AMERICAN LUNG ASSOCIATION®
Fighting for Air

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Joseph Chin, MD, MS
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: National Coverage Analysis on Lung Cancer Screening with Low Dosed Computed Tomography (CAG-00439N)

Dear Dr. Chin:

The American Lung Association appreciates the opportunity to submit the following comments regarding the open National Coverage Analysis on lung cancer screening with low dosed computed tomography (CT). The American Lung Association's comments are respectfully submitted and intended to wholeheartedly support a National Coverage Determination aligned with a minimum of the U.S. Preventative Services Task Force (USPSTF) recommendation for lung cancer screening.

Lung cancer screening with low-dose CT scans has been shown to save lives. According to the National Cancer Institute's National Lung Cancer Screening Trial (NLST), the receipt of three annual low dose CT scans was associated with a 20 percent decrease in mortality in those at highest risk of cancer. Recognizing this, the U.S. Preventive Services Task Force (USPSTF) released a recommendation on December 30, 2013 that certain high-risk populations be screened for lung cancer using this method. Most of the individuals in the high-risk population identified in the USPSTF recommendation are of the age that qualifies them for Medicare. **As such, the Lung Association strongly encourages CMS to include low-dose CT scans for lung cancer screening among Medicare's covered services for high risk-groups designated by USPSPTF at a minimum.** Coverage of low dose CT scans for lung cancer screening under Medicare will give high risk patients access to the only secondary prevention method currently available.

The American Lung Association believes that secondary prevention in the form of screening to find lung cancer in an early, curable stage will significantly improve survivability, giving patients and loved ones their first bit of hope when hearing the diagnosis of lung cancer. It is hoped that one day lung cancer will have similar survival rates to that of breast and prostate cancer; two other types of cancer with available screening modalities covered by various insurance companies and Medicare.

While lung cancer screening is a promising clinical strategy for the detection of pre-symptomatic lung cancer in individuals at the highest risk, it remains an emerging issue. The American Lung Association anticipates that additional subgroups such as chronic obstructive pulmonary disease (COPD) patients and certain occupational groups will eventually be considered good candidates for CT screening. The American Lung Association urges coverage for the high risk populations identified by the National Lung Screening Trial (NLST) and USPSTF as soon as possible, and for CMS to be flexible and amenable to change in coverage decisions in light of any new findings so that access to these screenings is expanded as appropriate for all people considered to be at high risk for lung cancer.

The Lung Association further implores CMS to contribute to the advances in lung cancer screening by collecting and making available much needed data on how screening is actually implemented under real world conditions. While the NLST shows screening for lung cancer among this high risk population will save lives, there are many things still to learn about other high risk populations who also might benefit. While the American Lung Association looks forward to additional discussions with CMS about the collection of specific data and measures, we also caution against creating potential barriers to screening.

American Lung Association Screening Recommendations

In 2012, the American Lung Association's Lung Cancer Screening Committee, chaired by Jonathan M. Samet, M.D., M.S., Director, University of Southern California's Institute for Global Health and Professor and Flora L. Thornton Chair, Department of Preventive Medicine, released guidelines to assist physicians and their patients in discussions about lung cancer screening. The guidelines echoed the call of the NLST and urged annual low-dose CT screens for the populations at greatest risk for developing lung cancer. The American Lung Association's guidelines (linked here and executive summary attached) emphasize the need for health professional and patient education on the benefits and risks of screening as well as the need for screening to be linked to multidisciplinary teams that can provide the best evaluation and follow-up on positive results.

The USPSTF identifies a slightly broader list of individuals who meet a "high risk" criteria and would be best served by an annual low-dose CT screen. The American Lung Association, at a minimum, recommends the broader population recommended by USPSTF.

Emphasis on Helping Smokers Quit

The American Lung Association wishes to acknowledge the important question asked by CMS in its request for comment regarding cessation. In order to maximize the number of lives saved and reduce the risk of more people developing lung cancer, part of this multidisciplinary approach must include a focus on tobacco cessation for patients who are still smoking. It is important that every patient be asked about tobacco use at every visit and the same holds true for every patient who is screened or discusses being screened with his or her physician. Clinicians may be hesitant to address the topic but tobacco users expect to be asked and will respond to sensitive, yet clear, advice to quit. This must be followed by referral to easily accessible evidence-based tobacco cessation services.

Medicare already covers a cessation benefit – with prescription tobacco cessation medications and eight sessions of individual cessation counseling per year. The American Lung Association urges CMS to integrate tobacco use screening and cessation treatments into the screening process for lung cancer – whether or not a patient ultimately meets the high risk criteria and qualifies for annual lung cancer screening.

Importance of No Cost-Sharing
The American Lung Association also urges CMS to ensure that lung cancer screenings delivered to the identified high risk populations are truly delivered with no cost-sharing to the patient. We are concerned about reports of insurance companies and screening centers charging "facility fees" to patients, which are technically outside the cost of the screening and therefore allowed. CMS must ensure that all aspects of the screening process are truly free to Medicare patients who qualify in order to maximize the number of lives saved.

Proposal Elicits Strong Response from Lung Cancer Patient Advocates
The American Lung Association offered lung cancer advocates the opportunity to weigh in with Medicare about the importance of screening for those at highest risk of developing lung cancer. Over 1,100 advocates took action and their comments are attached to these comments.

The American Lung Association urges CMS to move with all deliberate speed to finalize this National Coverage Analysis so that individuals in the high risk population identified in the USPSTF recommendation can begin to receive this preventive annual lung cancer screening with no cost-sharing.

Sincerely,

Harold Wimmer
National President and CEO

Attachment 1: American Lung Association – Providing Guidance on Lung Cancer Screening to Patients and Physicians (April 23, 2012)

Attachment 2: Personal Stories from Lung Cancer Advocates on the Importance of Screening

Attachment 3: Additional Comments to CMS regarding Screening

Providing Guidance on Lung Cancer Screening To Patients and Physicians

April 23, 2012

Executive Summary

Lung cancer is the leading cause of cancer death in both men and women in the United States. The disease has been closely associated with smoking since 1964, when the first Surgeon General's report concluded that tobacco smoke was a cause of lung cancer. Today, smoking is thought to cause up to 80-90 percent of lung cancer cases.

The American Lung Association (ALA) has been influential in strengthening laws and policies that protect everyone from secondhand smoke, preventing young people from starting and helping smokers quit with our smoking cessation programs. However, there remains the need to implement a comprehensive clinical strategy that assists in reducing the burden of lung cancer and increasing the significantly low survival rates. The five-year survival rate for lung cancer currently stands at 15.6 percent as compared to an over 90 percent survival rate for breast, colon and prostate cancers.

A clinical strategy for lung cancer that has showed promise is low dose computed tomography (CT) screening. The purpose of a CT screening test is to identify the presence of cancer in an individual that does not demonstrate any symptoms. In August of 2011, the National Cancer Institute released results from its National Lung Screening Trial (NLST), a randomized clinical trial that screened at-risk smokers with either low dose CT or standard chest x-ray. The study found that screening individuals with low dose CT scans could reduce lung cancer mortality by 20 percent compared to chest x-ray.

These exciting results led the ALA to reexamine their organization's current policy on lung cancer screening. As such, the ALA convened a Lung Cancer Screening Committee, chaired by Jonathan Samet, MD, MS, to review the current scientific evidence on cancer screening in order to assist the ALA in offering the best possible guidance to the public and those suffering from lung disease. This document is the first report of the American Lung Association Lung Cancer Screening Committee.

This report provides a comprehensive review of the available evidence on both the benefits and risks of lung cancer screening, as well as highlights areas where more research is needed. The Committee acknowledges that cancer screening is associated with both benefits and risks and unfortunately, the NLST could not answer a number of questions on the advantages and safety of screening in the general population. In spite of this, the Committee provides the following interim recommendations:

- The best way to prevent lung cancer caused by tobacco use is to never start or quit smoking.
- Low-dose CT screening should be recommended for those people who meet NLST criteria:
  - current or former smokers, aged 55 to 74 years
  - a smoking history of at least 30 pack-years

    - no history of lung cancer
- Individuals should not receive a chest X-ray for lung cancer screening
- Low-dose CT screening should NOT be recommended for everyone
- ALA should develop public health materials describing the lung cancer screening process in order to assist patients in talking with their doctors. This educational portfolio should include information that explains and clarifies for the public:
    - the difference between a screening process and a diagnostic test
    - the benefits, risks and costs (emotional, physical and economic)
    - that not all lung cancers will be detected through use of low dose CT scanning
- A call to action should be issued to hospitals and screening centers to:
    - establish ethical policies for advertising and promoting lung cancer CT screening services
    - develop educational materials to assist patients in having careful and thoughtful discussions between patients and their physicians regarding lung cancer screening
    - provide lung cancer screening services with access to multidisciplinary teams that can deliver the needed follow-up for evaluation of nodules.

Our hope is that this report will serve ALA well in its mission to guide the public on this very important personal and public health issue. We believe that the report, and the educational materials that stem from it, will be invaluable to the tens of million people at risk for lung cancer.

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