments to increase the upper age limit from 77 to 80 to align with the United States Preventive Services Taskforce (USPSTF) recommendation and to be consistent with private insurers. Commenters who supported the removal of the upper age limit believe that providers should be allowed to determine if lung cancer screening is appropriate on an individual basis. Many believe the upper age limit of 77 is not supported by clinical evidence and is based on arbitrarily chosen age cutoffs in various lung cancer screening clinical trials.

CMS finalized its proposed decision to cover patients aged 50-77 years of age. CMS indicates there continues to be no relevant published human clinical study literature regarding the use of low dose CT in

persons aged 77- to 80-years-old and therefore, the evidence is insufficient to determine if patients over 77 years would benefit from low dose CT screening for lung cancer.

15-Year Quit Smoking History

CMS received public comments that disagreed with retaining the beneficiary eligibility requirement of having quit smoking within the past 15 years. Many claimed there is no substantive data to support a significant reduction in lung cancer risk in this time frame while others state that multiple studies have concluded that there are benefits beyond the 15-year cut-off.

CMS finalized its proposal to retain the beneficiary eligibility requirement of having quit smoking within the past 15 years. CMS did not identify evidence to determine if persons who quit smoking more than 15 years ago would benefit from low dose CT screening for lung cancer. They assert evidence provided did not assess the important health outcome of mortality. Therefore, in the absence of relevant evidence, beneficiaries who have quit smoking greater than 15 years ago remain non-covered by Medicare.

Written Order

CMS received supportive comments on its proposal to remove the word ‘written’ from the written order requirement and remove the documentation requirement in the beneficiary’s medical record. CMS is also removing the requirement for written orders for subsequent annual lung cancer screening with low-dose CT. Orders for subsequent annual lung cancer screening with LDCT are standard practice and are no longer necessary as part of the NCD. CMS indicates eliminating the requirement for a written order will reduce administrative burden and facilitate improved access to lung cancer screening with LDCT.

Expanding Beneficiary Eligibility Beyond USPSTF

CMS is not adopting the commenters’ suggestion to expand the beneficiary eligibility criteria to include additional risk populations. Several commenters suggested expanding the beneficiary eligibility criteria beyond the USPSTF recommendation to include additional risk populations. Commenters suggested CMS should consider how lung cancer screening can further reach at-risk Medicare beneficiaries who have no smoking history but have other potential risk factors including long-term exposure to secondhand smoke, and environmental and occupational exposures. Commenters also noted that the current beneficiary eligibility criteria do not consider beneficiaries who smoked less than one pack per day or smoked for less than 20 years, including beneficiaries with occupational exposures, such as first responders. For an additional preventive service to be included for Medicare coverage, it must be recommended with a grade of A or B rating by the USPSTF. The studies used to inform the 2021 USPSTF recommendation either did not examine these additional at-risk populations or the evidence did not support an A or B rating.

Risk Prediction Models

One commenter suggested CMS incorporate using an accurate risk prediction model in the screening criteria. CMS indicates the risk prediction modeling information provided by commenters is a very low level of evidence and they do not consider it sufficient to make changes in the eligibility criteria for lung cancer screening with low dose CT.

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.

CMS received several comments on its proposed changes to this criterion. CMS sees SDM as a critical component of lung cancer screening with LDCT thus it will remain a requirement within the NCD. Some of the comments supported and appreciated CMS simplifying the requirements for the counseling and SDM visit, while many commenters, including the ACR, supported removing counseling and SDM as a requirement altogether. ACR agrees SDM should be encouraged and utilized but eliminated as a documentation requirement for coverage and reimbursement. Even with the simplified requirements there is an administrative burden and creates a barrier to screening. Screening services such as mammography and colon cancer screening do not have the same SDM requirement and the USPSTF only recommends an SDM visit before lung cancer screening.

CMS appreciates commenters recognizing the importance of counseling and SDM in lung cancer screening with LDCT and understands the additional concerns expressed. They agree that SDM is a critical component of lung cancer screening with LDCT due to the complexities around the discussion of low dose CT and benefits, harms, and patient adherence. While some commenters requested CMS strengthen rather than simplify the SDM criteria, in its final decision, CMS removed some specificity around documentation of the information on the beneficiary eligibility criteria and SDM elements to reduce provider burden and improve access to lung cancer screening with low dose CT.

CMS received comments encouraging the use of telehealth to complete the SDM visit if the requirement was retained. CMS appreciated the comments and support reducing barriers and increasing access to screening services through telehealth. CPT code G0296, defined as a counseling visit to discuss the need for lung cancer screening using low dose CT scanning (the service is for eligibility determination and shared decision making), is listed as a permanent telehealth code. The code is payable in the facility and the non-facility setting. You can access the complete list of [telehealth services](#).

Additionally, CMS clarified the NCD states that the counseling and shared decision-making visit must occur before the beneficiary's first lung cancer screening. The NCD does not prevent the SDM visit from occurring on the same day as the lung cancer screening exam or from occurring in conjunction with the actual lung cancer screening exam. If the counseling and shared decision-making visit occur before the beneficiary's first lung cancer screening exam, then it satisfies the NCD. As a reminder, this required counseling and shared decision-making the visit is only required before the first LDCT screening.

Furnished by Physician or Non-physician Practitioner (NPP)

CMS is finalizing its proposed decision to remove the requirement that the counseling and shared decision-making visit must be furnished by a physician or non-physician practitioner (NPP). This flexibility will reduce the burden on providers and broaden access to LDCT screening. The expansion allows for this service to be furnished by auxiliary personnel “incident to” a physician’s professional service. CMS received public comments supporting the removal of the requirement that the counseling and shared decision-making visit must be furnished by a physician or NPP while some commenters want to ensure that shared decision-making conversations still include a patient’s healthcare provider. This expansion allows other types of providers eligibility to furnish this service. Commenters acknowledged this expansion will ease the burden on physicians and NPPs and expand the number of providers who can deliver the counseling and shared decision-making visits.

CMS appreciates the support and understands the concern to include the beneficiary’s healthcare provider in these discussions. Also, CMS supports continued training for shared decision-making for all healthcare providers and encourages providers to consult with professional societies and provider groups for training opportunities.

Decision Aids

CMS received comments that generally supported the requirement that shared decision-making include one or more decision aids but cited the need for more specificity. Some comments favor the removal of the requirement to use decision aids, stating that since there is no designated, standard decision aid it creates more complexity and administrative burden for providers. CMS is finalizing its proposal to remove specifications for the components of the shared decision-making tools. CMS indicates in its analysis several professional organizations and societies suggest the use of decision aids but do not specify the elements required as part of the shared decision-making tool. CMS believes the tools and guidance have matured since the early inception of shared decision-making but are continuing not to require the use of a specific decision aid. Eligible practitioners may select from various available decision aids designed for this purpose and recognized by national professional medical organizations.

Reading Radiologist Eligibility Criteria

For purposes of Medicare coverage of lung cancer screening with LDCT, the reading radiologist must have board certification or board eligibility with the American Board of Radiology or equivalent organization.

Documented Training

CMS finalized its proposed decision to remove the training documentation requirement for the reading radiologist. Training requirements are included in the Maintenance of Certification (MOC) for reading radiologists. CMS indicates removing this requirement will reduce the documentation burden on the providers.

300 Chest CTs within the Past 3 Years

CMS finalized its proposed decision to remove the requirement for reading radiologists to document involvement in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years. Several commenters did not support this decision. Additionally, two

commenters indicated there are no provisions to require the American College of Radiology to mandate any certification or training for radiologists to read LDCT scans which would ensure a high-quality LDCT report. CMS states high-quality reporting will continue as training, including formal training, is more readily available to radiologists. Imaging centers or professional societies may choose to adopt an experiential requirement but eliminating this issue from the NCD reduces documentation requirements as part of coverage. Throughout the final decision, CMS indicates screening, is a more mature service than when CMS first issued an NCD and declares it is no longer necessary for CMS to dictate experience as part of the NCD.

CME Requirement

CMS did not finalize its proposed decision and has decided to eliminate the requirement to document participation in continuing medical education in accordance with current American College of Radiology standards removing this requirement from its final decision. A commenter requested clarification as to why this criterion was retained within the Reading Radiologist Eligibility Criteria. As written, the NCD does not specify any requirement for CME specific to lung cancer screening within the 75 CME credits required for Maintenance of Certification (MOC) and it is the same required documentation needed to submit to the ACR and ABR. CMS appreciated the commenter identifying this discordance and has concluded that the requirement is not meaningfully contributing to the policy because it is unclear and nonspecific. Further, board certification currently requires continuing education leaving it unnecessary to maintain this separate requirement.

Radiology Imaging Facility Eligibility Criteria

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

Radiation Dose

CMS finalized its proposed decision to remove the radiation dose requirement from the final NCD. Several commenters did not support the removal of the radiation dose criteria. They believe that eliminating this requirement could potentially cause confusion and no longer provide a distinction between low dose and regular dose screening protocols. CMS indicates in its response, multi-society, multi-disciplinary organizations with extensive expertise in LDCT scans, such as the American College of Radiology, have published guidelines on the radiation dose that should be emitted by the low dose CT scan. The guidelines also appear to support the effort to standardize the protocol for administering the low-dose CT scan. Given that there are readily available evidence-based guidelines and LDCT screening is now a mature technology, CMS is removing the radiation dose requirement from the NCD. This will allow guidelines to adapt, as needed. Requirements in an NCD remain static and could become outdated. An important aspect of LDCT screening is reducing radiation exposure to as low as reasonably achievable especially given the annual screening frequency and likely follow-up diagnostic imaging tests. The ACR recommended CMS reconsider its proposal to remove the radiology imaging facility eligibility criteria and instead seek modifications.

Lung Nodule Reporting System

CMS did not finalize its proposal to remove the requirement for utilization of a standardized lung nodule identification, classification and reporting system as part of the radiology imaging facility eligibility criteria. Some commenters, including the ACR, did not support the removal of this requirement and noted that Lung-RADS is an example of a system that is deemed appropriate by the lung cancer screening community and generally the one most used. The ACR believes that removing the standardized reporting system could impact the quality of lung cancer screens and affect patient management and care by increasing ambiguity in follow-up and clinical management recommendations made to ordering providers. Lung-RADS provides clear and consistent communication between the radiologist and the ordering providers by helping ordering providers decide on appropriate follow-up for suspicious results.

After considering the public comments, CMS states that utilizing a standardized lung nodule identification, classification, and reporting system are likely to standardize low-dose CT screening and the evaluation and management of abnormal lung nodule findings and to provide clear and consistent communication between the reading radiologist and the ordering providers. Additionally, the USPSTF notes in their low-dose CT lung cancer screening recommendation that data suggest that the use of Lung-RADS may decrease the rate of false-positive results in lung cancer screening (USPSTF, Krist; 2021). This criterion will remain a requirement for a radiology imaging facility.

Smoking Cessation Interventions

CMS finalized its proposed decision to remove the requirement for smoking cessation interventions for current smokers from the radiology imaging facility criteria. Some commenters did not support removing the requirement and other commenters did not agree with CMS stating that it is not appropriate for Medicare beneficiaries who are current smokers to receive smoking cessation interventions within the radiology imaging facility setting and therefore removing it as a requirement. Other commenters, including the ACR, supported the removal of this requirement and applauded CMS for streamlining the process to allow independent diagnostic testing facilities (IDTFs) the ability to perform and receive reimbursement for lung cancer screening. Since IDTFs are enrolled as a facility to perform diagnostic tests and smoke cessation interventions are considered therapeutic interventions, they did not satisfy the NCD criteria and were unable to receive reimbursement for the lung cancer screening service. Commenters believe the removal of this requirement expands access to lung cancer screening by increasing accessibility to screening sites.

CMS determined that while smoking cessation services are of critical importance, they need to balance the accessibility of LDCT screening. While smoking cessation services are appropriate for patients, CMS is not making it a requirement that imaging facilities furnish the service because it would prevent IDTFs from furnishing LDCT screening. CMS clarified that removing the requirement for imaging facilities to furnish smoking cessation services was not intended to downplay the importance of this intervention, but rather to expand the availability of LDCT screening. In its analysis, CMS has revised and clarified the language to state “it is not required for Medicare beneficiaries to receive smoking cessation interventions for current smokers within the setting of a radiology imaging facility.” It remains critically important to provide information about tobacco cessation or cigarette smoking abstinence to the patient at touchpoints between provider and patient along the clinical pathway.

CMS-Approved Registry

CMS finalized its proposed decision memo to remove the requirement that facilities participate in a CMS-approved registry. Some commenters, including the ACR, did not support the removal of this requirement. The registry provides guidance for required and optional fields, facilitates additional research, aids in quality audits, quality improvements, and establishes best practices. Concerns were raised that removing this requirement will likely result in lower overall quality of lung cancer screening. Additionally, CMS received responses that supported the removal of the registry requirement stating that it creates a financial disincentive to small radiology imaging facilities and a barrier to overall lung cancer screening, particularly for rural and minority populations. They point out that the only CMS-approved lung cancer screening registry requires that providers pay a fee to input their data into the registry. The commenters believe removing this requirement will expand access by encouraging more providers to offer lung cancer screenings.

CMS appreciated the comments and indicated the primary purpose for requiring the submission of data to a CMS-approved registry, as stated in the 2015 Decision Memo, was “to document compliance with the coverage criteria that are not evidenced on the health care claim. The registry will help ensure that only eligible beneficiaries will receive this screening service since only beneficiaries that meet the eligibility requirements will benefit from such screening.”

In addition, the most recent 2021 USPSTF recommendation statement changed from encouraging the development of a registry in 2014 to have no comment on the need for a lung cancer registry. Since the published studies, using data from the LCSR, fulfilled the purpose as outlined in the previous NCD, it is no longer necessary to mandate data collection through this NCD. CMS received comments that supported the development of a free lung cancer screening registry. CMS agrees that a registry that would be free to access would aid in eliminating the financial burden for smaller providers. CMS provided information on a proposed bill in Congress (H.R. 107-The Lung Cancer Screening Registry and Quality Improvement Act of 2021) that, if passed, would provide grant funding for the development of free lung cancer screening registries and encourage the development of quality measures in lung cancer. Lastly, commenters suggested CMS make the Lung Cancer Screening Registry (LCSR) data publicly available. CMS encouraged commenters and any interested party to reach out directly to the ACR for more information about data access. CMS hopes this change will reduce the administrative burden on providers and institutions.

Additional Comments

Evidence Review

A commenter supported CMS’ decision to not focus on meta-analysis studies in the evidence review. They believe there is too much heterogeneity in the existing RCTs of LDCT screening for meta-analysis results to be informative, and there is sufficient evidence in the small number of larger trials. CMS appreciates the supportive comment.

Commenters responded to the need for additional studies in populations aged above 77. One commenter remarked that additional studies would likely take several years to conduct any new research and the other commenter suggested CMS conduct coverage with evidence development (CED). CMS agrees with the need for additional evidence as their review concluded that there is an absence of

high-quality evidence to support lung cancer screening above age 77 with low dose CT. As stated in CMS' evidence review, data from randomized controlled trials provide the strongest evidence. In response to the commenter suggesting CMS initiate coverage with evidence development (CED), CMS determined that there was a lack of evidence as opposed to identifying that the evidence is promising in that age group. CMS notes the paradigm around CED is that the evidence is promising in demonstrating that an item or service is reasonable and necessary. In the absence of relevant published human clinical study evidence, populations aged above 77 will remain non-covered by Medicare.

Evidence-Based Guidelines

The American Cancer Society (ACS) and the National Comprehensive Cancer Network (NCCN) requested CMS update their respective sections within the Decision Memorandum (DM). ACS informed CMS that their 2013 guideline is currently being updated and has been taken down from their website. They provided interim language and asked that CMS replace their language in the DM. NCCN provided CMS with the most recent version of the NCCN Guidelines and requested they update the risk assessment image in the final DM. CMS has updated the ACS and NCCN sections within the Evidence-based Guidelines section of the DM to reflect these requests.

Quality Measures

Commenters advocated that lung cancer screening be added to hospital performance and quality measures in such reporting systems such as the Healthcare Effectiveness Data and Information Set (HEDIS), Merit-based Incentive Payment System (MIPS), and National Quality Forum (NQF). CMS indicated quality measures are beyond the scope of this NCD.

Coding Guidance

One commenter requested to include ICD-10 diagnosis codes for 'smoking in remission.' CMS indicated coding guidance is outside the scope of this national coverage analysis.

Effective Date

One commenter asked when the changes are effective. CMS indicates all NCDs are effective on the date the final decision memoranda are posted.

Conclusion

To make LCS more accessible and save even more lives, CMS should consider the following steps moving forward:

- Continue Medicare coverage for older current and former smokers past age 78.
- Continue coverage for beneficiaries who stopped smoking more than 15 years prior.
- Inform future screening improvements by reinstating registry participation requirements.
- Drop the requirement for a shared decision-making session before the first screening (a current barrier to care).

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