

June 14, 2021

Carl Li, M.D., MPH, Medical Officer
Attn: Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Electronically Submitted: CMS_caginquiries@cms.hhs.gov

Re: Public Comment on NCA for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) CAG-00439R

Dear Dr. Li:

The American College of Radiology® (ACR)¹, The GO₂ Foundation for Lung Cancer², and The Society of Thoracic Surgeons³ appreciate the opportunity to submit comments on the National Coverage Analysis for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT). Our organizations fully support CMS revising its lung cancer screening coverage to reflect the updated [U.S. Preventive Services Task Force \(USPSTF\) grade B recommendation](#) that expands the low-dose CT lung cancer screening risk criteria and appreciate CMS' prompt response to our National Coverage Determination (NCD) reconsideration request. In their comprehensive analysis, the USPSTF outlined that confirmatory mortality reduction benefit was reported by a second major randomized control study in a lower risk tobacco smoke-exposed cohort, with modest morbidity and greater study management efficiency. As CMS considers the extensive scientific evidence relevant to the Medicare population, we also request CMS to review [our previous joint letter](#) which outlined specific areas of concern associated with the existing February 2015 NCD. The information presented below builds on these recommendations to further improve the early detection of lung cancer and foster equitable care.

We agree directionally with the USPSTF's recommendations to revise eligibility criteria for lung cancer screening coverage and strongly urge that Medicare coverage must also be updated to reflect the most recent guidelines and clinical standards, which aim to remove barriers that keep at-risk populations from accessing these lifesaving exams. The arc of evidence published since the last CMS NCD has supported the mortality benefit of this service while outlining many screening management refinements which have reduced morbidity while improving screening work-up efficiency. Based on this improving benefits to harms ratio, we urge CMS to **revise and lower** the screening eligibility age to 50 years and smoking history criteria to 20 pack-years for Medicare beneficiaries, which would align with the recently published

¹ The ACR is a professional organization representing 40,000 radiologists, radiation radiologists, nuclear medicine physicians, and medical physicists, committed to advancing the science and quality of radiological care for patients.

² The GO₂ Foundation for Lung Cancer is a national non-profit organization, founded by patients and survivors, dedicated to saving, extending, and improving the lives of those vulnerable, at-risk, and diagnosed with lung cancer.

³ The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

National Comprehensive Cancer Network (NCCN) 2021 Lung Cancer Screening Clinical Practice Guidelines in Oncology, and the American Academy of Family Physicians updated March 2021 recommendation.^{4, 5} In addition, the final USPSTF recommendations to lower the initial age and smoking history requirements for lung cancer screening reconfirm the lifesaving ability of these tests and present an opportunity for providers to re-engage screening age patients to save more lives, including African Americans and women who tend to smoke fewer cigarettes than white males. The growing evidence for scientific benefit relevant to the Medicare population builds on our recommendations to CMS during the initial 2015 NCD and brings into sharp focus that the principal challenge at-hand, which is to ensure equitable access of screening to all of the communities that can benefit by reducing barriers to implementation (refer to **Appendix A** for modifications to existing coverage guidelines).

We also strongly urge CMS to revise the following key areas to mitigate known barriers for LDCT lung cancer screening uptake in the Medicare population:

- **Eliminate** the annual screening eligibility criteria: 15-year smoking cessation quit date.

We recommend CMS remove the 15-year smoking quit date risk criteria for annual LDCT LCS. The joint societies strongly disagree with the CMS and USPSTF criteria that continues to limit screening to current smokers or those who have quit smoking within 15 years. Also, current NCCN guidelines do not have this restriction on screening eligibility.⁴ First, there is no substantive data that supports a 15 year quit date resulting in a significant diminution in lung cancer risk that would warrant cessation of lung cancer screening. Second, our joint societies call attention to the potential harms of continued smoking that could result from the 15-year quit smoking screening requirement and argue that this is misguided. This NCD criterion unintentionally but paradoxically incentivizes Medicare patients to continue or resume smoking in order to obtain or continue screening. Patients beyond the 15-year quit date are no longer eligible for insurance coverage and would have to incur out-of-pocket costs on a self-pay basis or not get screened. The unintended consequence is significant, perverse, and should be eliminated. 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.

- **Eliminate** the annual screening eligibility criteria: upper age limitation of 77 years.

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

⁴ Wood DE et al. NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening, Version 1.2021. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf. Accessed 06.07.2021

⁵ Clinical Preventive Service Recommendation: lung cancer. American Academy of Family Physicians. Published 2021. Accessed June 08, 2021. <https://www.aafp.org/family-physician/patient-care/clinical-recommendations/all-clinical-recommendations/lung-cancer.html>.

health care provider and should not be subject to arbitrary oversight especially given the evolving trends highlighting the importance of personalized medicine.

It is well-established that the medical appropriateness of lung cancer therapy is subject to physiologic status, comorbidities, and the ability to undergo treatment. CMS should recognize that lung cancer risk is not eliminated at age 77, nor that individuals with lung cancer over age 77 are ineligible for curative intent therapy, including surgery. Health status, personalized medicine, and individualized decisions more appropriately inform providers and their patients in determining when to stop cancer screening. Personalized considerations are essential determinants of the harms and benefits of screening and, therefore, we believe that **decisions to continue or cease screening should be individualized based on a person's overall health and preferences**. This is also recommended by NCCN per their lung cancer screening guidelines.⁴ CMS should consider the increasing life expectancy in the U.S., advances in lung cancer treatments, increased benefits of early detection with LDCT screening (overall improvements over the last decade), multiple publications regarding safety and efficacy of lung cancer surgery for individuals over age 77, real-world evidence of screening older individuals including registries and other types of studies outside of randomized controlled clinical trials, and a personalized medicine approach by replacing the upper age limit with clinical guidance (e.g., discontinue screening once a person develops a health problem that substantially limits life expectancy or the ability or willingness to have curative therapy).

- **Eliminate** the “Counseling and Shared Decision Making (SDM)” NCD criteria to ensure the current language and requirements do not act as a barrier to screening uptake.

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 is 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. For example, there are no SDM requirements for coverage of screening mammography or colon cancer screening. CMS can increase screening uptake and reduce burdens by eliminating the list of NCD SDM criteria that are often misunderstood and considered too time-intensive, complex, and/or an impediment for the primary care and ordering clinician community. This can present as a barrier or bottleneck to screening with the ultimate burden on those patients who do not get screened and therefore are less likely to receive a potential lung cancer diagnosis at an early stage when the disease is more easily treated/cured. The Shared Decision Making conversation at the initial Lung Screen can never anticipate all potential risks and procedures that might or might not occur in the future of the individual patient. The vast majority of lung screening patients will never undergo an invasive procedure. For those who do require a procedure, informed consent and SDM is always performed prior each procedure.

The maturity and effectiveness of LDCT LCS across settings are significant.⁶ We are hopeful that CMS will give weight to and recognize the advances and improvements made over the last decade in radiation dose optimization in CT technology. We also hope it gives weight to the low dose protocols established by professional societies (e.g., ACR, AAPM), standardized reporting, and management systems (i.e., Lung-RADS)⁷, incidental findings white papers, and incidental findings resources and management⁸. These advances in standardized screening protocols and implementation, the magnitude of annual lung cancer deaths, persistent low screening uptake in the U.S., and existing and potential NCD SDM criteria burdens, should all bear thoughtful consideration by CMS in revising the NCD language. 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.

- **Formally instruct** all Medicare Administrative Contractors (MACs) to cover/reimburse LDCT performed in all facilities, including Independent Diagnostic Testing Facilities (IDTFs)

Our joint societies strongly urge CMS to provide explicit instruction to MACs that LDCT at IDTFs be fully reimbursed with no additional delay and/or denial. Per the original November 2015 NCD, we do not believe CMS intended to denote low dose CT lung cancer screening as a therapeutic exam or intervention, as the coverage decision included explicit language noting smoking cessation “**counseling**” (therapeutic exam) as part of the Shared Decision Making (G0296) service. 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. The referring provider is responsible for all other components of screening.

CMS should revise the radiology imaging facility criteria language to state “makes available smoking cessation interventions” for patients eligible for lung cancer screening and to clarify smoking cessation interventions can include any of the following: educational materials, pamphlets, videos, etc. MACs should be instructed to cover LDCT LCS performed in IDTFs and all facilities from the date of the initial NCD (Feb. 2015). 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.

⁶ Copeland A, Criswell A, Cuipek A, et al. [Effectiveness of Lung Cancer Screening Implementation in the Community Setting in the United States | JCO Oncology Practice \(ascopubs.org\)](#). DOI: 10.1200/JOP.18.00788 Journal of Oncology Practice 15, no. (July 01, 2019) e607-e615.

⁷ Lung CT Screening Reporting & Data System (Lung-RADS). <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads>

⁸ <https://www.acr.org/Clinical-Resources/Incidental-Findings>

- **Review** the reading radiologist and imaging facility eligibility criteria to determine if changes are needed.

During the time of this review, our organizations do not propose any changes to the reading radiologist section of the NCD. The ACR is committed to both increasing our work with screening facilities and radiologists to provide education on lung cancer screening performance ⁹ by using their own 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.

Lung cancer kills more people each year than breast, colon, and prostate cancers combined. Annual lung cancer screening with LDCT in high-risk patients greatly reduces lung cancer deaths. Less than 15% of Americans who met previous USPSTF screening criteria are tested each year. More widespread screening could save 30,000–60,000 lives in the United States each year ¹⁰. Lack of coverage for those who need it and paradoxical barrier to access (e.g. SDM requirements) has contributed to severe underuse of lung cancer screening, which has undoubtedly cost lives. Several studies confirm that annual screening with LDCT provides greater benefit in decreasing lung cancer mortality and in life-years gained. Although Medicare and nearly all private payers cover lung cancer screening, public awareness of this life-saving screening benefit is woefully low. **We believe a public health awareness campaign targeted to patients and providers would make a profound difference in lung cancer screening uptake.** We believe CMS has a unique responsibility and opportunity to increase public awareness of LDCT screening benefits and encourage its adoption.

Our organizations appreciate the opportunity to submit recommendations to the Centers for Medicare and Medicaid Services on Screening for Lung Cancer with LDCT. If you have any questions or comments on our letter, please do not hesitate to contact Alicia Blakey, Senior Economic Policy Analyst at ablakey@acr.org.

Respectfully Submitted,



William T. Thorwarth, Jr, MD, FACR
Chief Executive Officer
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⁹ <https://www.acr.org/Clinical-Resources/Lung-Cancer-Screening-Resources>

¹⁰ <https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html>



Laurie Fenton Ambrose,
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Appendix A: Modifications to Existing Coverage Criteria

The Centers for Medicare & Medicaid Services (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 only if all of the following 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; Age 50 or above;~~
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least ~~30~~ 20 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current or former 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.

* The calculation of pack years smoked should only be required for the initial/baseline screening and not applicable for subsequent visits as this information will be unchanged for future visits.

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 applicable, the visit must satisfy the written order criteria.

~~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.~~

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.~~

Reading radiologist 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 below.

Radiology imaging facility eligibility criteria:

- Performs LDCT with volumetric CT dose index (CTDI_{vol}) of ≤ 3.0 mGy (milligray) for standard size patients (defined to be 5' 7" and approximately 155 pounds) with appropriate reductions in CTDI_{vol} for smaller patients and appropriate increases in CTDI_{vol} for larger patients;
- Utilizes a standardized lung nodule identification, classification and reporting system; example: [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.
- Makes available smoking cessation materials ~~interventions~~ for patients eligible for lung cancer screening; smoking cessation materials can include any of the following: educational materials, pamphlets, videos etc; 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:

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