



December 16, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: Reconsideration—Proposed National Coverage Determination for Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (CAG-00439R)

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to provide comments on the reconsideration of the Proposed National Coverage Determination for Lung Cancer Screening with Low Dose Computed Tomography (LDCT).

The American Lung Association is the oldest voluntary public health association in the United States, representing the millions of Americans living with lung diseases, including lung cancer. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

In 2021, an estimated 235,760 new cases of lung cancer are expected to be diagnosed.<sup>1</sup> Lung cancer remains the leading cause of cancer deaths, with 131,880 deaths expected in 2021.<sup>2</sup> The Lung Association strongly supports lung cancer screening for high-risk populations as early detection and treatment improves the chances of survival. Screening individuals at high risk is essential to saving lives, particularly since lung cancer is typically found in the later stages and has an overall 5-year survival rate of only 21.8%.<sup>3</sup>

The Lung Association remains concerned about the low uptake of lung cancer screening. The Lung Association is committed to continuing to improve lung cancer screening rates for the high-risk population in Medicare by educating patients, providers and policymakers about eligibility for screening and addressing other challenges and barriers to improving utilization.

In February 2015, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination for lung cancer screening with LDCT for individuals who are between the ages of 55 and 77, have a tobacco smoking history of at least 30 pack-years, currently smoke or have quit within the last 15 years, are asymptomatic (no signs or symptoms of lung cancer), and receive a written order for lung cancer screening with LDCT. Since that time,

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<sup>1</sup> Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2021. CA: A Cancer Journal for Clinicians. 2021.

<sup>2</sup> *Id.*

<sup>3</sup> US National Institutes of Health, National Cancer Institute, SEER Cancer Statistics Review 1975-2017. Available at: [https://seer.cancer.gov/csr/1975\\_2017/](https://seer.cancer.gov/csr/1975_2017/).

additional scientific evidence has become available that strongly supports the expansion of this eligibility criteria, as well as other updates to Medicare's coverage policy. The Lung Association offered comments on updating the national coverage determination for lung cancer screening during the June 2021 comment period<sup>4</sup> and is pleased to offer the following recommendations on the proposed decision memo:

#### **Age Range**

The Lung Association supports CMS' proposal to lower the age for individuals to start screening from 55 to 50 years, but urges CMS to raise the upper age limit from 77 to 80 years as well. In March 2021, the United States Preventive Services Task Force (USPSTF) finalized an update to its 2013 recommendation for lung cancer screening for individuals at high risk, expanding eligibility to individuals between the age of 50 and 80.

Lowering the age range would be an important step forward in addressing racial disparities associated with lung cancer. For example, Black individuals have a younger average age of onset of lung cancer and are more likely to be diagnosed at advanced stages compared to white individuals.<sup>5</sup> Lowering the age of eligibility for screening from 55 to 50 years will therefore be critical in improving early detection for this and other populations at high risk for lung cancer.

The Lung Association urges CMS to increase the upper age limit to 80 years to match the USPSTF guidelines. USPSTF has a rigorous, evidenced-based process for developing and updating all of its recommendations. As part of its update to the 2013 recommendation for lung cancer screening, USPSTF commissioned a systematic evidence review that included over 223 publications.<sup>6</sup> USPSTF also commissioned modeling studies to examine key variables, including various ages to begin and end screening.<sup>7</sup> These studies provide a strong rationale for CMS to adopt the expanded age range of 50 to 80 years for lung cancer screening.

Aligning eligibility criteria between USPSTF and Medicare could also help to address low uptake of lung cancer screening. According to the American Lung Association's 2021 State of Lung Cancer Report, only 5.7% of those at high risk were screened nationally.<sup>8</sup> Standardizing guidelines across different payers would simplify efforts to educate providers, patients and other stakeholders about the eligibility criteria and facilitate screening for more individuals at high risk.

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<sup>4</sup> American Lung Association Comments to CMS re National Coverage Analysis for Lung Cancer Screening. June 17, 2021. Available at: [https://www.lung.org/getmedia/ca77747d-bc6e-43e2-ae42-bb08ccb7f18b/american-lung-association-comments-medicare-lung-cancer-ncd-\(final\).pdf](https://www.lung.org/getmedia/ca77747d-bc6e-43e2-ae42-bb08ccb7f18b/american-lung-association-comments-medicare-lung-cancer-ncd-(final).pdf).

<sup>5</sup> Annangi, S., Nutalapati, S., Foreman, M.G. et al. Potential Racial Disparities Using Current Lung Cancer Screening Guidelines. *J. Racial and Ethnic Health Disparities* 6, 22–26 (2019).

<sup>6</sup> Jonas DE, Reuland DS, Shivani SM, et al. Screening for lung cancer with low-dose computed tomography: updated evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. Published March 9, 2021. doi:10.1001/jama.2021.0377

<sup>7</sup> Meza R, Jeon J, Toumazis I, et al. Evaluation of the benefits and harms of lung cancer screening with low-dose computed tomography: modeling study for the US Preventive Services Task Force. *JAMA*. Published March 9, 2021. doi:10.1001/jama.2021.1077

<sup>8</sup> American Lung Association. State of Lung Cancer Report. 2021. Available at: <https://www.lung.org/research/state-of-lung-cancer/key-findings>.

### *Pack Year History*

The Lung Association supports the recommendation to lower the pack year eligibility for lung cancer screening from 30 pack years to 20 pack years. This change was also included in the final USPSTF recommendation after the thorough review process mentioned above. In particular, results from the NELSON trial, which enrolled individuals with less than 30 pack year histories (half of a pack per day for more than 30 years or three-fourths of a pack per day for more than 25 years), confirm the benefits of screening for individuals with lighter pack year histories.<sup>9</sup>

Additionally, as with the decrease in the eligibility age from 55 years to 50 years mentioned above, research has shown that the decrease in the pack year history from 30 to 20 years is especially important to improve early detection and survival rates among Black individuals.<sup>10</sup> Data also show that Latino and Hispanic smokers have fewer pack year histories than white smokers, suggesting that reducing the pack year threshold will particularly benefit these populations as well.<sup>11</sup>

### *Continuing Screening 15 Years After Quitting*

The Lung Association believes that there is strong evidence to support including patients who have quit smoking for more than 15 years in CMS' final eligibility criteria. Since 2015, multiple studies have concluded that that there are benefits of screening beyond the 15-year cut-off.<sup>12,13,14,15</sup> For example, one recent meta-analysis concluded that "at the critical screening threshold of 15 years since quitting, the percentage of excess risk for lung cancer remains high and only marginally declines at time points afterward, excluding millions of former smokers who

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<sup>9</sup> de Koning HJ, van der Aalst CM, de Jong PA, et al. Reduced lung-cancer mortality with volume CT screening in a randomized trial. *N Engl J Med.* 2020;382(6):503-513. doi:10.1056/NEJMoa1911793

<sup>10</sup> Aldrich MC, Mercaldo SF, Sandler KL, Blot WJ, Grogan EL, Blume JD. Evaluation of USPSTF Lung Cancer Screening Guidelines Among African American Adult Smokers [published online ahead of print, 2019 Jun 27] [published correction appears in *JAMA Oncol.* 2019 Aug 1;]. *JAMA Oncol.* 2019;5(9):1318-1324.

<sup>11</sup> Kaplan RC, Bangdiwala SI, Barnhart JM, et al. Smoking among U.S. Hispanic/Latino adults: the Hispanic community health study/study of Latinos. *Am J Prev Med.* 2014;46(5):496-506. Medline:24745640 doi:10.1016/j.amepre.2014.01.014

<sup>12</sup> Luo YH, Luo L, Wampfler JA, et al. 5-year overall survival in patients with lung cancer eligible or ineligible for screening according to US Preventive Services Task Force criteria: a prospective, observational cohort study. *Lancet Oncol.* 2019;20(8):1098-1108. doi:10.1016/S1470-2045(19)30329-8

<sup>13</sup> Wang Y, Midthun DE, Wampfler JA, et al. Trends in the Proportion of Patients With Lung Cancer Meeting Screening Criteria. *JAMA.* 2015;313(8):853-855. doi:10.1001/jama.2015.413;

<sup>14</sup> McKee BJ, Regis S, Borondy-Kitts AK, Hashim JA, French Jr RJ, Wald C, McKee AB. NCCN Guidelines as a model of extended criteria for lung cancer screening. *J Natl Compr Canc Netw.* 2018;16:444-449. doi:10.6004/jnccn.2018.7021;

<sup>15</sup> Tindle HA, Stevenson Duncan M, Greevy RA, et al. Lifetime Smoking History and Risk of Lung Cancer: Results From the Framingham Heart Study [published correction appears in *J Natl Cancer Inst.* 2018 Oct 1;110(10):1153]. *J Natl Cancer Inst.* 2018;110(11):1201-1207. doi:10.1093/jnci/djy041

remain at elevated risk of malignancy.<sup>16</sup> The Lung Association urges CMS to include patients who have quit smoking for more than 15 years in the final eligibility criteria.

#### *Shared Decision-Making Visit*

In our June 2021 letter, the Lung Association urged CMS to consider whether there were improvements that could be made to the shared-decision making process to reduce administrative and other requirements that create barriers to broad access to the lung cancer screening benefit. The proposed decision memo includes changes removing the restriction for the type of practitioner who can furnish the counseling and shared decision-making visit, removing the specificity of redundant documentation requirements and eliminating the requirement for a written order. The Lung Association supports these changes and believes they will be a step forward in addressing the barriers to broader uptake of lung cancer screening by individuals at high risk.

#### *Registry*

Finally, the Lung Association has concerns with CMS' proposal to remove the requirement that radiology imaging facilities collect and submit data to a CMS-approved low dose CT lung cancer screening registry. This requirement supports collection of a common, minimum set of data elements for purposes of continued research and evaluation of lung cancer screening. The Lung Association believes it is still beneficial to incentivize this data collection in order to facilitate additional research on lung cancer screening, including additional expansions of eligibility criteria. We encourage CMS to consider alternative approaches to reducing the financial and other burdens of the current requirement while still preserving this critical data collection.

#### *Conclusion*

The number one strategic imperative of the American Lung Association is to defeat lung cancer, and expanding screening for those at high risk is critical to improving survival rates. The Lung Association urges CMS to expand eligibility for lung cancer screening to individuals ages 50 to 80 years old and who have a tobacco smoking history of at least 20 pack-years, as well as include patients who have quit smoking for more than 15 years. Thank you for considering our comments.

Sincerely,



Harold P. Wimmer  
National President and CEO

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<sup>16</sup> Reitsma M, Kendrick P, Anderson J, et al. Reexamining Rates of Decline in Lung Cancer Risk after Smoking Cessation: A meta-analysis [published online ahead of print, 2020 Jun 30]. *Ann Am Thorac Soc*. 2020;10:1513/AnnalsATS.201909-659OC. doi:10.1513/AnnalsATS.201909-659OC