December 8, 2014

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Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

By Online Submission

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

Dear Ms. Syrek Jensen:

The Lung Cancer Alliance (LCA), The Society of Thoracic Surgeons (STS), and the American College of Radiology (ACR), a coalition representing lung cancer patients, diagnostic radiologists, radiation oncologists, nuclear medicine physicians, medical physicists, and thoracic surgeons, appreciate the opportunity to comment on the recently proposed National Coverage Determination (NCD) for Lung Cancer Screening with Low Dose Computed Tomography (CAG-00439N). LCA, STS, and ACR, hereafter referred to as the “Joint Societies,” applaud the Centers for Medicare and Medicaid’s (CMS) proposed decision to extend this life saving benefit on to the Medicare age population.

The Joint Societies are in agreement that the overarching public health priority is to ensure equitable access to high quality screening programs built on existing frameworks of evidence based protocols and multi-disciplinary care according to best practices.

In this regard, the Joint Societies respectfully request CMS to make targeted modifications to the proposed decision regarding the age bracket for individuals eligible to receive low-dose CT (LDCT) lung cancer screens, the definition of asymptomatic patients, the requirement of provider visits to obtain an order for annual follow-up screening, and the 15-year smoking cessation threshold as outlined in our letter. Additionally, the Joint Societies are hopeful that this document will help clarify and strengthen aspects of eligibility criteria outlined for qualifying radiologists and radiology imaging centers, as well as CMS-approved national lung screening data registries.

Finally, the Joint Societies wish to express our continued desire to work constructively with you and your staff on any other potential issues related to other regulatory requirements that may be under consideration to ensure CMS does not inadvertently restrict equitable access especially for populations at highest risk.

Our comments and recommendations are as follows.
**Comments**

1. **Beneficiary eligibility criteria: Age 55-74 years**
   - Recommendation: CMS adopt the USPSTF recommendation (55-80 years)

*The Joint Societies strongly oppose the decision to restrict access to this life saving screening test to high risk patients 74 years old and younger.* The median age of diagnosis for this particular disease is 70 years and a cap of 74 would exclude a large patient group where this exam is medically necessary and appropriate.

*In lieu of the provisions outlined in the proposed NCD, our organizations urge CMS to adopt the United States Preventive Services Task Force's (USPSTF) recommendation of offering annual LDCT lung cancer scans to high risk patients between the ages of 55 and 80.* The USPSTF provided robust mathematical modeling to justify this broader age range for patients eligible for LDCT screens and concluded the evidence, as a whole, deserved a “B” rating. It is important to note that the findings of the National Lung Screening Trial (NLST), which was funded by CMS's sister agency, the National Cancer Institute, served as the foundation of the USPSTF’s recommendations. In addition, the USPSTF’s work was supported by the Agency for Healthcare Research and Quality and ultimately published in a well-respected peer-reviewed journal, specifically the *Annals of Internal Medicine* (Appendix #1). Furthermore, the National Comprehensive Cancer Network (NCCN) Lung Cancer Screening Guidelines, developed by a broad multi-disciplinary team of lung cancer specialists and epidemiologists recommend screening “until a patient is no longer eligible for definitive treatment,” and the American Association for Thoracic Surgery (AATS) guideline (Appendix #2) recommends annual screening through 79 years of age. The AATS guideline expands to upwards of 79 years as the risk of developing lung cancer is higher each year than the year before due to aging. For this reason, combined with the peak incidence of lung cancer at 70 years and the average life expectancy remaining greater than 9 additional years for all Americans up to age 79 years, AATS developed a recommendation for annual screening applicable to this upper age bracket. In addition, a recent article published in *PLOS Medicine* concludes that smokers aged 65-80 years are a high risk group who would benefit from screening (Appendix #3). Evidence shows advances in surgical techniques are very safe and an effective curative treatment in the upper age bracket (80).

Along with concerns surrounding limited patient access, our organizations are concerned that excluding patients between the ages of 75-80 from this benefit creates a lack of uniformity among governmental recommendations, as well as an unintentional exacerbation of health care disparities. Given the USPSTF explicit recommendation, many may view stopping at age 74 to be a case of age discrimination and an arbitrary decision to tailor recommendations based solely on the NLST clinical trial inclusion criteria, rather than on a preponderance of evidence gained from the NLST, other trials, mathematical modeling, and pre-existing data. Since a lack of Medicare coverage for 75-80 year-olds disproportionately impacts lower income elderly Americans, such a decision by CMS may be perceived as unfairly limiting access to lung cancer screening in those at highest need and with the least resources and advocacy.
The Joint Societies believe that the USPSTF recognized that NLST was a very long and massive randomized clinical trial (RCT) that required considerable financial resources and human capital to complete. In light of these realities, our organizations are confident that the Task Force fully understood that a similar type of RCT for high risk patients between the ages of 75 and 80 was highly unlikely. As a result, the USPSTF relied upon sophisticated mathematical modeling when determining an accepted age bracket for high risk patients capable of receiving annual LDCT lung cancer screens. In short, the Joint Societies strongly urge CMS to recognize the same realities and adopt the USPSTF recommendation of high risk patients between the ages of 55 and 80 being eligible to receive annual LDCT lung cancer screens.

2. **Beneficiary eligibility criteria: Asymptomatic (no signs or symptoms of lung disease)**

   - Recommendation: CMS revise NCD language to “Asymptomatic (symptoms suggestive of lung cancer)” and delete “(no signs or symptoms of lung disease)”

The Joint Societies recommend that CMS revise the definition of “Asymptomatic” patients as currently outlined in the NCD so that it reads “Asymptomatic (no symptoms suggestive of lung cancer).” Our organizations urge the deletion of the phrase, “… no signs or symptoms of lung disease,” outlined in the parenthesis.

This revised language will help clarify the medically appropriate indications and intent surrounding “asymptomatic” and eliminate any concerns about the current language inadvertently excluding patients who should be eligible to receive this important screening procedure. While we agree that symptoms or signs of an acute process, such as pneumonia, or active symptoms or signs of lung cancer should trigger a diagnostic exam in lieu of a screening LDCT, patients with chronic obstructive pulmonary disease (COPD), a smoking cough, asthma, emphysema, and other pulmonary symptoms are at particularly high risk of lung cancer and should not be excluded from LDCT lung cancer screening exams. By holding to a strict standard of “no signs or symptoms of lung disease,” we believe CMS unintentionally creates a barrier to a majority of patients who are at high risk of cancer and should be eligible for screening, as well as potentially creates a system that results in retrospective denial of payment if a patient is deemed to have had “symptoms.” Refining the current definition of asymptomatic patients to those without signs or symptoms of lung cancer allows appropriate high risk patients to retain access to this important procedure.

3. **Beneficiary eligibility criteria: A lung cancer screening counseling and shared decision making visit** includes the following elements (and is appropriately documented in the beneficiary’s medical records): A written order for LDCT lung cancer screening that meets the following criteria: For Subsequent LDCT lung cancer screenings: the beneficiary must receive a written order, which may be furnished during any appropriate visit (for example: during the Medicare annual wellness visit, tobacco cessation counseling services, or evaluation and management visit) with a physician (as defined in Section 1861 (r)(1) of the Act) or qualified non-physician practitioner
(physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Act).

- **Recommendation:** CMS retain and implement the provider shared decision-making visit and written order requirement only for the initial screen. These beneficiary eligibility criteria should be deleted for the subsequent screens.

The Joint Societies agree it is important to require a written order and shared decision-making consultative visit for the first screen, however, we believe it is inappropriate to continue these requirements for future/subsequent screens. Instead, our organizations recommend CMS implement the written order requirement and provider shared decision-making visit only for the initial screen.

Once a decision to screen an individual is implemented, a major component of a successful screening program is the patient adhering to a regimen of annual follow-up screens. To mandate additional provider visits in order for patients to obtain orders for subsequent lung cancer screenings will create added costs to both patients and Medicare, as well as threaten to decrease adherence and delay care by creating a barrier to annual follow-up LDCT.

### 4. Beneficiary eligibility criteria: Current smoker or one who has quit smoking within the last 15 years.

- **Recommendation:** CMS delete the 15 year smoking cessation requirement.

The Joint Societies recommend CMS delete the 15 year smoking cessation eligibility criteria. It is important that CMS weigh the unintended consequences of this smoking cessation threshold. More specifically, as outlined in previous comment letters, our organizations are concerned that this arbitrary time period by which patients must have ceased tobacco use will actually incentivize patients to restart their smoking habit to either become eligible or retain eligibility for the screening benefit. While we recognize the 15 year smoking cessation threshold was part of the NLST inclusionary trial criteria, there is no evidence that lung cancer risk falls off substantially after 15 years smoking cessation. We ask that CMS implement their final decision based on the broader impact of a public policy decision. The final lung cancer screening NCD must utilize language and standards that ultimately prevent, rather than encourage smoking.

### 5. Radiology imaging center eligibility criteria: Has participated in past lung cancer screening trials, such as the National Lung Screening Trial, or an accredited advanced diagnostic imaging center with training and experience in LDCT lung cancer screening;

- **Recommendation:** CMS recognize the ACR CT Accreditation as an approved Advanced Diagnostic Imaging Accrediting body and the ACR’s Lung Cancer Screening Center (LCS) Designation program as an accepted center certification.

- **Recommendation:** CMS grandfather those sites that were previously accredited and designated as an accredited provider of chest CT and LCS designation, such as the ACR’s CT Accreditation and ACR’s LCS Center Designation and
allow grandfathered sites a three year grace period to meet the newer thresholds defined by the NCD.

- **Recommendation**: CMS delete “advanced diagnostic imaging center” AND delete “experience” and replace with “provider of chest CT”. The new language would state “… or an accredited provider of chest CT with training in LDCT lung cancer screening;”

The Joint Societies request that CMS recognize the ACR CT Accreditation as an approved accrediting body and the ACR’s Lung Cancer Screening Center Designation as an accepted certification program meeting the “with training and experience in LDCT lung cancer screening” imaging center criteria. The ACR’s accreditation program has approved status from CMS under the Medicare Improvements for Patients and Providers Act (MIPPA) and the College has the historical knowledge, experience and existing framework in facilitating the NCD imaging center criteria. In addition, obtaining CT accreditation from the ACR is a prerequisite for the College’s lung cancer screening designation. The ACR’s CT Accreditation and LCS Designation are available to all centers, including community-based facilities, and the College is prepared to process applications rapidly. In only several months since the ACR LCS Designation program was launched, it already has over 300 sites processed and that number is increasing daily.

In responding to the imaging center eligibility criteria, our joint organizations would like to offer comments on the language stating “with training and experience in LDCT lung cancer screening”. The Joint Societies request that CMS delete the word “experience” and, as a point of clarification, refer to a center certification/designation that includes training elements, such as the ACR’s LDCT LCS Designation. This revision would help clarify CMS’ intent and works parallel to the ACR’s existing framework that includes “training” criteria under the personnel qualifications section (i.e., 200 chest CT cases in the prior 36 months). The word “experience” is unclear, as this typically is associated with physician specific criteria.

In addition, the Joint Societies recommend CMS grandfather those sites that were previously accredited and designated as an accredited provider of chest CT with LCS designation, such as the ACR’s CT Accreditation and ACR’s LCS Center Designation; AND allow any grandfathered sites a three year grace period to meet the newer thresholds defined by the NCD. While the CMS NCD designation/certification criteria are similar to the ACR LDCT LCS Designation, there are some differences in thresholds (e.g., supervision and interpretation of 200 vs. 300 chest CTs) that would create administrative and financial burdens to those existing centers that have already met the benchmarks defined for a quality screening program. CMS can streamline their process and head off these types of barriers by grandfathering existing accredited and certified/designated facilities and offer a three year transition period for those centers to meet the new thresholds.

The joint organizations recommend CMS delete “advanced diagnostic imaging center” and replace with “provider of chest CT.” The new language would state “… or an accredited provider of chest CT with training and experience in LDCT lung cancer screening.” This revision is necessary, as some centers with Advanced Diagnostic Imaging (ADI) accreditation may not be accredited in chest CT. The broader scope of ADI encompassing other imaging
modalities creates a potential loophole and can easily be addressed with revised language specifying “an accredited provider of chest CT.”

**CMS-approved National Registries**

*The Joint Societies fully support CMS-approved national clinical practice lung cancer screening registries and will be reaching out to CMS CAG separately on this topic.* As mentioned in our prior correspondence, the ACR National Radiology Data Registry (NRDR), for example, is CMS recognized for Physician Quality Reporting System (PQRS). As part of NRDR, the ACR clinical practice lung cancer screening registry is well on its way to being programmed and available in early 2015 using the elements provided in the September 26, 2014 stakeholder letter. We are available to explore further in facilitating the imaging center eligibility NCD criteria.

6. Radiology imaging center eligibility criteria: Must use LDCTs with an effective radiation dose less than 1.5 mSv;

   ➢ *Recommendation: CMS revise the wording to reflect “Must use LDCT with volumetric CT Dose Index (CTDIvol) of \( \leq 3.0 \text{mGy (milligray)} \) for standard size patients (defined to be 5’7” and approximately 155lb) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients”.*

*The Joint Societies recommend that CMS utilize dose to phantoms captured in mGy and revise the radiology imaging center eligibility criteria language to reflect “Must use LDCT with volumetric CT Dose Index (CTDIvol) of \( \leq 3.0 \text{mGy (milligray)} \) for standard size patients (defined to be 5’7” and approximately 155lb) with appropriate reductions in CTDIvol for smaller patients, and appropriate increases in CTDIvol for larger patients”. While we agree with CMS’ intent in placing specific dose parameters as part of the imaging center criteria, the use of an effective radiation dose with mSv (millisieverts) may be confusing. More commonly, volumetric dose (CTDIvol) and use of dose to phantoms in mGy is accepted as the metric for radiation output. In addition, a one size fits all radiation dose limit does not address varying patient sizes and adjustments in dose that are medically needed. The recommended revised language above captures both the volumetric dose limit for a standard size patient as well as including appropriate dose reductions and increases based on patient size.*

Provided below is text taken from the American Association of Physicists in Medicine (AAPM) Lung Cancer Screening Protocols that addresses the dose measurement. In addition, text is provided from the ACR LDCT LCS Designation regarding dose. Both of these resources support the recommended change.
AAPM Protocols

Effective Dose
Effective dose is defined in ICRP 103 as a population dose metric and should not be used to estimate dose or risk to an individual. From a screening population point of view, one method to estimate the effective dose is to calculate the Dose Length Product (DLP) and then apply a conversion factor described in AAPM TG Report 96 to estimate the effective dose. For an idealized standard sized patient (defined above) and a 25 cm scan length, and using the k factor of 0.014 mSv/mGy*cm; these protocols should result in an effective dose below 1 mSv (see table below).

Dose values for an idealized standard sized patient (NOT for any individual)

<table>
<thead>
<tr>
<th>Dose Descriptor</th>
<th>Value</th>
<th>Reported at Scanner (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTDIvol*</td>
<td>≤ 3.0 mGy</td>
<td>Y</td>
</tr>
<tr>
<td>DLP*</td>
<td>≤ 75 mGy*cm</td>
<td>Y</td>
</tr>
<tr>
<td>Effective Dose (DLP x .014)**</td>
<td>≤ 1.0 mSv</td>
<td>N**</td>
</tr>
</tbody>
</table>

* The CTDIvol and DLP values in this table are for an idealized patient only; individual patients may have higher or lower values to reflect adjustment for patient size.

** Effective Dose is calculated for a population and should NOT be reported for an individual

ACR Designated Lung Cancer Screening Center requirements

- Radiation exposure levels consistent with lung screening protocols and not routine chest scans; the protocol shall have a CT Dose Index volume (CTDIvol) of < 3 mGy, for a standard size patient (5’7, 154lb) (using 32-cm diameter CTDI phantom)
- Exposure values be reduced for smaller-sized patients and increased for larger-sized patients using either manual methods (operator adjustment of technique via a technique chart) or automated methods (such as automatic tube current modulation and/or kV selection)

7. Radiologist eligibility criteria: Current certification with the American Board of Radiology or equivalent organization
   ➢ Recommendation: CMS replace Board Certification requirement with “Board Certification or Eligibility”.

The Joint Societies recommend CMS allow “Board Eligibility” in addition to board certification under the radiologist eligibility criteria. Please note a recent revision and official definition of “board eligible” is now time limited. Residents are eligible to take their Certifying
Exam 15 months after completion of training. (see [http://www.theabr.org/ic-gen-board-eligibility](http://www.theabr.org/ic-gen-board-eligibility)). Provided below is the American Board of Radiology (ABR) respective language.

After you have completed your residency training at a program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada (RCPSC), you are board eligible. You then will have six full calendar years to attain certification by passing both the Core and Certifying exams.

Generally, you will be eligible to take the Certifying Exam 15 months after completion of training, provided you have passed the Core Exam. You must pass both the Core and the Certifying examinations within the six-year board-eligible period.

If your board eligibility expires, you must take one additional year of training in a department with an ACGME- or RCPSC-accredited diagnostic radiology residency program in order to return to board-eligible status. The ABR must approve the additional year before it begins, and the training must occur after expiration of board eligibility status. During this period, your status would be “not certified, not board eligible.” At the end of that year, the department chair or program director must attest to satisfactory completion of the experience. After that documentation has been provided to the ABR, you would be able to re-enter the certification process and again would be required to pass both the Core and Certifying examinations within a new six-year period of board eligibility.

**Summary**

Our Joint Societies – LCA, STS, and ACR– greatly appreciate the opportunity to provide comments on the Proposed Decision Memorandum and to voice our overall support in expanding this lifesaving benefit to the Medicare population. However, we continue to have very significant concerns about the proposal to limit this screening benefit to high risk individuals ages 55-74. We strongly believe that a coverage decision excluding those patients’ ages 75-80 years old would neglect a significant patient population at high risk of lung cancer, as well create a confusing and socially disparate policy that increases rather than decreases health care disparities in the elderly by creating a barrier to lung cancer screening access for lower income, elderly Americans.

In addition, our joint recommendations also address the definition of asymptomatic patients, order writing requirements for annual follow-up LDCT, the 15-year smoking cessation threshold, and accreditation and designation.

As noted in the opening of this letter, we consider equitable access to high quality screening the overarching public health priority and we look forward to continued dialogue and collaboration with CMS in developing and implementing a safe and effective national coverage policy that will save thousands of lives.
Sincerely,

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Lung Cancer Alliance

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   Cindy Moran, ACR  
   Chris Sherin, ACR  
   Pam Wilcox, ACR  
   Angela Kim, ACR  
   Anita McGlothlin, ACR
Appendices/Attachments

Moyer VA, MD, MPH on behalf of the U.S. Preventive Services Task Force
http://annals.org/article.aspx?articleid=1809422&resultClick=3

Jaklitsch MT, MD, Jacobson FL, MD, MPH, Austin JHM, MD et al.

Tammema MC, Church TR, Hocking WG, et al.