



**The Society
of Thoracic
Surgeons**



December 16, 2021

Tamara Syrek Jensen, JD, Director
Joseph Chin, MD, Deputy Director
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 the [Proposed NCD for Screening for Lung Cancer with Low Dose Computed Tomography \(LDCT\)](#) CAG-00439R

Dear Ms. Jensen and Dr. Chin:

The GO₂ Foundation for Lung Cancer¹, American College of Radiology® (ACR)², and The Society of Thoracic Surgeons (STS)³ appreciate the opportunity to submit comments on the Proposed National Coverage Decision for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT).

Our organizations applaud the Centers for Medicare and Medicaid Services' (CMS) expanded lung cancer screening eligibility criteria reflecting a lower start age of 50 years and lower smoking history of 20 pack-years parallel with the [U.S. Preventive Services Task Force \(USPSTF\) grade B recommendation](#). We support the efforts made by CMS to simplify and streamline the patient workflow for lung cancer screening in the *radiology imaging facility* and its clarification that smoking cessation is performed by the health care provider within the context of a shared decision making consultation, as Medicare Administrative Contractors (MACs) have misidentified LDCT lung cancer screening (LCS) imaging as a

¹ 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.

² The ACR is a professional organization representing 40,000 radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, committed to advancing the science and quality of radiological care for patients.

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.

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“therapeutic test and intervention” and erroneously denied beneficiaries coverage when performed in independent diagnostic testing facilities.

We strongly **disagree** with CMS’s *evidence review summary* rationale and proposed decision to 1) stop screening once a person has not smoked for 15 years, 2) stop screening at age 77 years, 3) require counseling and shared decision making visit before a beneficiary can obtain Medicare coverage for their first lung cancer screening, and with 4) the removal of the radiology imaging facility eligibility criteria.

Our joint societies continue to urge CMS to remove items 1-3 from the final National Coverage Determination (NCD) as inherent barriers to lung cancer screening access for individuals at high risk for developing lung cancer. We strongly urge the agency to modernize its evidence review towards increasing lung cancer screening and survivorship in the Medicare population. The proposed CMS evidence summary on these topics is too narrow, and contradicts the evidence review and research summary prepared by the AHRQ used by the USPSTF. We urge CMS to recognize that clinical trials have **limited** ability to define the extent of a high risk population for lung cancer. Given the primacy of lung cancer mortality burden across the United States population, and with the historic challenges with health disparities related to tobacco use, there is a critical need to provide Medicare coverage in a responsible and equitable fashion to address the need of the at-risk populations. To this end, we encourage CMS to fully consider other studies including modeling and real world data to address the Medicare population and public health benefit of early detection and health equity. In addition to our recommendations below, we refer CMS to our formal comments dated [March 9th](#) and [June 16th, 2021](#) calling for broader evidence review with a public health outlook.

At a minimum, CMS should allow Medicare patients the same benefit as recommended by the USPSTF for the upper age screening eligibility criteria of 80 years based on their modeling evidence. It is unjust and inequitable to disregard the medically fit, upper age group of the Medicare population based on the proposed CMS evidence review that excluded all modeling, driving patients to pay out of pocket to receive this life saving service. The focus on lung cancer screening discontinuation should be based on an individual’s overall health, comorbidities, and ability or willingness to undergo treatment rather than age limits and an arbitrary 15-year quit smoking time frame.

I. Delete the annual screening eligibility criterion that discontinues screening once an individual turns 78 years old.

We recommend CMS remove the upper age cutoff of >77, as decisions to discontinue screening should be individualized and based on the overall health status of the patient. This is also recommended in the National Comprehensive Care Network (NCCN) lung cancer screening guideline.⁴ The one size fits all approach for lung cancer screening and upper age limit is antiquated and medically contraindicated for a sizeable risk population that may have healthy lifestyles and little or no comorbidities.

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, such as, **“discontinue screening once a person develops a health problem that substantially limits life expectancy or the ability or willingness to have curative intent therapy.”**

With the increasing life expectancy of the American population, in 2014 Varlotto et al. investigated whether lung cancer screening benefits individuals 75–84 years old, concluding that screening may benefit individuals at increased risk of lung cancer in the upper age group. Specifically, they found that the survival benefits of aggressive therapy are similar in females between 55–74 and 75–84 years old.⁴

Well-established data from institutional reports and registry analyses document the favorable patient outcomes from the surgical management of early-stage lung cancer. Objective assessments of surgical efficacy should use contemporary results reported within the last decade, including screening studies [e.g., International Early Lung Cancer Action Program (I-ELCAP)].⁵ In addition, other advances in other therapeutic modalities including stereotactic body radiation therapy (SBRT), standard radiation therapy (RT), chemotherapy, and immunotherapy have dramatically increased survival beyond 77 years of age.

The CMS evidence summary indicates that no randomized clinical trials (RCTs) included the upper age in their study populations. However, it is vitally important to apply context and modernize the CMS evidence approach. Although the RCT studies and enrollment parameters CMS identified a good target population, they were not intended or framed to define the extent of lung cancer risk or to limit screening access and eligibility as previously pointed out by the USPSTF. CMS is inadvertently misrepresenting the NLST and other studies by concluding the RCTs omission of the upper age population is the basis for not allowing Medicare patients screening coverage once they turn 78 and beyond.

In addition, CMS is misinterpreting various clinical guidelines and standards from organizations and again, should apply context and revise the evidence review and proposed decision. It’s incongruous and inaccurate for CMS to conclude that the screening guidelines from the American College of Radiology, and the National Comprehensive Care Network, etc., included recommendations that restrict the aging Medicare population from reasonable and medically appropriate screening. The context is crucial, as these are evolving and advancing guidelines that often reflect key coverage parameters by Medicare or the USPSTF to help educate due to broad and significant coverage implications.

⁴ Varlotto JM, DeCamp MM, Flickinger JC, et al. Would Screening for Lung Cancer Benefit 75 to 84 Year-Old Residents of the United States? [Front Oncol.](#) 2014; 4: 37. Published online 2014 Mar 7. doi: [10.3389/fonc.2014.00037](#).

⁵ [I-ELCAP Publications](#) | [I-ELCAP](#).

Specifically, while NCCN guidelines notes in a footnote that “there is uncertainty about the upper age limit to initiate or continue screening” they follow this with recommendations that “consider screening beyond age 77 years as long as patient functional status and comorbidity allow consideration for curative intent therapy.” The algorithm of NCCN guidelines quite specifically avoids an upper age limit because of recognition by the panel that non-inclusion of older age individuals in the large randomized trials is a pragmatic detail of trial design and does not define the true upper age limit for benefit from early detection. NCCN panel experts from pulmonary medicine, thoracic radiology, thoracic surgery, epidemiology, medical oncology, and patient advocacy have consensus that the end of screening should be an individualized decision between an individual and their health care provider based on health status, comorbidity, and patient values that determine eligibility for curative-intent therapy.

The proposed decision by CMS to cease screening at age 78 and/or when an individual has stopped smoking for >15 years is not justified by the omission of evidence outlined in the review summary. This acts as a barrier to patient access for a reasonable and medically appropriate lung cancer screening test in the Medicare population.

II. Delete the screening eligibility criterion that discontinues annual screening for individuals who quit smoking > 15 years ago

We strongly urge CMS to delete the 15-year smoking quit date screening eligibility criterion, as there is no substantive data to support a significant reduction in lung cancer risk at that time frame. Current NCCN guidelines do not have this restriction for recommended screening eligibility.⁴ 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 treatment.

CMS is misrepresenting RCT enrollment criteria as the basis for not allowing Medicare patient screening coverage once they stop smoking for 15 years. It is well-known that these RCTs were not intended or designed to limit screening eligibility. For example, the NLST 15-year quit smoking enrollment criterion was not and is not indicative of the broader high-risk screening population and does not represent the clinical utility of screening for those individuals having quit smoking for more than 15 years. The USPSTF and CMS are arbitrarily re-applying the 15-year quit smoking restriction based on NLST study entry criteria alone. This inappropriately limits eligibility for screening and in doing so dismisses the level of higher-risk lung cancer among the population that quit smoking more than 15 years ago.

To require and wait for an RCT for individuals that stopped smoking more than 15 years ago when there is data that concludes **40% of all lung cancers still occur in the 15 years since quit (YSQ) smoking population** is a flaw in the draft coverage decision⁶. The existing evidence on the objective relative risk

⁶ Tindle HA, Duncan MS, Greevy RA, et al. Lifetime Smoking History and Risk of Lung Cancer: Results From the Framingham Heart Study. JNCI J Natl Cancer Inst. 2018;110(11): djy041.

for lung cancer after the 15 YSQ smoking does not support excluding screening for 4 out of 10 lives diagnosed with lung cancer.⁷

CMS is misunderstanding various clinical guidelines and standards from organizations and, should apply relevant context and revise their evidence review and proposed decision. NCCN has eliminated a quit date limitation to screening eligibility as they recognize that risk remains high for former smokers, even beyond 15 years of cessation, as well as the perverse incentive that this criterion may have to encourage individuals to resume smoking to remain eligible for screening. It is inaccurate and misleading for CMS to conclude that the screening guidelines from the American College of Radiology, and the National Comprehensive Care Network (NCCN), etc., include recommendations that are used to restrict the screening population that stopped smoking 15 years ago or more. As mentioned, the context is important for these evolving and advancing guidelines which often include key coverage considerations by Medicare and the USPSTF. These guidelines were not intended to exclude screening from the respective Medicare population (15 YSQ) but rather help educate due to broad and significant coverage parameters/restrictions instituted by federal agencies like CMS etc.

In a prospective study, Yang et al. observed two cohorts of individuals with lung cancer and identified the chronological patterns among 1) eligible individuals per USPSTF lung cancer screening risk criteria and 2) those individuals who would have “missed out” on screening who were outside the USPSTF criteria. The lung cancer incidence levels among those who would have “missed out” were high, demonstrating continued high-risk. The largest group (approximately 30%) of individuals among the cohort that “missed out” was *solely* based on a quit smoking date of more than 15 years ago. The authors concluded that their “current and previous studies provide evidence that former smokers with **15 to 30 quit-years remain at high-risk and should be considered eligible for LDCT screening for lung cancer. The current USPSTF recommendation to stop screening after 15 years of smoking cessation is not reflective of the continued high-risk.**” Their results underscored that the inclusion of former smokers that have quit smoking more than 15 years may yield substantial increases to screen-detected lung cancers with more lives saved.⁸

The 2021 USPSTF relaxation of age and pack-years requirements was prompted in part to increase the proportion of Black individuals eligible for screening given their younger age at diagnosis of lung cancer and higher risk of lung cancer associated with fewer smoking pack-years compared with White individuals.^{2,6} As recently as November 24, 2021, Potter et al., found the impact of the 15-year quit smoking screening restriction on black women to be significant. While the proportion of Black women diagnosed with lung cancer eligible for screening increased by 50% under the updated 2021 USPSTF guidelines, still 66% of patients with lung cancer would have been ineligible for screening. Removing the 15 YSQ requirement would increase the proportion of Black women eligible for screening from 33.9% to 48.2%. Similar recent findings by Pasquinelli et al. looked at racial disparities and risk

⁷ Reitsma M, Kendrick P, Anderson J, et al. Reexamining Rates of Decline in Lung Cancer Risk after Smoking Cessation: A meta-analysis. ANNALSATS Articles in Press. 2020;10.1513/AnnalsATS.201909-659OC.

⁸ Yang P, Wang Y, Wampfler JA, et al. Trends in Subpopulations at High Risk for Lung Cancer. J Thorac Oncol. 2016;11(2):194-202.

prediction models versus USPSTF. In their analysis, they found that 49.1% would qualify for screening among a Black cohort of ever-smokers ineligible by the USPSTF criteria and would be deemed ineligible due to the 15-year quit smoking restriction. The study concluded that the PLCOm2012 model was preferable to USPSTF criteria at identifying Black ever-smokers for screening and that broader use of the model in racially diverse populations may help overcome racial disparities in lung cancer screening and outcome.

At a time when lung cancer deaths remain the number one cancer killer and when screening uptake trends are very low⁹, CMS should not diminish and discriminate against thousands of Americans who stopped smoking more than 15 years ago when real world evidence and observational studies, etc. shows this population remains at a high-risk of lung cancer. Given public health responsibility, health maximization, efficiency, justice, and proportionality¹⁰, to exclude millions of former Medicare and Medicaid smokers who remain at high-risk of lung cancer based on an arbitrary threshold of 15 years since having quit smoking is not supported by the evidence and is punitive against Medicare beneficiaries that have managed to stop smoking.

The proposed NCD criterion (15 YSQ restriction) 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, reduce harms, and further promote screening we urge CMS to remove the 15-year smoking cessation quit date.

III. Remove the “Counseling and Shared Decision Making (SDM)” requirement altogether to ensure the current NCD language does not act as a barrier to screening uptake.

We recognize that CMS has made efforts to streamline the SDM criterion in the proposed NCD. However, SDM is not a coverage requirement for any other cancer screening and lung cancer should be no different.

Our joint societies fully support the importance of SDM and the provider/patient conversation as a valuable part of **all** cancer screenings and other tests. However, the added burden of medical record documentation should not be a requirement for lung cancer screening by tying it to coverage and reimbursement. The NCD process is not the best mechanism for ensuring responsible and appropriate SDM and best practice standards and instead should be directed to medical professional societies, accrediting bodies, and groups like the National Quality Forum.

⁹ Okereke IC, Nishi S, Zhou J. Trends in lung cancer screening in the United States, 2016-2017. *J Thorac Dis.* 2019;11(3):873–881. doi: [10.21037/jtd.2019.01.105](https://doi.org/10.21037/jtd.2019.01.105). PMID: PMC6462682.

¹⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4196023/>

CMS should mirror the USPSTF approach emphasizing the importance of smoking cessation counseling, SDM, and other *practice considerations*¹¹ and **reference appropriate national bodies** for quality screening implementation and other best practice measures. Patient/provider informed discussions regarding risks and benefits 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. Individuals should be offered the opportunity to discuss smoking abstinence or cessation by trained health care professionals as appropriate.

We disagree with CMS' proposed NCD and basis (i.e., complex patient criteria, benefits, harms, adherence) for requiring SDM before the initial lung cancer screening although we acknowledge such concerns were included in the 2015 NCD during its early adoption. The maturity and effectiveness of LDCT LCS across settings all reported over the last five years are significant.¹² CMS should give weight to and recognize the advances and improvements made over the last decade in radiation dose optimization in CT technology, the low dose protocols established by professional societies (e.g., ACR, AAPM), standardized reporting, and management systems (i.e., Lung-RADS)¹³, incidental findings white papers, and incidental findings resources and management¹⁴. 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 and removing the proposed NCD language.

Significant concerns remain among medical professional societies, physician groups, screening centers, patient communities, and other stakeholders that the counseling and SDM requirement in the proposed NCD has had an unintended yet major barrier to lung cancer screening. This is especially problematic with medically underserved populations. The SDM proposed NCD requirement results in an unfortunate health equity issue, as marginalized populations have much less access to health care professionals in both urban and rural settings. This also targets a group of patients that have been stigmatized and underrepresented in screening compared to other cancer types.

The joint societies urge CMS to remove the "Counseling and Shared Decision Making (SDM)" NCD requirement altogether to ensure equitable access and mitigate this barrier to lung cancer screening uptake.

IV. Maintaining Radiology Imaging Facility Eligibility Criteria for Quality Assurance

¹¹ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening#bootstrap-panel--6>

¹² 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 \(ascopubs.org\)](https://ascopubs.org/journal/JCO/15/7/607/2019). DOI: 10.1200/JOP.18.00788 Journal of Oncology Practice 15, no. (July 01, 2019) e607-e615.

¹³ Lung CT Screening Reporting & Data System (Lung-RADS). <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads>

¹⁴ <https://www.acr.org/Clinical-Resources/Incidental-Findings>

We disagree with CMS' proposal to remove the radiology imaging facility eligibility criteria. While this may expand access to care, we want to ensure quality assurance remains central to new and continued screening programs as LCS is made available to more Americans and programs will need to grow and expand to reach individuals eligible for screening. We recommend CMS reconsider removing the radiology imaging facility eligibility criteria and instead seek modifications. We recommend maintaining the radiology imaging facility eligibility criteria to safeguard Medicare beneficiaries from harm. We recommend the following criteria:

- Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy (milligray) for standard size patients (defined to be 5' 7" and approximately 155 pounds) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients;
- Utilizes a standardized lung nodule identification, classification and reporting system;
- Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed.

Radiation Dose

We support the required standardized volumetric CT dose index criteria to monitor radiation dose and minimize the risk for patients undergoing this screening option. We agree with CMS's analysis that found 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" (Mazzone, Panel Report 2021). If the dose criteria are eliminated there will be no distinction between low dose and regular dose protocols.

Lung Nodule Reporting System

We recommend maintaining 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, provide consistency in lung cancer screening CT interpretations, and facilitate outcome monitoring. Lung-RADS is an example of a system that is deemed appropriate by the lung cancer screening community. As lung cancer screening programs screen more patients, this will be even more critical. Society guidelines are being updated to reflect current practices and experience of screening programs to reflect updates to the 2021 USPSTF screening recommendations. Without a lung cancer screening reporting tool, this will blur the lines with management recommendations for incidentally detected lung nodules designed for patients at much lower risk of lung cancer, such as the well-recognized Fleischner criteria.

Lung Cancer Screening Registry

Our joint societies support maintaining the registry reporting for lung cancer screening programs. We have reviewed the CMS approved registry minimum required data elements and believe they capture the information necessary to screen the appropriate patients and monitor the screening population. The information available through registry reporting helps practices and program coordinators establish best practices and high-quality lung cancer screening programs that are 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.

We have reviewed the reading radiologist training eligibility criteria and support modifications outlined in the proposed decision memo. Specifically, we support CMS's proposal to remove the training documentation requirement, the requirement of interpretation of 300 chest CT in three years, and the radiology facility eligibility criteria. We support CMS retaining the eligibility criterion that the reading radiologist must be board certified or board eligibility with the American Board of Radiology or equivalent and must have documented participation in continuing medical education in accordance with current American College of Radiology standards.

Expanded access to lung cancer screening will help doctors strike a blow against the nation's leading cancer killer. Screening providers, particularly those starting new screening programs, should seek quality assurance activities to maximize the lifesaving benefit of lung cancer screening. The ACR is committed to both increasing our work with screening facilities and radiologists to provide education on lung cancer screening performance by using 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. This effort took 15-20 years to develop for breast cancer screening in the absence of such data. The Coverage and Analysis Group must similarly align its coverage activities with the Center for Clinical Standards and Quality to ensure favorable outcomes for Medicare beneficiary lung cancer screening.

Summary

Despite the seven years since the Feb. 2015 NCD, lung cancer screening rates remain low due to several contributing factors^{15,16}, including the screening discontinuation at 78 years of age, discontinuation of screening once an individual stops smoking for >15 years, the SDM requirement tied to coverage, and certain radiology imaging facility eligibility criteria.

We believe there is sufficient evidence to conclude that lung cancer screening with LDCT is reasonable and necessary for the early detection of illness or disability and appropriate for Medicare beneficiaries under the conditions recommended by the current NCCN guidelines. We recommend that CMS' final NCD echo the current NCCN guidelines and remove the aforementioned screening restrictions. NCCN evaluates emerging and ongoing evidence on an annual basis as part of their guidelines process, producing well-respected national cancer guidelines/standards, and are responsible stewards of

¹⁵ Jemal A, Fedewa SA. Lung cancer screening with low-dose computed tomography in the United States – 2010 to 2015. JAMA Oncol. 2017;39:1278-1281.

¹⁶ National Academies of Sciences, Engineering, and Medicine. 2017. Implementation of lung cancer screening: Proceedings of a workshop. Washington, DC: The National Academies Press. <https://www.ncbi.nlm.nih.gov/books/NBK431132/>.

evidence for lung cancer screening across the Medicare population and beyond. In addition, we recommend that CMS retain the radiology facility criteria necessary to ensure the quality of lung cancer screening during a time period of screening growth to include millions more individuals in the United States in order to minimize unintended harms.

Our joint societies commend CMS for revising the NCD to help reach the lung cancer screening eligible population and appreciate the opportunity to comment on this important life-saving preventive service. We welcome further dialogue and encourage NCD adoption of *patient centered language*.¹⁷

If you have any questions, please contact Anita McGlothlin, Director of Economics and Health Policy, at amcglothlin@go2foundation.org.

Sincerely,

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¹⁷ <https://www.iaslc.org/IASLCLanguageGuide>