June 21, 2024

Tamara Syrek Jensen, JD, Director  
Carl Li, MD, Lead 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: Request for Reconsideration of NCD for Screening for Lung Cancer with Low-dose Computed Tomography (LDCT) – CAG-00439R (Publication 100-3; Manual Section 210.14; Version 2)

Dear Ms. Jensen and Dr. Li:

The GO2 for Lung Cancer 1, the American College of Radiology® (ACR) 2, and The Society of Thoracic Surgeons 3, formally request a reconsideration of the National Coverage Determination (NCD) for Screening Lung Cancer with Low-dose Computed Tomography (LDCT), and revise with the evidence-based guidelines published by the American Cancer Society (ACS) and the National Comprehensive Care Network (NCCN). Our joint societies ask for the removal of both the 15 years since quitting smoking criterion and the upper age limit to screening in response to the current body of evidence which has been incorporated into the updated ACS and NCCN evidence-based guidelines. 4, 5

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1 The GO2 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 radiologists, 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 healthcare 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.
Both the ACS and NCCN screening guidelines expanded the screening eligibility criteria and are estimated to capture five million additional lives at higher risk for lung cancer. Given the recent evidence, the magnitude of impact, and the number of lives at risk, we urge the Centers for Medicare and Medicaid Services (CMS) to prioritize and expedite the NCD reconsideration process for low-dose CT lung cancer screening with a focus on the following key areas:

- Remove the 15 years since quitting smoking history eligibility criterion for annual screening;
- Remove the upper age limit for annual screening;
- Address the statutorily defined benefit category; and
- Relevance, Usefulness, and Medical Benefits of Lung Cancer Screening to the Medicare Population

I. **Our joint societies strongly urge CMS to expeditiously remove the 15 years since quitting smoking criterion currently required for annual screening.**

Kondo et al. completed an independent systematic review requested by the ACS Guideline Development Group and looked at lung cancer diagnosis and mortality beyond 15 years since quitting (YSQ) smoking in individuals with a 20+ pack-year history. Their findings show the risk of lung cancer not only persisted beyond 15 years after quitting smoking but actually elevated the risk of those who have not smoked in 15 or more years for two or three decades.⁶

Landy et al. quantified the counteracting effects of years since quitting smoking and concomitant aging on lung cancer risk, including exceeding the 15 YSQ smoking, and concluded that because of aging, absolute lung cancer risk increases beyond 15 YSQ, which does not support exemption from screening or curtailing screening once it has been initiated. They further concluded that compared with relaxing the United States Preventive Services Task Force (USPSTF) quit-year criterion, augmentation using the Life Years From Screening – CT prediction model could prevent most of the deaths at substantially superior efficiency while also preventing deaths among individuals who currently smoke with low intensity or long duration.⁷

Meza et al. addressed the impact of increasing lung cancer screening eligibility by relaxing the maximum years since quitting smoking threshold with a simulation modeling study. They found that **expanding screening to persons who formerly smoked and have greater than 15 YSQ would result in considerable increases in deaths averted and life-years gained.**⁸

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Dr. Tammemagi published an article titled “Time to quit using quit time as a lung cancer screening eligibility criterion” that evaluates the historical and current body of evidence, including a comprehensive discussion regarding the USPSTF and CMS lung cancer recommendation and coverage, timeliness barriers with their processes and cycles, contrasted by the NCCN guideline review cycle and completed annually at minimum, and how USPSTF and CMS rate to today’s swiftly advancing world of science in lung cancer. This author points to the ACS guideline and its careful review of the evidence, their removal of the 15 YSQ, and encourages the USPSTF, CMS, and other organizations to expeditiously remove the YSQ limitations, as hundreds of thousands of high-risk individuals currently do not have access to screening because of this existing quit-years eligibility rule. He further states that it can be considered unethical to delay correction of the currently flawed screening criteria, depriving thousands of former smoking individuals of the lifesaving benefits of LCS.⁹

Based on the ACS findings and recent publications (Kondo/Landy/Meza/Tammemagi), if the 15 years since quitting criterion is removed and if all eligible individuals followed the updated ACS guideline, there would be an increase in lung cancer screening eligible individuals from 14.2 million to 19.2 million, with 21% more life years gained. These studies clearly indicate the benefits of screening after 15 years of having stopped smoking and, therefore, the 15 years since quit time as a lung cancer screening eligibility criterion should be removed as evidenced by both the NCCN guideline and recently updated ACS guideline. People should not be excluded from screening who stopped smoking more than 15 years ago, as this is a population that has lasting and rising risk due to aging and smoking history.¹⁰,¹¹,¹²,¹³

II. **Our joint societies strongly urge CMS to remove the upper age limit criterion currently required for screening eligibility.**

There is an inconsistency between CMS and the USPSTF with the upper age limit to initiate or continue low dose CT lung cancer screening (77 vs 80 years). The upper age limit for annual screening was previously imposed due to a perceived lack of evidence and as a legacy of the inclusion criteria of the National Lung Screening Trial, which has imprinted into policies and coverage decisions. The screening criteria are sometimes reiterated by guidelines to educate providers and patients on covered benefits and eligibility imposed by CMS, USPSTF, etc. Additionally, in the recent ACS guideline, the upper age limit for screening was expanded to 80 years, and the NCCN guideline removed the upper age limit altogether, as it is well-established that medical appropriateness of lung cancer screening and treatment is subject to physiologic status, comorbidities, and the ability to undergo

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curative intent therapy. The evidence-based benefit of screening these individuals beyond 77 and 80 years is far
greater than previously published risks as included in these guidelines.\textsuperscript{14,15}

Varlotto et al. investigated whether screening for lung cancer might benefit individuals 75-84 years because of
the increasing life expectancy of the American population. They concluded that screening for lung cancer may
benefit individuals at increased risk of lung cancer in that upper age group. More specifically, they found that
the survival benefits of aggressive therapy are similar in females between 55–74 and 75–84 years old.\textsuperscript{16}

It is essential to recognize that cancer risk continues to increase with advancing age and does not decrease at
age 77 or 80. Many of these individuals continue to be eligible for curative intent treatment with good outcomes
and a favorable prognosis.\textsuperscript{17} 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, including screening studies [e.g., International Early Lung
Cancer Action Program (I-ELCAP)].\textsuperscript{18} 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.\textsuperscript{19,20,21,22}

A person-centered approach is critical when addressing risks and benefits. While age and smoking history are
used for risk assessment, other potential risk factors for lung cancer can be identified during the informed
patient-provider discussion, including the overall health of the individual and comorbidities and their healthcare
values regarding ongoing screening. Both the ACS and NCCN guidelines endorse shared decision making (i.e.,
informed discussion) and recommend extending lung cancer screening for individuals who are likely to benefit

\textsuperscript{14} Andrew, Oeffinger, K. C., Shih, T., Walter, L. C., Church, T. R., Elizabeth T.H. Fontham, Elkin, E. B., Etzioni, R., Guerra, C. E., Perkins, R. B.,
\textsuperscript{15} NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice
N., Lipton, A., Ali, S. M., Richkesar P. M. Mahraj, Gilbert, C. R., & Yao, N. (2014). Would Screening for Lung Cancer Benefit 75- to 84-Year-
\textsuperscript{17} NCCN. (2023, October 18). NCCN Clinical Practice Guidelines in Oncology Lung Cancer Screening [Review of NCCN Clinical Practice
\textsuperscript{18} I-ELCAP Publications – I-ELCAP – IELCART. (n.d.). Retrieved June 14, 2024, from https://www.ielcap.org/home/ielcap/research/ielcap-
publications/
https://doi.org/10.1007/s00432-020-03154-5
stereotactic body radiation therapy for elderly patients aged ≥80 years with pathologically proven early-stage non-small cell lung cancer:
\textsuperscript{21} Gridelli, C., Peters, S., Velcheti, V., Attili, I., & de Marinis, F. (2023). Immunotherapy in the first-line treatment of elderly patients with
advanced non-small-cell lung cancer: results of an International Experts Panel Meeting by the Italian Association of Thoracic Oncology
\textsuperscript{22} Tsukita, Y., Tozuka, T., Kushiro, K., Hosokawa, S., Sumi, T., Uematsu, M., Honjo, O., Yamaguchi, O., Asao, T., Sugisaka, J., Saito, G.,
or Chemoimmunotherapy in Older Adults With Advanced Non–Small Cell Lung Cancer. JAMA Oncology.
https://doi.org/10.1001/jamaoncol.2023.6277
Our organizations strongly believe the existing shared decision making discussion is sufficient to offer this life-saving benefit to those that are 77 and beyond.

III. Statutorily Defined Benefit Category

Our joint societies recognize that to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage. Since January 1, 2009, and pursuant to §1861(ddd) of the Social Security Act, the Secretary may add coverage of "additional preventive services" if certain statutory requirements are met. We believe the following benefit category is probable or relevant and appropriate for the CMS NCD reconsideration request for low dose CT lung cancer screening.

42 CFR §410.64 Additional preventive services

Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Social Security Act) that these services are all of the following:

- Reasonable and necessary for the prevention or early detection of illness or disability.
- Recommended with a grade of A or B by the United States Preventive Services Task Force.
- Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

IV. Relevance, Usefulness, and Medical Benefits of Low Dose CT Lung Cancer Screening to the Medicare and Portions of the Medicaid Population

Low dose chest CT, as the only proven tool for the early detection of lung cancer to reduce lung cancer mortality, is a reasonable and necessary, noninvasive, CT exam that is straightforward and easy to perform with minimal patient effort required. In addition, CT systems are authorized by the Food and Drug Administration (FDA) with indications for low-dose lung cancer screening. We believe that CMS has the authority to update the NCD based on the current body of evidence, the updated ACS and NCCN guidelines, the CMS NCD General Methodological Principles, the impact and projected number of lives saved, and the medical appropriateness for additional individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

The effectiveness of low-dose CT lung cancer screening is remarkable, and current and emerging literature continue to provide further evidence of this lifesaving benefit. Henschke et al., in a November 2023 Radiology publication, concluded that the 10-year and 20-year lung cancer survival rate of 80% is sustained

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within the International-Early Lung Cancer Action Program (I-ELCAP) cohorts. Further, cancer epidemiology demonstrates a substantial reduction in lung cancer mortality since the initiation of lung cancer screening which has been the primary driver of record-breaking annual reductions in overall cancer mortality in the United States.

In addition, Flores et al. found that stage shift from later to earlier stage disease over the last decade was associated with improved mortality among people with lung cancer. Yang et al., looked at the association between improved survival and low dose CT screening and the diagnostic shift from late to early-stage of lung cancer, highlighting the importance of early detection. Ganti et al. evaluated the incidence, prevalence, survival, and initial treatment in patients with non-small cell lung cancer in the US and concluded that the increased incidence of stage I at diagnosis likely reflects improved evaluation of incidental nodules. Hendrick et al., found that the lung cancer screening benefits far outweigh the risks of future harms associated with exposure to radiation during screening and diagnostic follow-up tests. Low-dose CT lung cancer screening has progressed, is proven effective, and programs have been successfully implemented across settings, including community hospitals.

Summary

Lung cancer is the leading cause of cancer death and accounts for about 1 in 5 of all cancer deaths. The ACS estimates over 125k lung cancer deaths in 2024 in the United States, a figure that is greater than the mortality rates of colon, breast, and prostate cancers combined. Every year, a staggering number of Americans die from a disease that is preventable, treatable, and even curable. Screening uptake is slowly increasing but remains low. In a recent study, the 2022 LCS prevalence was 16.4% and 19.6% using 2021 and 2013 USPSTF criteria. It is important that CMS and other government agencies quickly act to remove artificial barriers for individuals who would benefit from screening.

Our joint societies applaud CMS for expanding the lung cancer screening eligibility criteria in 2022. We strongly recommend and support an expedited and prioritized NCD reconsideration to remove specific screening risks.

eligibility criteria that remain a barrier to individuals at high risk for lung cancer. These changes would align with the current and compelling evidence-based guidelines from the ACS and NCCN. Specifically, we advocate removing the 15 years since quitting smoking and upper age criteria.

Thank you for this opportunity to help save millions of lives by expanding lung cancer screening.

Sincerely,

Laurie Fenton Ambrose  
Co-Founder, President and CEO  
GO2 for Lung Cancer

Jennifer C. Romano, MD, MS  
President  
The Society of Thoracic Surgeons

William T. Thorwarth Jr., MD, FACR  
Chief Executive Officer  
American College of Radiology

Cc: Scientific Leadership Board