



The Society
of Thoracic
Surgeons



March 9, 2021

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Attn: Coverage and Analysis Group
Centers for Medicare and Medicaid Services
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ncdrequest@cms.hhs.gov

Re: Formal Reconsideration Request for [National Coverage Determination on Screening for Lung Cancer with Low Dose CT](#) - CAG-00439N

Dear Ms. Jensen and Dr. Chin:

The GO₂ Foundation for Lung Cancer, The Society of Thoracic Surgeons, and the American College of Radiology® (ACR®), formally request the Centers for Medicare and Medicaid Services (CMS) reconsider the existing Feb. 2015 National Coverage Determination (NCD) on Screening for Lung Cancer with Low Dose CT (CAG-00439N) in light of the updated [U.S. Preventive Services Task Force \(USPSTF\) grade B recommendation](#) that expands low dose CT lung cancer screening risk criteria. In addition, CMS should consider scientific evidence for this screening test relevant to the Medicare population that was not reviewed by CMS during the initial NCD and presented at a subsequent date.

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. 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. 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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Lung cancer screening (LCS) with low dose CT (LDCT) is recommended by the USPSTF with a grade B recommendation for certain individuals. The USPSTF (five-year review) updated its Dec. 2013 recommendation for this preventive service.

Given the impact, the updated USPSTF recommendations could have on the Medicare population's lung cancer diagnosis and death rate prevalence, we request that CMS reconsider the LDCT lung cancer screening NCD CAG-00439N and update the policy accordingly. The updated USPSTF screening recommendation included a systematic evidence review on the accuracy of screening for lung cancer with LDCT, an assessment of the benefits and harms of screening for lung cancer, as well as collaborative modeling studies from Cancer Intervention and Surveillance Modeling Network (CISNET) addressing the optimum age to begin screening, the optimum screening interval, and the relative benefits and harms of different screening strategies.

We urge CMS to:

1. Consider updating the NCD to reflect the recent USPSTF grade B recommendation that expands annual lung cancer screening with low dose CT by **lowering the start age** and **smoking pack-year** eligibility criteria;
2. Revise its screening risk criteria to mirror the National Comprehensive Cancer Network (NCCN) 2021 Lung Cancer Screening Guidelines;
3. Revise Counseling and Shared Decision Making criteria; and
4. Clarify requirements for Medicare Administrative Contractors (MACs) to cover and reimburse LDCT lung cancer screening performed in all facilities and specifically Independent Diagnostic Testing Facilities (IDTFs).

Per the [Federal Register Notice](#) regarding the Medicare Program, Revised Process for Making Medicare National Coverage Determinations, Section IV. B-J, instructions for the Formal Reconsideration Request of an Existing NCD, listed below are the key areas our joint societies have included in this NCD (CAG-00439N) reconsideration request:

- I. Relevance, Usefulness, and Medical Benefits of LDCT LCS to the Medicare Population
- II. Statutorily Defined Benefit Category
- III. Design, Purpose, and Method of Lung Cancer Screening with LDCT
- IV. NCD reconsideration recommendations per the USPSTF regarding annual LDCT lung cancer screening risk criteria: **revise and lower** the screening eligibility age to 50 years and smoking history criteria to 20 pack-years in the Medicare population
- V. NCD reconsideration recommendations to **revise** the following key areas to safeguard against barriers in LDCT lung cancer screening uptake in the Medicare population:
 - **Eliminate** the annual screening eligibility criteria: current smoker or one who has quit smoking within the last 15 years per NCCN guidelines
 - **Eliminate** the annual screening eligibility criteria: upper age limitation to 77 years per NCCN guidelines

- **Revise** the “Counseling and Shared Decision Making (SDM)” NCD criteria to ensure the current language and requirements do not act as a barrier to screening uptake
- **Formally instruct** all Medicare Administrative Contractors (MACs) to cover/reimburse LDCT performed in all facilities, including Independent Diagnostic Testing Facilities (IDTFs)

I. **Relevance, Usefulness, and Medical Benefits of LDCT LCS to the Medicare and Portions of the Medicaid Population**

Over [135K lung cancer deaths](#) will occur in 2020 in the United States alone, a figure that is greater than the mortality rates of breast, prostate, and colon cancer combined.^{1,2} Every year, a staggering number of people die from lung cancer, which remains the number one cancer killer in the U.S. and worldwide.

Lung cancer is the second most common type of cancer in the United States. In 2020, an estimated 228,820 Americans were diagnosed with lung cancer.³ Lung cancer remains the leading cause of cancer for both women, men, African Americans, and every racial and ethnic subgroup.

LCS LDCT is the only procedure proven to reduce lung cancer mortality in individuals at high-risk for lung cancer. Commonly, lung cancer is tied to a poor prognosis: just 10% of patients have a 5-year survival rate when diagnosed at a later stage. However, when diagnosed at an early stage, lung cancer is more responsive to treatments and patients have a much better prognosis with an increased 5-year survival rate of up to 90%.^{4,5}

Evidence is sufficient to conclude that lung cancer screening with LDCT is reasonable and necessary for the prevention or early detection of illness or disability and appropriate for Medicare beneficiaries under the conditions recommended by the NCCN. 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 evidence for lung cancer screening across the Medicare population and beyond. Additionally, the evidence review and screening recommendation by the USPSTF (five-year review update) supports the benefits of LDCT lung cancer screening outweigh harms in the Medicare population.

¹ <https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html>

² [Recommendation: Lung Cancer: Screening | United States Preventive Services Taskforce \(uspreventiveservicestaskforce.org\)](#).
[Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement | Cancer Screening, Prevention, Control | JAMA | JAMA Network](#).

³ National Cancer Institute. Cancer Stat Facts: Lung and Bronchus Cancer. <https://seer.cancer.gov/statfacts/html/lungb.html>.

⁴ <https://seer.cancer.gov/statfacts/html/lungb.html>

⁵ Knight SB, Crosbie PA, Balata H, et al. Progress and prospects of early detection in lung cancer. [Open Biol.](#) 2017 Sep; 7(9): 170070. Published online 2017 Sep 6. doi: [10.1098/rsob.170070](https://doi.org/10.1098/rsob.170070).

It is important to underscore that studies have shown the majority of patients, up to two-thirds of those newly diagnosed with lung cancer, were not included in the Dec. 2013 USPSTF risk criteria.^{6,7} Cheung et al. analyzed the eligible screening population between CY 2010 and 2015 based on the Dec. 2013 USPSTF lung cancer screening criteria and concluded preventable lung cancer deaths averted under these criteria decreased by 6.3 percent (8,122 fewer deaths averted in 2015 than 2010). The eligible screening population decreased from 9.5 million in 2010 to 8.0 million in 2015 due to decreases in smoking prevalence and intensity.⁸

The USPSTF updated recommendations, with expanded lung cancer screening risk criteria, is a vital step in the right direction but much work is still needed. While the updated USPSTF recommendation more closely resembles the NCCN lung cancer guideline with a lowered screening age starting at 50 years and a 20 pack-year smoking history, NCCN eliminates the 15-year quit smoke date and upper age cut-off within their screening criteria. NCCN lung cancer screening guidelines are medically appropriate criteria for the higher at-risk Medicare population and remove screening uptake barriers.

Given the magnitude of lung cancer deaths across the United States population, and that lung cancer has both the highest cancer death rate, a responsible and equitable plan for **expanded** Medicare coverage of screening is needed for the at-risk populations. Our joint societies urge CMS to expand and revise the LDCT lung cancer screening NCD.

If CMS were to expand the NCD risk criteria, we could save 30,000–60,000 lives in the United States each year.⁹ This cost-effective lung cancer screening test could save more lives than any cancer screening test in history.

II. 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

⁶ Wang Y, Midthun DE, Wampfler JA, et al. Trends in the proportion of patients with lung cancer meeting screening criteria. *JAMA*. 2015;313:853–5.

⁷ 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.

⁸ Cheung LC. Preventing Lung Cancer Mortality by Computed Tomography Screening: The Effect of Risk-Based Versus U.S. Preventive Services Task Force Eligibility Criteria, 2005–2015. *Annals of Internal Medicine*. LETTERS Annals.org. 2 January 2018.

⁹ <https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html>.

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.

Low dose chest CT, as the only proven tool for the early detection of lung cancer, is reasonable and necessary. The CT is easy to perform, non-invasive and tolerated very well by patients.

The USPSTF recommends annual screening for lung cancer with low-dose CT 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. In addition, NCCN lung cancer screening guidelines recommend the same lower age and pack-year smoking history for their recommended screening risk criteria but with no upper age limitations and no quit smoking history.

Lung cancer screening with LDCT is recommended with a grade B by the USPSTF. Based on the results of the National Lung Screening Trial (NLST), Nederlands-Leuvens Longkanker Screenings Onderzoek (NELSON) trial, the revised USPSTF grade B recommendation and analysis, NCCN guidelines, as well as other studies and body of literature, recommendations, and guidelines from major organizations, patient advocacy groups, and stakeholders, **the evidence is sufficient to determine that screening for lung cancer with LDCT is reasonable and necessary for the prevention or early detection of illness or disability for the Medicare population age 50 years and beyond with a 20 pack-year smoking history.**

Based on the results of the sources cited, lung cancer screening using LDCT is shown to reduce lung cancer mortality compared to screening with chest radiogram (x-ray) for the defined Medicare population age 50 years and beyond with a 20 pack-year smoking history.

III. Design, Purpose, and Method of Lung Cancer Screening with LDCT

In addition to our joint society comments and request, please refer to the updated USPSTF grade B recommendation for screening for lung cancer with low dose CT, NCCN 2021 Lung Cancer Screening Clinical Practice Guidelines in Oncology, and the Feb. 2015 CMS NCD CAG-00439N. These include scientific evidence, clinically relevant data, relevance to LDCT lung cancer screening, as well as the design, purpose, and method of lung cancer screening with LDCT directly impacting the Medicare population.

IV. Our joint societies recommend that CMS revise and lower the Medicare beneficiary screening eligibility age to 50 years and smoking history criteria to 20 pack-years for annual lung cancer screening with LDCT

These recommended revisions are consistent with the recently updated USPSTF recommendation that lowers the starting age for annual lung cancer screening to age 50 [previously age 55] and lowers the smoking history to 20 pack-years [previously 30 pack-years]. In addition, this is consistent with the recently published NCCN 2021 Lung Cancer Screening Clinical Practice Guidelines in Oncology.

As per the USPSTF evidence review, smoking history and older age are the two most important risk factors for lung cancer.^{10,11,12} The relative risk of lung cancer in smokers is approximately 20-times that of nonsmokers, which increases with cumulative quantity and duration of smoking, increases with age, and for former smokers, decreases with increasing time since quitting. The USPSTF identified adults ages 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years to be at high-risk, and recommends screening for lung cancer with annual LDCT in this population. Similarly, NCCN guidelines have the equivalent recommended start age and smoking history risk criteria but removes the upper age limitation and quit smoking history conditions.

The USPSTF identified LDCT with high sensitivity and reasonable specificity for the detection of lung cancer, with demonstrated benefit in screening persons at high-risk.^{13,14,15} Other screening tests include sputum cytology, chest x-ray, and biomarkers but are all considered “not beneficial” per the USPSTF.^{16,17}

V. Our joint societies request that CMS strongly consider revising key NCD sections to safeguard against barriers in screening uptake including LDCT lung cancer screening risk criteria (quit smoking history; upper age limitation), counseling and Shared decision Making (SDM), and Medicare Administrative Contractor coverage denials (IDTF setting) per the *Radiology Imaging Facility* criteria

¹⁰ Samet JM. Health benefits of smoking cessation. *Clin Chest Med*. 1991;12(4):669-679.

¹¹ 4. American Cancer Society. Key Statistics for Lung Cancer. <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/key-statistics.html>. Accessed June 3, 2020.

¹² Siegel RL, Miller KD, Jemal A. Cancer statistics, 2015. *CA Cancer J Clin*. 2015;65(1):5-29.

¹³ Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365:395-409.

¹⁴ Pinsky PF, Church TR, Izmirlian G, et al. The National Lung Screening Trial: results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013;119(22):3976-3983.

¹⁵ 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.

¹⁶ Hiraes Casillas CE, Flores Fernández JM, Padilla Camberos E, et al. Current status of circulating protein biomarkers to aid the early detection of lung cancer. *Future Oncol*. 2014;10(8):1501-1513.

¹⁷ Oken MM, Hocking WG, Kvale PA, et al. Screening by chest radiograph and lung cancer mortality: the Prostate, Lung, Colorectal, and Ovarian (PLCO) randomized trial. *JAMA*. 2011;306:1865-73.

Annual Screening Eligibility Risk Criteria – 15-year quit smoking history (eliminate)

We recommend CMS remove the 15-year smoking quit date risk criteria for annual LDCT LCS. The joint societies strongly disagree with the CMS and USPSTF criteria that still limit screening to current smokers or to those who have quit smoking within 15 years and recommend it be eliminated. Provided below are substantive and compelling comments to support this recommendation and if approved by CMS, could save thousands of Medicare and Medicaid beneficiary lives.

It is important to understand the history and fully recognize where the 15-year smoking quit date criteria came from and objectively determine why it is still embedded as risk criteria today for lung cancer screening recommendations (USPSTF) and coverage decisions (CMS). The 15-year quit smoking cutoff was initially utilized in the NLST as a study enrollment criterion. While this was a good target population for risk, this was strictly a clinical trial enrollment parameter and limited by the scope of the study. The NLST 15-year quit smoking enrollment criterion was not intended to be utilized as a measure of the appropriate at-risk screening population. CMS must recognize clinical trials, such as NLST, have **limited** external generalizability and medical appropriateness. The 15-year quit smoking date enrollment criterion by NLST was not and is not indicative of the broader high-risk screening population nor a representation of the clinical utility of screening for those individuals having quit smoking for more than 15 years. Unfortunately, the USPSTF and CISNET modeling and analysis continue to re-use and re-apply the 15-year quit smoking date based solely on the NLST study entry criteria. This inappropriately limits eligibility for screening and does not evaluate the level of high-risk among the population that has quit smoking for more than 15 years.

While the NLST enrollment study criterion may have been a useful starting point, **we must do better** for the lung cancer community and the Medicare population and identify the actual at-risk group. We cannot continue to remain immovable and impeded by a study enrollment criterion from a clinical trial dating back from 2010. Instead, CMS should consider other types of studies such as Yang et al. that addresses the 15-year quit smoking cutoff and beyond with conclusions that high-risk of lung cancer remains after that 15-year quit date.

In a prospective study, Yang et al. observed two cohorts of individuals with lung cancer and identified the chronological patterns among 1) those eligible individuals as per the USPSTF lung cancer screening risk criteria and 2) those individuals who would have “missed out” on screening/outside of the USPSTF lung cancer screening criteria. The lung cancer incidence levels among those who would have “missed out” on screening were at high rates and demonstrated a continued high-risk status. Of significance, the study showed that the largest percentage (approximately 30%) were among the cohort that “missed out” on screening and was *solely* based on having quit smoking more than 15 years ago.

The study authors concluded “Our 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.**” They found that the current USPSTF screening

criteria exclude many patients who are at high-risk for the development of lung cancer and underscored that the inclusion of former smokers that have quit smoking more than 15 years, may yield substantial increases to screen-detected lung cancers and result in more lives saved with a medically acceptable amount of exposure to radiation and cost.¹⁸

In addition, the 15-year smoking quit date screening eligibility criteria is inconsistent with the NCCN lung cancer screening guidelines^{19,20} that otherwise are equivalent in criteria with the updated USPSTF recommendation. Furthermore, this smoking quit date erects a barrier to screening for those who would otherwise be eligible and meet the age and pack-years smoking history criteria.

While studies indicate that the relative risk of lung cancer decreases with years since quitting (YSQ) smoking, it is important to recognize that **40% of all lung cancers still occur in the 15 YSQ smoking population**²¹. The level of evidence of the reducible relative risk of lung cancer after 15 YSQ smoking does not support the exclusion of screening for every 4 out of 10 lives diagnosed with lung cancer.²²

Given public health responsibility, health maximization, efficiency, justice, and proportionality²³, it is unwarranted 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.

To improve equitable access to LDCT lung cancer screening, CMS should consider real world data, in addition to clinical trials, during their coverage reconsideration and determination processes regarding screening criteria. The populations included in the clinical trials that ultimately serve as the basis for screening criteria development are often not representative of the broader at-risk patient population. This disparity highlights the critical need to consider real world evidence, such as Post Market Surveillance, observational studies, epidemiological studies, and analysis of data from appropriate registries, and other established surveys and data sources, as an additional factor in addressing the unique impact across disparate underserved populations including racial and ethnic minorities, rural and lower socioeconomic populations, LGBTQ individuals, and others.²⁴

For example, Reese et al. evaluated the recently updated USPSTF recommendation for lung cancer screening among women and racial/ethnic minority populations. They found that Black and Hispanic smokers are likely to continue to be underrepresented among individuals eligible for lung cancer screening, despite data that suggests their risk of lung cancer is equivalent to or greater than that of

¹⁸ 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.

¹⁹ https://www.nccn.org/store/login/login.aspx?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

²⁰ https://www.nccn.org/patients/guidelines/content/PDF/lung_screening-patient.pdf#page=18

²¹ 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.

²² 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.201909-6590C.

²³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4196023/>

²⁴ Pasquinelli MM, Kovitz KL, Koshy M, et al. Outcomes From a Minority-Based Lung Cancer Screening Program vs the National Lung Screening Trial. *JAMA Oncol.* 2018;4(9):1291-1293. doi:10.1001/jamaoncol.2018.2823.

White smokers. This study also found that raising or lowering the screening criteria based on age and smoking history are unlikely to have a meaningful effect on reducing inequities across racial/ethnic groups, and lung cancer screening criteria are likely to remain biased against Black and Hispanic smokers unless the criteria are adapted for different racial/ethnic groups.²⁵

At a time when lung cancer deaths remain the number one cancer killer and when screening uptake trends are very low²⁶, 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.

Our joint societies call attention to the potential harms of continued smoking, as a result of the 15-year quit smoking screening requirement. This NCD criterion incentivizes Medicare patients to continue smoking (to obtain 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.

CMS bears the burden of the unfortunate effect of this NCD criterion that unintentionally incentivizes smoking, and causes potential downstream harm to the Medicare population. Cigarette smoking is the number one risk factor for lung cancer and in the U.S. and is linked to 80-90% of lung cancer deaths. The USPSTF defined the relative risk of lung cancer as 20-times greater vs. non-smokers as well as the cumulative effect of smoking with duration etc. Smoking also increases the risk of other cancers and is a significant contributor to cardiovascular disease.²⁷

Regardless of intention, this incentivization of the continued smoking cannot be overlooked by CMS and is in direct conflict with the smoking cessation guidelines for lung cancer screening. CMS could remove this harm by lifting the 15-year quit date and mirror the NCCN guidelines.

Annual Screening Risk Criteria – Upper age cutoff (eliminate)

We recommend CMS eliminate the upper age cutoff, as decisions to cease screening are individualized based on the overall health status. It is important that lung cancer screening is recommended to individuals who are designated as high-risk (as already set by USPSTF as age ≥50 years, smoking ≥20 pack-years, etc.) and who are candidates for definitive treatment. A balancing of risks and benefits of treatment for lung cancer is an individualized decision between a patient and his/her health care provider and should not be subject to arbitrary oversight especially given the importance and era of personalized medicine.

²⁵ Reese TJ et al. Evaluation of Revised US Preventive Services Task Force Lung Cancer Screening Guideline Among Women and Racial/Ethnic Minority Populations. *JAMA Network Open*. 2021;4(1):e2033769. doi:[10.1001/jamanetworkopen.2020.33769](https://doi.org/10.1001/jamanetworkopen.2020.33769).

²⁶ 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.

²⁷ https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/index.html.

Modern treatment of lung cancer has significant experience in treating patients over age 77.^{28,29} This includes surgical management of early-stage lung cancer with advanced therapeutic modalities, such as video-assisted thoracic surgery for lobectomy or wedge resection in the elderly and octogenarians, resulting in shorter hospital stays, decreased complications³⁰, and improved overall survival.³¹ In addition, stereotactic body radiation therapy (SBRT) for early-stage non-small cell lung cancer is extremely safe and effective in the elderly.³² Furthermore, with expanding and emerging approaches to treatment for lung cancer, provider-patient decision making is medically necessary and appropriate versus treatment exclusions based solely on age.

The broad brush, 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 no or few comorbidities. Alternatively, CMS can utilize and encourage personalized medicine by replacing its upper age cutoff of 77 years with a clinically-based approach, such as, *“Screening should be discontinued once a person develops a health problem that substantially limits life expectancy or the ability or willingness to have curative therapy.”*

It is well-established that the medical appropriateness of lung cancer screening and therapy is subject to physiologic status, comorbidities, and the ability to undergo treatment. CMS should recognize that lung cancer risk is not eliminated at age 77. Health status, personalized medicine, and individualized decisions more appropriately inform providers and their older patients in determining when to stop cancer screening. Personalized considerations are essential determinants of the harms and benefits of screening and, therefore, we believe that **decisions to continue or cease screening should be individualized based on a person’s overall health and preferences**. This is also recommended by NCCN per their lung cancer screening guidelines.

In 2014, 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 and concluded that screening for lung cancer may benefit individuals at increased risk of lung cancer 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.³³

²⁸ https://www.nccn.org/store/login/login.aspx?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf.

²⁹ https://www.nccn.org/patients/guidelines/content/PDF/lung_screening-patient.pdf#page=18.

³⁰ Koren, J., Bocage, J., Geis, W. et al. Major thoracic surgery in octogenarians. *Surg Endosc.* 17. 2003;632–635.

<https://doi.org/10.1007/s00464-002-8953-0>.

³¹ Feszko A, McKeown E, Wilson JL, et al. Assessing Survival and Grading the Severity of Complications in Octogenarians Undergoing Pulmonary Lobectomy. *Can Respir J.* 2017;6294895. doi: 10.1155/2017/6294895. Epub 2017 Feb 8.

³² Kreinbrink P, Blumenfeld P, Tolekidis G, et al. Lung stereotactic body radiation therapy (SBRT) for early-stage non-small cell lung cancer in the very elderly (≥80years old): Extremely safe and effective. *J Geriatr Oncol.* 2017;8(5):351-355. doi: 10.1016/j.jgo.2017.07.002. Epub 2017 Jul 21.

³³ 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](https://doi.org/10.3389/fonc.2014.00037).

Within the framework of the NLST, the issue of benefit versus harm for surgical management of early-stage lung cancer has already been answered with the demonstration of a significant decrease in lung cancer and all-cause mortality. Outside the NLST, well-established data are documenting the results of surgical management of early-stage lung cancer including both institutional reports and registry analyses. Objective assessments of surgical efficacy should use contemporary results reported within the last decade such as data from screening studies [e.g., International Early Lung Cancer Action Program (I-ELCAP)].³⁴ In addition to surgical management of early-stage lung cancer, other therapeutic modalities have advanced including SBRT, standard RT and chemotherapy, and immunotherapy that can have a dramatic impact on increased survival.

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), high-risk population above age 77, real world evidence 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 (e.g., discontinue screening once a person develops a health problem that substantially limits life expectancy or the ability or willingness to have curative therapy).

Counseling and Shared Decision Making (SDM) NCD Criteria (**revise**)

The joint societies encourage CMS to revisit the “Counseling and Shared Decision Making (SDM)” NCD criteria and **revise** the current language and requirements to ensure it does not act as a barrier to screening uptake.

While the *informed discussion* is important and medically appropriate, CMS may elect to revise their *counseling and SDM* NCD language and consider mirroring the USPSTF approach with an emphasis on informed discussion importance. CMS has the opportunity to increase screening uptake and reduce burdens by eliminating the list of NCD SDM criteria that are often misunderstood and considered too time-intensive, complex, and/or an impediment for the primary care and ordering clinician community. This can present as a barrier or bottleneck to screening with the ultimate burden on those patients who do not get screened and are stripped of the opportunity to get a lung cancer diagnosed early and cured. While SDM should be encouraged and utilized, CMS may want to eliminate the NCD requirement for SDM entirely, especially since it is not required for coverage of screening mammography or colon cancer screening.

Less than 4% of eligible patients take advantage of lung cancer screening exams, largely attributed to a lack of awareness of the benefits. Despite the seven years since the Feb. 2015 NCD, lung cancer

³⁴ [I-ELCAP Publications | I-ELCAP](#).

screening rates remain extremely low due to several contributing factors including the complex eligibility requirements and the requirement for SDM often cited as barriers.^{35,36}

To increase LCS utilization, screening programs and the accompanying steps for enrollment should embrace patient-centric models that streamline processes and increase patient compliance.³⁷ For example, while SDM is an important component of enrollment in a lung cancer screening program, consideration should be made for providing opportunities for the SDM appointment or consultation to occur in conjunction with the actual screening exam. In this type of scenario, a patient can be referred by a PCP or healthcare provider to a radiology department or center that performs LCS—a center that is well-versed in the SDM process and content that needs to be discussed, has standardized information associated with the pros/cons of screening (false-positive, false-negative, overdiagnosis rates, and radiation exposure)—and can provide succinct and accurate information to potential LCS patients, including requisite pre-authorizations prior to the exam taking place during the same visit. Streamlining these processes will help patients avoid unnecessary delays in the screening process and will also offload the burdensome SDM requirements from busy providers who are sometimes uncomfortable with the SDM process and/or present inconsistent or inaccurate information to potential LCS patients.

In the 2015 LDCT LCS NCD, CMS stated *“We are establishing specific beneficiary, provider and imaging facility eligibility requirements, along with inclusion of a counseling and shared decision making visit to ensure that the benefits of screening outweigh harms for the Medicare population.”* In addition, CMS responded to public comments in the NCD expressing concerns around *“potential for significant harms in starting a lung cancer screening program, including the risk for false-positive results leading to additional tests and treatments that may be more harmful”* as a contributing factor for requiring counseling and shared decision making visit with a list of criteria in order to refer a patient on for LDCT LCS.

Since the 2015 NCD and the 2010 NLST, reporting, management protocols, and technology have significantly improved and advanced with higher specificity and sensitivity with standardized approaches. Low dose CT technology has advanced and is now far more refined, in addition to standardized reporting and management tools. For example, the ACR Lung CT Screening Reporting and Data System (Lung-RADS), NELSON, Lahey Hospital, and I-ELCAP define a positive test as a two-step process resulting in a more accurate level of sensitivity and specificity.^{38,39,40} Also, measures to define the accuracy of screening must specify whether they relate to Baseline (prevalence) or annual follow-

³⁵ 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.

³⁶ 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/>.

³⁷ Kanodra NM, Pope C, Halbert CH, et al. *Ann Am Thorac Soc.* 2016 Nov; 13(11):1977-1982.

³⁸ [Lung Rads | American College of Radiology \(acr.org\)](#).

³⁹ [Protocol Documents | I-ELCAP](#).

⁴⁰ De Koning HJ, Van der Aalst CM, Jong PA, et al., Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial. *N Engl J Med* 2020; 382:503-513. DOI:10.1056/NEJMoa1911793.

up (incidence) rounds of screening as these contexts are different. The context is important, as the rate of cancer detection should be the same for each annual screening round but different from the detection rate at baseline.

There have been many approaches reported since the NLST that improve the efficiency of LDCT detection of early lung cancer which should be recognized. Specifically, ACR Lung-RADS addresses false-positives and reduces this rate by 75% compared to prior studies. The NELSON Dutch/Belgian screening trial concludes the accuracy of screening with 95% sensitivity and 98% specificity and compared to breast and colon cancers, the lung cancer screening accuracy is remarkable. Also, while the NLST reported a 26% false-positive rate, with a two-step cancer detection process, this rate was reduced to 12.8% (Lung-RADS) and reduced even further to 5.3% (Lung-RADS) after baseline, 3% (I-ELCAP), and 2.1% (UKLS). Regarding overdiagnosis, a study concluded there was no overall increase in lung cancer incidence in the LDCT arm versus in the chest x-ray arm with the extended follow-up in the NLST.⁴¹

The maturity and effectiveness of LDCT LCS across settings are significant.⁴² We are hopeful that CMS will give weight to and recognize the advances and improvements made over the last decade in radiation dose optimization in CT technology, as well as the low dose protocols established by professional societies (e.g., ACR, AAPM), standardized reporting, and management systems (i.e., Lung-RADS), incidental findings white papers, and incidental findings resources and management⁴³. These advances in standardized screening protocols and implementation, the magnitude of annual lung cancer deaths to the low screening uptake in the U.S., and existing and potential NCD SDM criteria burdens, should all bear thoughtful consideration by CMS in revising the NCD language.

Substantial concerns remain among medical professional societies, physician groups, screening centers, patient communities, and other stakeholders that the *counseling and SDM* criteria as written in the NCD are a major barrier to lung cancer screening. We recommend this be revisited and revised by CMS to safeguard against barriers to uptake in screening.

Independent Diagnostic Testing Facilities (IDTFs) – Coverage and Reimbursement for LDCT LCS (instruct)

The joint societies strongly urge CMS to **provide clear and concise NCD language and instructions** to all Medicare Administrative Contractors (MACs) to cover/reimburse low dose CT lung cancer screening

⁴¹Pinsky P. et al. - National Lung Screening Trial Research Team. Lung Cancer Incidence and Mortality with Extended Follow-up in the National Lung Screening Trial. *J Thorac Oncol.* 2019;14(10):1732-1742. doi: 10.1016/j.jtho.2019.05.044. Epub 2019 Jun 28.

⁴²Copeland 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://doi.org/10.1200/JOP.18.00788). DOI: 10.1200/JOP.18.00788 *Journal of Oncology Practice* 15, no. 7 (July 01, 2019) e607-e615.

⁴³<https://www.acr.org/Clinical-Resources/Incidental-Findings>

performed in all facilities and specifically *Independent Diagnostic Testing Facilities* (IDTFs) per the Feb. 15 LCS LDCT NCD.

Our joint societies and numerous CT accredited IDTF screening centers that meet the NCD requirements have shared with CMS CAG and MACs the prevalent and ongoing erroneous denials across MACs for LDCT lung cancer screening. The unfair and burdensome consequence of the erroneous MAC denials predominantly impacts the Medicare beneficiary but also the IDTF.

The Medicare patient may have to pay entirely out of pocket if denied coverage by the MAC for the preventive service LDCT LCS test they would otherwise be eligible for at 100% coverage as a result of 1) the place of service (IDTF) ineligibility misinterpretation, and 2) misclassification of LDCT LCS as a “therapeutic test and intervention.”

Medicare patients have less access to screening sites if their local IDTF is denied by a MAC. This may result in patients having to travel to a distant or unfamiliar area and requires patient scheduling to a faraway location. Increased travel time and limited access to screening sites can present as barriers to uptake in screening. Surveys related to screening challenges have found that the most common reason for declining screening, was difficulty with travel, related to the distance between the home and screening site, lack of public transportation, and/or cost of the trip or hospital parking. A study showed that competing priorities may also prevent screening eligible patients including a decline in caregiver responsibilities.⁴⁴ Among the top three reasons for missed medical appointments includes lack of transportation⁴⁵ and should be considered by CMS as a significant barrier.

For example, an elderly Medicare patient with a heavy smoking history may feel too burdened to follow through in scheduling and physically getting to their lung cancer screening appointment. A simple remedy via formal MAC instruction per the NCD or through a Change Request Transmittal Notice can be implemented by CMS and these beneficiary burdens could be fully prevented and resolved. CMS national should provide clear and formal instructions to the MACs on this topic regarding IDTF settings and coverage and reimbursement for LDCT lung cancer screening.

Since Feb. 2015, a reoccurrence of LDCT lung cancer screening denials remains chronic when performed in an IDTF setting despite having met the NCD requirements. Based on flawed Medicare contractor interpretation of the NCD, MACs have erroneously denied low dose CT lung cancer screening tests when performed in the IDTF setting because they have misidentified LDCT LCS imaging as a “**therapeutic test and intervention**” and thus, denied by the MAC as a non-covered service because IDTFs are not approved to perform therapeutic exams or interventions.

It is incongruous and in error to classify an imaging CT of the chest for lung cancer screening (LDCT) as a “**therapeutic test and intervention**” and MACs should be instructed to cover LDCT LCS performed in

⁴⁴ Ali N, Lifford KJ, Carter B, et al. Barriers to uptake among high-risk individuals declining participation in lung cancer screening: a mixed methods analysis of the UK Lung Cancer Screening (UKLS) trial. *BMJ Open* 2015;5(7):e008254.

⁴⁵ <https://clinmedjournals.org/articles/jfmdp/journal-of-family-medicine-and-disease-prevention-ifmdp-4-090.pdf>

IDTFs and all facilities from the date of the initial NCD (Feb. 2015). Given the prolonged MAC denial and misinterpretations of the NCD, it may be helpful and necessary for CMS to inform and instruct MACs that LDCT LCS is considered a non-invasive imaging test. It is analogous to other non-invasive annual imaging screening tests in diagnostic radiology which are appropriately performed in the IDTF setting.

To resolve this MAC error and burden to Medicare beneficiaries, CMS provided MLN guidance⁴⁶ (MM9246) in 2017 that states the “NCD for lung cancer screening Medicare benefit is available in ALL FACILITIES including IDTFs.” As we know, MACs are not required to follow MLN guidance and, therefore, remain emboldened to reply to stakeholders, professional societies, and IDTFs of the same regardless of their level of awareness of this MLN guidance from CMS.

In Oct. 2018, more than 35 bipartisan members of the U.S. House of Representatives cosigned [a letter](#) to the Secretary of the Department of Health and Human Services and the CMS Administrator to express opposition to MACs denying reimbursement for LDCT lung cancer screenings performed at IDTFs.⁴⁷ To ensure patient access to these lifesaving screening services, the bipartisan members of Congress, many of whom served on the powerful House Ways and Means and Energy and Commerce Committees, urged CMS to resolve this critical issue via a Change Request Transmittal. Unfortunately, and despite these efforts, the issue remains unresolved. As such, the joint societies strongly urge CMS to provide explicit instruction to MACs that LDCT at IDTFs be fully reimbursed with no additional delay and/or denial.

In Jan. 2021, Palmetto GBA MAC posted a Local Coverage Billing and Coding Article titled *IDTFs and Low Dose CT Scan for Lung Cancer Screening 71271 (A58641)* but again have missed the mark on their clarification, as the MAC article mislabels LDCT lung cancer screening as including a *therapeutic activity* and, therefore, a therapeutic exam. The article goes on to state this is covered in an IDTF setting *when a business arrangement between the physician and IDTF to cooperatively provide the therapeutic activity is met*, etc.⁴⁸

We do not believe CMS intended to mandate low dose CT lung cancer screening as a therapeutic exam or intervention nor does the Feb. 2015 NCD indicate such. CMS includes explicit language within the NCD regarding smoking cessation “**counseling**” (therapeutic exam) embedded as part of the Shared Decision Making (G0296) service. MACs should be advised the therapeutic exam or intervention is part of the counseling and Shared Decision Making visit for lung cancer screening HCPCS code G0296 and separate and distinct from the LDCT LCS imaging test.

⁴⁶ [mm9246 \(cms.gov\)](https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=58641&Cntrctr=All&UpdatePeriod=488).

⁴⁷ <https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-October-6-2018-Issue/Congressmen-Oppose-Lung-Cancer-Screening-Restrictions-on-IDTFs>.

⁴⁸ <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=58641&Cntrctr=All&UpdatePeriod=488>

Page 65 (see excerpt below) of the *discussion section* of the CMS NCD, provides clarity regarding the Radiology Imaging Facility eligibility criteria for “**makes available**” smoking cessation interventions for “**current smokers**” which is met by all imaging facilities, IDTFs, as well as hospitals by providing or offering smoking cessation **education materials**, etc.

*Since “[s]moking is widely recognized as the leading cause of lung cancer” (NCI - <http://seer.cancer.gov/statfacts/html/lungb.html>), smoking cessation interventions were integral interventions in published trials. According to the 2011 Medicare Current Beneficiary Survey (MCBS), 14 percent of beneficiaries reported to be current smokers, and 44 percent reported as former smokers, although pack-year information is not collected. Additionally, we received public comments that also addressed tobacco cessation interventions. Therefore, based on the evidence reviewed and public comments received, **we are modifying the imaging facility eligibility criteria to require that smoking cessation interventions, such as educational materials, be made available.***

In most imaging departments and facilities including hospitals, smoking cessation materials such as brochures are made available to **current smokers**. Never has the LDCT lung cancer imaging test been defined by the medical community as a therapeutic exam that requires a physician from the *radiology imaging facility* etc. If smoking cessation therapy is needed, the patient should be referred to the appropriate tobacco treatment specialist. This type of therapy is not appropriately met by a *radiology imaging facility* and radiologists are not trained in this therapeutic field.

Although the CMS discussion (clarification on intent) is not specifically listed under the *Radiology Imaging Facility* eligibility criteria section, this again is addressed and stated in the **NCD discussion section**. However, CMS may want to revisit the *Radiology Imaging Facility* eligibility criterion NCD section to compose clear and unequivocal language regarding the provision of smoking cessation education materials meeting these criteria and clarify that LDCT LCS imaging test should not be misconstrued as a *therapeutic exam or intervention*.

Summary

The evidence reviewed by the USPSTF and NCCN, their updated recommendation and guideline, findings in the NLST and NELSON studies, evidence-based multi-society and multi-disciplinary recommendations, clinical guidelines, supporting literature, and stakeholder comments, support the joint society NCD reconsideration request.

We commend the USPSTF and fully support the expanded patient population and risk criteria in their updated recommendation for lung cancer screening (i.e., expanded younger age and reduced smoking history) and urge CMS to consider the new evidence and reflect these updates in their NCD, as relevant to the Medicare population. Also, we commend the NCCN for their recent 2021 lung cancer screening guideline and risk criteria and urge CMS to consider this supporting evidence and revise their NCD with equivalent risk criteria for the Medicare population (eliminating the 15-year quit smoking history and upper age cutoff).

It is also important to revisit and revise sections of the NCD that may be ambiguous or considered a barrier to screening uptake including the *Counseling and Shared Decision Making* criteria and the *Radiology Imaging Facility* criteria (i.e., LDCT LCS deemed a non-covered service when performed in an IDTF setting and misclassified as a therapeutic exam or intervention).

We are confident that CMS will agree the evidence is sufficient to conclude that lung cancer screening with LDCT is reasonable and necessary for the prevention or early detection of illness or disability and appropriate for Medicare and a portion of Medicaid beneficiaries under the conditions outlined in this NCD reconsideration request.

Our joint societies thank CMS for reconsidering this NCD based on additional supporting evidence and stakeholder concerns and feedback. We appreciate this opportunity to comment on this important life-saving preventive service impacting the Medicare population.

We look forward to working with you during this process to provide evidence, stakeholder feedback, and expert opinions on the LDCT lung cancer screening NCD. To further explore any questions regarding our joint society comments and formal NCD reconsideration request, please contact Anita McGlothlin, Director of Economics and Health Policy, at amcglathlin@go2foundation.org.

Sincerely,



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