

# CLINICAL GUIDELINES

Lung-Cancer Screening Program Guidelines  
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## **Introduction:**

The purpose of a lung-cancer screening program is to detect early lung cancers in high-risk individuals. Patients with early stage lung cancers have lower lung-cancer mortality rates suggesting the potential for early detection to reduce morbidity and mortality.

## **Background and Issues:**

The cost-benefit ratio of lung screening is not a straightforward calculation, which has led to controversy and public debate. There is only one high quality study advocating the benefits of screening, the National Lung Screening Trial (NLST) study, and the results of this study are based on only 26,722 patients (another 26,732 assigned to the chest x-ray arm of the study).<sup>1</sup>

The NLST study examined the benefits of screening for lung cancer with low dose computed tomography (LDCT) and chest x-ray (CXR) in a population of patients 55-74 years of age with >30 pack-year smoking history. The study reported that lung screening with LDCT resulted in a 20% decrease in lung cancer mortality. Screening with LDCT prevented 87 lung cancer deaths; however, 356 lung cancer deaths still occurred. In order to achieve these results, patients received 10,246 LDCT exams, 322 biopsies and 671 surgeries with 228 complications, 8 major complications and 16 iatrogenic deaths. In addition, there were costs arising from the work up of the non-pulmonary incidental findings detected in 7.5% of patients and intangible costs such as the long-term risks of radiation exposure and patient anxiety.

Patients who undergo screening can be falsely reassured. Of the 1,060 cancers found with LDCT, only 649 were found as a result of a positive scan. 44 cancers were detected following a negative scan and 367 occurred after the 3 year screening period.

After publication of the NLST study and endorsement of lung screening by the US Preventive Services Task Force (USPSTF), CMS announced that they would cover lung cancer screening LDCT but only after extended debate. Committee members expressed concern over the large variability of radiologist false positive rates and that the NLST results would not be reproduced in a community setting. There was also concern that the risks of screening would be increased and the benefits decreased in the more elderly Medicare population: Only 25% of patients in the NLST study were in the Medicare-aged population. This last concern was tempered with the publication of a more recent study confirming the positive benefits of lung screening relative to costs in the elderly population.<sup>2</sup>

In response to these concerns, CMS approved coverage with explicit requirements concerning patient eligibility, radiologist eligibility, center eligibility, low dose CT technique and reporting requirements.

### **Patient Eligibility:**

One of the most important variables in maximizing the efficacy of a lung-cancer screening program is to limit screening to populations with a high prevalence of disease and to subjects who can benefit significantly from early detection. With increasing age and comorbidities, the potential for prolonged life and improved quality of life decreases. Patients should be healthy enough and willing to undergo surgery or ablative therapy should an early cancer be detected. Eligibility criteria for lung screening differs somewhat between the US Preventative Services Task Force (USPSTF), the Centers for Medicare & Medicaid Services (CMS) and subspecialty organizations.

### **US Preventive Services Task Force Eligibility Recommendations<sup>4</sup>:**

The USPSTF gave the evidence supporting lung screening with the following eligibility criteria a grade B.

- Ages 55 - 80 years;
- Smoking history of 30 pack-year;
- If no longer smoking, stopped smoking in the past 15 years. Screening should be discontinued once a person has not smoked for 15 years; and
- Screening should not be performed or should be discontinued if the patient has or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery or ablative therapy.

The Affordable Care Act requires most health plans to cover preventive health care services that receive a grade of “B” or higher without cost sharing. As a result, these criteria should form the basis of eligibility for private insurers.

## **CMS Lung Screening Eligibility Requirements<sup>9</sup>:**

CMS recently approved coverage for lung screening using low dose computed tomography (LDCT) once a year. Medicare eligibility requirements differ somewhat from the USPSTF criteria:

- Ages 55 - 77 years;
  - Asymptomatic (no signs or symptoms of lung cancer);
  - Tobacco smoking history of 30 pack-year; and
  - Current smoker or smoker who has stopped in the past 15 years - screening discontinued once a person has not smoked for 15 years.
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- For the initial LDCT lung cancer screening service, a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit, furnished by a physician or qualified non-physician practitioner including the following with documentation in the patient's medical records:
    - Determination of eligibility;
    - Shared decision making, including a discussion of the benefits and harms of screening, follow-up testing, over-diagnosis, false positive rate and total radiation exposure;
    - Counseling on the importance of adherence to the screening program, the impact of comorbidities and the willingness to undergo treatment; and
    - Counseling on the importance of smoking cessation if a current smoker or maintaining smoking abstinence if a former smoker, and offering Medicare-covered tobacco cessation counseling services if appropriate.
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- For subsequent LDCT lung cancer screening visits, a written order furnished during any appropriate visit (i.e. during a Medicare annual wellness visit, tobacco cessation counseling services or evaluation and management visit).
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- Written orders for both initial and subsequent LDCT lung cancer screenings must include the following:
    - Beneficiary DOB;
    - Actual pack-year smoking history (number);
    - Current smoking status, and for former smokers, the number of years since quitting;
    - Statement that the patient is asymptomatic; and
    - NPI of the ordering practitioner.

Since these eligibility criteria are stated in the recently published national coverage decision (NCD), they will form the basis for Medicare coverage.

## **NCCN and ATTS Eligibility Recommendations<sup>5,10</sup>:**

The National Comprehensive Cancer Network (NCCN) and the American Association for Thoracic Surgery (AATS) also recommend screening in patients 50 years of age or older with a  $\geq 20$  pack- year smoking history and at least one additional risk factor:

- Age >50 years with smoking history of >20 pack-year and one additional risk factor (family history of lung cancer, lymphoma, COPD, pulmonary fibrosis, high radon exposure, occupational exposure and exposure to second hand smoke).

McKee et al. in a 2015 study found the cancer detection rate in this group of patients to be substantially similar to that in a second group of patients using the NLST criteria.<sup>3</sup> These eligibility criteria might be relevant to labor groups and certain self-insured plans.

## **Asbestos and Other Occupational Exposures:**

Although based on lesser evidence, there may be some demand for screening LDCT in patients with asbestos and other occupational exposure (silica, cadmium, arsenic, beryllium, chromium, diesel fumes, nickel, coal smoke and soot) and no smoking history or lesser smoking histories.

Current guidelines recommend chest x-ray and pulmonary function testing for screening patients with a history of asbestos exposure.<sup>11</sup> CT is only recommended if the PFTs and/or clinical exam suggest disease and the chest x-ray is normal, or if the chest x-ray shows findings of uncertain significance. CT can assist in differentiating pleural plaques from overlying soft tissue densities and rounded atelectasis and CT is more sensitive for pleural plaques. These recommendations encompass concerns about excessive radiation doses which would have been incurred if older CT systems had been used for screening. With modern CT techniques and equipment, the radiation dose has been markedly decreased and LDCT may ultimately replace chest x-ray as the preferred screening modality.

Eisenhower et al. in a 2014 study of 4446 individuals exposed to asbestos showed that LDCT was more sensitive for asbestosis and pleural changes, and recommended screening with LDCT in patients >55 years of age with an asbestos exposure of at least 17 years and at least 28 years since first exposure.<sup>12</sup>

Ollier et al. in a 2014 meta-analysis found that LDCT is effective in detecting asymptomatic lung cancer in workers with a history of asbestos exposure.<sup>13</sup> The study found that the cancer detection rate was similar to the reported in patients with a history of heavy smoking (1%).<sup>1</sup> Of the 49 lung cancers detected, 18 were early stage 1 cancers. The smoking history was heterogeneous in the studies reviewed, however, previous studies have shown that asbestos exposure increases the risk of lung cancer in even in nonsmokers (up to 5-fold).<sup>14,15</sup> The authors concluded that screening with LDCT could reduce mortality in patients with a history of asbestos exposure. While the study did not recommend specific patient parameters for screening, 5/7 studies reported an average asbestos exposure duration of 17.7-29.7 years. LDCT screening might be considered in patients:

- Age > 50 with an asbestos exposure of at least 17 years of duration regardless of smoking history.

These eligibility criteria might be relevant to some labor groups.

### **CMS Radiologist Eligibility Criteria<sup>9</sup>:**

- Board certification or board eligibility with the American Board of Radiology or equivalent organization;
- Documented training in diagnostic radiology and radiation safety;
- Involvement in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years;
- Documented participation in continuing medical education in accordance with the current American College of Radiology standards; and
- Furnish lung cancer screening with LDCT in a radiology imaging facility that meets the facility requirements below.

### **CMS Radiology Imaging Center Eligibility Criteria<sup>9</sup>:**

- Must use LDCTs with a volumetric CT dose index (CTDIvol) of  $\leq 3.0$  mGy for standard sized patients, appropriate dose reductions in smaller patients and appropriate dose increases in larger patients (dose modulation);
- Uses a standardized lung nodule identification, classification and reporting system (Lung-RADS);
- Makes smoking cessation interventions available to patients;
- Collects and submits data to a CMS-approved registry for each LDCT cancer screening performed. The data collected and submitted must include, at a minimum, the following elements:

<i><b>Data Type</b></i>	<i><b>Minimum Required Data Elements</b></i>
Facility	Identifier
Radiologist (reading)	National Provider Identifier (NPI)
Patient	Identifier
Ordering Practitioner	National Provider Identifier (NPI)
CT scanner	Manufacturer, Model.
Indication	Lung cancer LDCT screening – absence of signs or symptoms of lung cancer
System	Lung nodule identification, classification and reporting system
Smoking history	Current status (current, former, never). If former smoker, years since quitting. Pack-years as reported by the ordering practitioner. For current smokers, smoking cessation interventions available.
Effective radiation dose	CT Dose Index (CTDIvol).
Screening	Screen date Initial screen or subsequent screen

- The ACR registry has been approved by CMS for use in the lung screening program.

### **ACR Certification for Lung Screening Centers<sup>8</sup>:**

Certification of screening facilities is not currently required by CMS or private insurers, however if interested the requirements for ACR certification are listed below:

- Subspecialty interpretations
- Structured reporting with patient management recommendations
- Provider referral system if accepting self-referral patients
- Smoking cessation materials or referral to a cessation program
- Equipment requirements (no non-helical or single slice scanners)
- CT quality control program (detailed in ACR CT Quality Control Manual)
- Screening image protocol resulting in a CTDIvol of  $\leq 3$  mGy, for a standard size patient (5'7", 154 lb, using 32 cm diameter CTDI phantom). Cannot use a routine chest protocol.
- Use automatic dose modulation program or manually adjust for smaller or larger patients.
- Participation in the ACR Dose Index Registry

### **ACR Recommended CT Technique (AAPM Protocol<sup>6</sup>):**

CT technique should be optimized to limit the radiation dose to patients. The average effective dose in the NLST study was 1.5mSv. The following low dose screening protocol is recommended:

- One breath-hold (thoracic motion is problematic)
- Thin image thicknesses ( $\leq 2.5$  mm,  $\leq 1.0$  mm preferred)
- Coronal and sagittal reformations. MIPS may be helpful and are encouraged
- CTDIvol  $< 3.0$  mGy for a standard sized patient with dose modulation or manual adjustments for smaller and larger patients
- Typically requires a 16-detector row (or greater) scanner to meet these requirements
- No IV or oral contrast

Manufacturer specific protocols are available on the AAPM web site.<sup>6</sup>

### **ACR Standardized Diagnostic Criteria and Patient Management Protocols: Lung-RADS<sup>7</sup>:**

Standardization of diagnostic criteria and patient management is important in order to realize the positive benefit to risk ratio for lung cancer screening with LDCT. CMS requires all interpreting radiologists to utilize a lung nodule identification, classification and reporting system. At CDI we recommend using the ACR Lung-RADS reporting system for this purpose. (Table 1)

The ACR Lung-RADS reporting system directly addresses concerns about over diagnosis. During the screening phase of the NLST trial, 39.1% of participants in the LDCT group had at least one positive pulmonary finding, and 96.4% of these were false positives. Overcalling pulmonary nodules increases patient anxiety, increases the number of follow-up CT scans and biopsies, and increases morbidity and mortality arising from biopsies and/or surgery. The NLST study used a size threshold of 4mm. This threshold has been increased to 6 mm in the ACR Lung-RADS protocol.<sup>7</sup>

Table 1: ACR Lung-RADS (<http://www.acr.org/Quality-Safety/Resources/LungRADS>)

Category	Category Descriptor	Category	Findings	Management	Probability of Malignancy	Estimated Population Prevalence
Incomplete		0	prior chest CT examination(s) being located for comparison part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is	n/a	1%
Negative	No nodules and definitely benign nodules	1	no lung nodules nodules with specific calcifications: complete, central, popcorn, rings and fat containing nodules solid nodule(s): < 6 mm new < 4 mm	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	part solid nodule(s): < 6 mm total diameter on baseline screening			
			non solid nodule(s) (GCN): < 20 mm OR ≥ 20 mm and unchanged or slowly growing category 3 or 4 nodules unchanged for ≥ 3 months			
Probably Benign	Probably benign finding(s) - short term follow up suggested; includes nodules with low likelihood of becoming a clinically active cancer	3	solid nodule(s): ≥ 6 to < 8 mm at baseline OR new 4 mm to < 6 mm	6 month LDCT	1-2%	5%
			part solid nodule(s): ≥ 6 mm total diameter with solid component < 6 mm OR new < 6 mm total diameter			
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	non solid nodule(s) (GCN) ≥ 20 mm on baseline CT or new solid nodule(s): ≥ 8 to < 15 mm at baseline OR growing < 8 mm OR new 6 to < 8 mm	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component	5-15%	2%
			part solid nodule(s): ≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR with a new or growing < 4 mm solid component			
		4B	endobronchial nodule solid nodule(s): ≥ 15 mm OR new or growing, and ≥ 8 mm	chest CT with or without contrast, PET/CT tissue sampling depending on the "probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.	> 15%	2%
			part solid nodule(s) with: a solid component ≥ 8 mm OR a new or growing ≥ 4 mm solid component			
Other	Clinically Significant or Potentially Clinically Significant Findings (non lung cancer) Modifier for patients with a prior diagnosis of lung cancer who return to Screening	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy	As appropriate to the specific finding	n/a	10%
Prior Lung Cancer		C	modifier - may add on to category 0-4 coding modifier - may add on to category 0-4 coding		-	-



As noted above, an additional 7.5% of participants had significant incidental findings on the LDCT exams not related to the lung. These findings should be managed according to subspecialty guidelines which are summarized in the *CDI Quality Institute Incidental Finding Guidelines* Document (S: share drive in the folder labeled CDI guidelines).

### **Other Program Considerations:**

- Patient management issues:
  - Many of the patient management issues are similar to those encountered with breast cancer screening;
  - Patient registries are useful to track patients and to encourage compliance with screening recommendations;
  - Electronic reminders help to increase patient compliance and to minimize risk exposure;
  - Direct patient notification may also increase compliance and manage risk, and is necessary if you are accepting self-referral patients; and
  - Patients with high-grade findings should be referred to a multidisciplinary care team.
- The use of patient advocates or a nurse counselor is encouraged, particularly if the center accepts self-referral, and may perform or assist with any of the following functions:
  - Prescreen patients to help determine eligibility in occupational cases;
  - Schedule exams;
  - Discuss with the patient the meaning of a negative scan, a “small nodule” scan and a suspicious scan;
  - Be proactive in ensuring that the results of the exam are received by the referring doctor and/or patient;
  - Assist with referral of patients with high risk findings to the appropriate pulmonary or thoracic subspecialists;
  - Encourage or facilitate compliance with follow-up recommendations in patients with negative and low risk findings; and
  - Assist with or manage counseling cessation programs.
- Consider enhancements:
  - Upgrade exam with post-processing to quantitate and illustrate and grade lung texture – normal, emphysema, ground-glass, reticular, honeycombing, etc. (Imbio, LLC). (Figure 1)
  - Upgrade exam with information on coronary artery calcifications (Agatston score). (Figure 2)
  - Enhancements may support a higher billing rate for commercial insurers
  - Additional information might bolster efforts at smoking cessation.



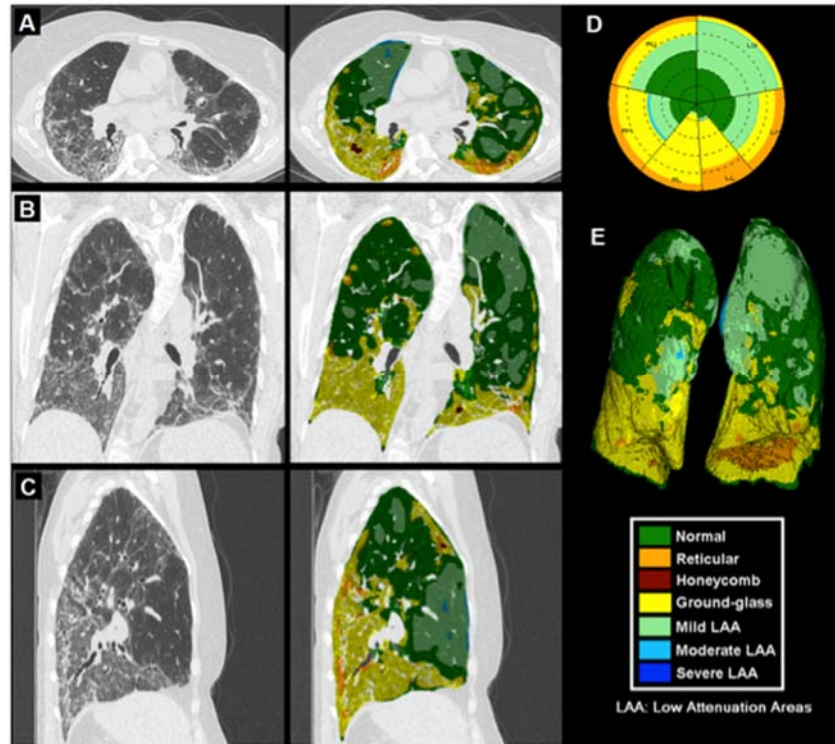
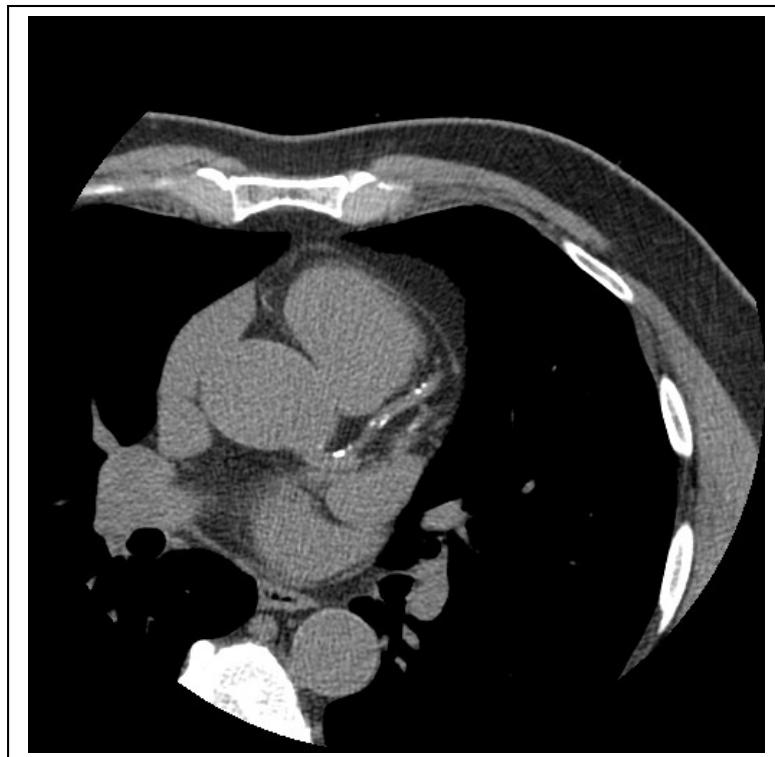


Figure 1: Lung texture analysis by Imbio, LLC.

Figure 2: Coronary artery calcifications



This is a guideline, not a policy. It is a summary and distillation of relevant literature and subspecialty guidelines. The purpose of the CDI Quality Institute guidelines is to promote quality and continuity, where appropriate for medical practices within the CDI/Insight enterprise, and to provide relevant and up to date background information to support the development of policies within each individual practice. Guidelines should be adjusted for local standards of care, associated hospital or network policies, hospital versus outpatient settings, different patient populations and your own risk tolerance. Guidelines should also be modified to account for new information or publications that become available between revisions.

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