VIA ELECTRONIC FILING

June 17, 2021

Kimberly Long
Lead Analyst
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

Re: **National Coverage Analysis (NCA) for Screening for Lung Cancer with Low-Dose Computed Tomography (LDCT) (CAG-00439R)**

Dear Ms. Long:

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 235,760 Americans diagnosed with lung cancer each year and the estimated 582,631 Americans living with the disease,[1] we are writing in response to the reopening of the National Coverage Determination (NCD) on lung cancer screening (LCS) by the Centers for Medicare and Medicaid Services (CMS). LUNGevity Foundation has had a long-standing focus on the early detection of lung cancer, and we have strategically invested in both translational and implementation sciences research to increase lung cancer screening and early detection.

Lung cancer continues to be the largest cause of cancer-related mortality in the United States.[1] When detected at an early stage, the 5-year relative survival is 59.8%. Only 18% of lung cancer cases will be diagnosed at the localized stage, where curative surgery is available.[1] In contrast, 56% of lung cancer cases are diagnosed in the metastatic setting, which has a 5-year relative survival of 6.3%.

LDCT screening for the early detection of lung cancer is a promising technology for the early detection of lung cancer. The National Lung Screening Trial clearly demonstrated that use of LDCT led to a 20% decrease in mortality from lung cancer in the LDCT group, compared with the radiography group.[2] Based on the NLST results, the US Preventive Services Task Force (USPSTF) recommends lung cancer screening. In 2015, CMS approved

coverage of LDCT screening for lung cancer screening, providing the following criteria were met:

- Age 55 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 30 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
- Receives a written order for LDCT lung cancer screening, including certification that before beneficiary's first lung cancer LDCT screening, the beneficiary has received counseling and shared decision-making visit

Despite CMS' decision to cover lung cancer screening, a 2019 study showed that only a small proportion (approximately 2%-16%) of eligible patients were being screened.[3] In light of new evidence, the USPSTF Recommendation Statement on screening for lung cancer updated their initial recommendations from 2015, which now state "***annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery***."[4]

We support the request by the GO2 Foundation for Lung Cancer, The Society of Thoracic Surgeons, and the American College of Radiology® ("the requesters") for CMS to reconsider the existing February 2015 NCD on Screening for Lung Cancer with LDCT (CAG-00439N) in light of the updated USPSTF grade B recommendation. Specifically, we urge CMS to implement the following recommendation to reduce the challenges currently seen with lung cancer screening.

Lower the minimum age for LCS eligibility to age 50 from the current 55, and the required smoking history to 20 pack-years from the current 30 pack-years to match new USPSTF criteria

Implementation of the 2021 USPSTF guidelines will strategically increase screening access for different populations (for example, **African Americans** and **women),** who would remain ineligible by the 2013 guidelines.

- In a recent cohort study looking at of 48,364 adult smokers in the United States, it was found that a larger percentage of African Americans were diagnosed with lung

cancer, compared to Whites. When the 2013 USPSTF criteria were applied, a majority of African American patients did not qualify for lung cancer screening because they had a lower pack-year history, compared to Whites (17% vs. 31%, respectively). The same study found that African American smokers diagnosed with lung cancer had significantly lower median smoking pack-years compared with White smokers, and were also diagnosed with lung cancer at an earlier age. The authors reported that "***modifying the minimum age to 50 years for African American smokers would increase the percentage eligible for screening and also allow detection of earlier-stage disease that would otherwise be missed with the present age minimum of 55 years.***"[5] Furthermore, decreasing the pack-year requirement from 30 pack-years to 20 pack-years would correct for the lower pack-year history seen in African Americans, making screening more accessible and decreasing screening disparities between Whites and African Americans by expanding eligibility by 107% for African Americans.[6]

- It is well known that women start smoking at an older age compared to men and smoke fewer cigarettes per day, leading to cumulative fewer pack-years compared to men.[7] A recent study in the *New England Journal of Medicine* demonstrated that despite a decline in smoking prevalence in women since 1965, there has been an increase in the incidence of lung cancer in women (specifically in White and Hispanic women), compared to men. Application of the 2021 USPSTF guidelines would expand eligibility by 96% for women, thereby increasing the potential of early detection of lung cancer in women.[6]

As described above, the 2021 USPSTF guidelines have the potential to bridge existing health disparities and also allow a slightly younger population with a lower pack-year history to derive benefits of lung cancer screening. For LDCT to become a public health good, we urge the CMS to align reimbursement criteria with the 2021 USPSTF guidelines.

Eliminate the maximum 15 years since quitting (YSQ) limitation for screening eligibility among those who formerly smoked

Currently, individuals who have had 15 or more YSQ (currently **ineligible** for screening) but averaged 45 pack-years of smoking have risk similar to that of individuals who used to smoke who have a history of >30 pack-years and have had <15 YSQ (currently **eligible** for screening), after adjusting for other risk factors.[8] The Framingham Heart study showed that 40.8% of all lung cancers seen in the study had occurred in those who had ever smoked and had quit smoking for more than 15 years.[9] A retrospective study looking at the implications of the 2013 USPSTF screening criteria in a well-defined cohort (1984 through 2011) of individuals found that the proportion of lung cancer patients who smoked more than 30

pack-years declined, while the proportion of former smokers, especially those who quit smoking more than 15 years ago, increased, especially the number of women.[10] Together, these findings suggest that eliminating the maximum YSQ limitation will expand the benefits of screening to those who are still at risk of developing lung cancer but remain currently ineligible.

Remove Counseling and Shared Decision Making (SDM) as a condition for LCS coverage and reimbursement. SDM should be integrated into discussion of screening with patients, but not be a rigid reimbursement requirement, which creates a referral barrier and is not required with other recommended cancer screenings.

SDM is an excellent opportunity for patient-centered care.[11] LUNGevity Foundation firmly believes that all patients should be empowered with knowledge on the risks and benefits of lung cancer screening. Currently, CMS mandates a shared decision-making engagement with all lung cancer screening-eligible beneficiaries.

However, there are several barriers to conducting SDM in a patient-centric manner. Several studies have noted that primary-care providers feel ill-equipped to conduct SDM.[12,13] Physicians also noted other barriers such as insufficient time, competing clinical priorities, difficulty accessing SDM aids, limited patient comprehension, and anticipated patient emotions.[12,14] Furthermore, current SDM aids are written above the recommended sixth-grade reading level advised by the American Medical Association and are largely written for English speakers. There is a paucity of SDM aids that are culturally appropriate for diverse populations. In addition, current decision aids do not take into account a patient's numeracy skills, which impact how a patient will make an informed decision based on the SDM visit.[15-17]

Given the complexity of SDM, we agree with the requesters' suggestion on bundling the SDM with the actual LDCT event. This bundling would ensure that the SDM occurs in a dedicated radiology clinic with staff who are well-versed in SDM and have access to standardized information to conduct SDM in a patient-centric fashion.

In summary, LUNGevity urges CMS to reconsider the existing February 2015 NCD on Screening for Lung Cancer with LDCT (CAG-00439N) in light of the updated USPSTF grade B recommendation and increase coverage to CMS beneficiaries, as per the requesters' suggestions. The comments outlined above can be discussed with me, my staff, and LUNGevity's Scientific Advisory Board, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care. I can be reached at 240-454-3100 or aeferris@LUNGevity.org if you have any questions or would like to engage in further dialogue.

Thank you for your attention to this important matter.

Sincerely,

Andrea Stern Ferris
President and Chief Executive Officer
LUNGevity Foundation

ABOUT LUNGEVITY:

LUNGevity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

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