



## Clinical Review Criteria Low-Dose CT Screening for Lung Cancer

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### Criteria

#### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (210.14)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	<a href="#">Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)</a>

#### For Non-Medicare Members

Service	Criteria
<b>Low-dose CT screening</b>	<p><b>Low-dose CT screening for lung cancer will be covered when the patient meets the following criteria:</b></p> <p><b>Ages 50 through 79:</b> Annual screening for lung cancer with low dose computed tomography is recommended for patients who:</p> <ul style="list-style-type: none"> <li>• Have at least a 20 pack-year smoking history,</li> <li>• Currently smoke or quit less than 15 years ago, and</li> <li>• Have no significant comorbidities that would preclude surgical treatment or limit life expectancy.</li> </ul> <p><b>Ages 80 and over:</b> Annual lung cancer screening with LDCT is not recommended.</p> <p><b>Discontinuation</b> Discontinuation of lung cancer screening is recommended at 15 years following the patient's quit date, or as appropriate for health status.</p>
<b>Multiple Myeloma</b>	For low-dose whole body CT for Multiple Myeloma use the <a href="#">PET Scan Criteria</a>

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

### Background

Lung cancer is the third most common cancer and the leading cause of cancer death in the United States. According to the U.S. Preventive Services Task Force (USPSTF), nearly 90% of individuals with lung cancer die

of the disease. However, when detected at an early stage, non–small cell lung cancer (NSCLC) has a better prognosis and can be treated with surgical resection. (The majority of lung cancer cases are NSCLC.)

The most important risk factor for lung cancer is smoking, which results in approximately 85% of all U.S. lung cancer cases. The incidence of lung cancer increases with age, occurring most commonly in individuals aged 55 years or older. Increasing age and cumulative exposure to tobacco smoke are the two factors most strongly associated with the occurrence of lung cancer.

The USPSTF found adequate evidence that annual screening with low-dose computed tomography (LDCT) in current and former smokers aged 55 to 79 years who have significant cumulative tobacco smoke exposure can prevent a substantial number of lung cancer deaths. LDCT has greater sensitivity for detecting early-stage cancer than chest X-ray and sputum cytology; however, it also has a very high rate of false positives (about 95%). For the benefits to outweigh the harms, screening needs to be limited to those who are at the highest risk for lung cancer.

## Medical Technology Assessment Committee (MTAC)

### **Low-Dose CT Screening for Lung Cancer**

#### **12/12/2001: MTAC REVIEW**

**Evidence Conclusion:** There is no evidence on the diagnostic accuracy of the low-dose CT test for lung cancer screening. That is, an independent, blind, comparison of the low-dose CT tests with a gold standard (e.g. high-dose CT) for an appropriate group of patients. In the Henschke study, only patients with certain findings on low-dose CT were recommended to have high-dose CT. There are also no studies comparing the diagnostic accuracy of low-dose CT screening to the current standard, chest radiography. The only available evidence on low-dose CT screening for lung cancer is prospective reports of screening programs. Henschke set up a protocol to screen individuals at increased risk of lung cancer. They found that more non-calcified nodules, malignant nodules and stage I malignant disease was found using low-dose CT than could be detected by chest radiography. These data suggest that low-dose CT may be useful for lung cancer screening. The data presented in the Henschke study are insufficient for evaluating the question of whether screening with low-dose CT reduces disease-specific mortality. Even though more nodules and more stage I nodules were identified than with chest radiography, it is not known whether this early identification will lead to decreased mortality from lung cancer. (Previous randomized controlled trials evaluating the effectiveness of chest radiography for lung cancer screening did not find a difference in mortality in the screened and unscreened groups). Alternatively, CT screening may not increase disease-specific survival due to lead-time bias and over diagnosis bias. Randomized controlled trials comparing CT screening to no screening would provide more rigorous information about its effectiveness as a screening strategy.

**Articles:** The search yielded 54 articles, many of which were review articles, opinion pieces or dealt with technical aspects of the procedure. There were no randomized controlled trials or meta-analyses. Five case series with relevant clinical outcomes were identified. Four were studies conducted in Japan and one was a study conducted at Cornell University. Of the four Japanese studies, there were two studies by Sone et al. and two studies by Kaneko et al. The Sone articles were an earlier and later report on the same project, as were the Kaneko articles. Neither of the Japanese screening projects had specific clinical inclusion and exclusion criteria. The Sone study screened the general population and the Kaneko study screened people who were members of a non-profit organization, the Anti-Lung Cancer Association (ACLA). In addition, neither Japanese screening project appeared to have a consistent protocol that was followed. The Cornell University study by Henschke et al. screened only individuals at high-risk of lung cancer and had clear eligibility criteria as well as screening and follow-up protocols. None of the articles were designed to evaluate the diagnostic characteristics of the low-dose CT test (e.g. sensitivity, specificity). *An evidence table was created for the Henschke study:* Henschke CI, McCauley DI, Yankelevitz DF, Naidich DP, McGuinness G, Miettinen OS, Libby DM, Pasmantier MW et al. Early Lung Cancer Action Project: Overall design and findings from baseline screening. *Lancet* 1999; 354: 99-105. See [Evidence Table](#)

The use of CT Scanning in the screening of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria 2* for effectiveness of diagnostic test.

### **Low-Dose CT Screening for Lung Cancer**

#### **8/15/2011: MTAC REVIEW**

**Evidence Conclusion:** The National Lung Screening Trial (NLST), a large RCT that included 53,454 participants, examined whether screening high-risk individuals for lung cancer annually for three years with either LDCT or chest x-ray would reduce lung cancer mortality. Results from the NLST suggest that in high-risk patient's annual lung cancer screening for three years using LDCT reduced lung-cancer mortality with a number needed to screen

to prevent one cancer death of 320. However, before recommending a screening test there are other factors to consider such as overdiagnosis, cost-effectiveness, false positive results, and other potential harms such as radiation-induced cancer. The effect of overdiagnosis and radiation-induced cancer could not be directly measured in this trial and cost-effectiveness analyses are currently underway. With regard to false positive results, across the three rounds of screening, 96.4% of the positive results in the LDCT and 94.5% in the x-ray group were false positive results. Additionally, 39.1% of subjects in the LDCT group and 16.0% in the x-ray group had at least one positive screening test during the screening phase of the trial (NSLT 2011). A recent interim analysis from a RCT that included 2,472 men who were at high-risk for lung cancer examined whether yearly lung cancer screening using LDCT in combination with a medical interview and physical exam would reduce lung cancer mortality compared to yearly medical interview and physical exam alone. After approximately 3 years of follow-up, significantly more men in the intervention group were diagnosed with lung cancer [intervention 60 (4.7%) vs. control 34 (2.8%),  $P=0.02$ ]. However, there was no significant difference in lung cancer mortality between the two groups [intervention 20 (1.6%) vs. control 20 (1.7%),  $P=0.84$ ]. Conclusion: Results from the NLST suggest that screening high-risk patients with LDCT annually for three years may reduce lung-cancer mortality; however, despite these positive results there are many other questions that still need to be answered such as screening frequency and duration. In 2007, the California Technology Assessment Forum evaluated the use of low-dose spiral computed tomography (LDCT) screening for lung cancer. They concluded that while the use of LDCT to screen for lung cancer in high-risk populations appeared promising, there was insufficient published evidence to recommend the use of LDCT outside of the investigational setting. Since the 2007 technology assessment, two randomized controlled trials (RCTs) were selected for review that examined the effectiveness of screening high-risk individuals for lung cancer using LDCT compared to chest x-ray.

**Articles:** The following studies were critically appraised: National Lung Screening Trial (NLST). Reduced lung-cancer mortality with computed tomographic screening. *N Engl J Med* 2011. [Epub ahead of print] See [Evidence Table](#) Infante M, Cavuto S, Lutman FR, et al. A randomized study of lung cancer screening with spiral computed tomography: three-year results from the DANTE trial. *Am J Respir Crit Care Med* 2009; 180:445. See [Evidence Table](#)

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### **Low-Dose CT Screening for Lung Cancer**

#### **10/15/2012: MTAC REVIEW**

**Evidence Conclusion:** The Danish Lung Cancer Screening (DLCST), a RCT that included 4,104 participants, examined whether screening high-risk individuals yearly with LDCT would reduce lung cancer mortality compared to usual care (no screening). Results from this trial suggest that after 5 years of screening, LDCT did not reduce lung cancer mortality or all-cause mortality compared to usual care. Significantly more lung cancers were diagnosed in the screening group compared to the control group (69 vs. 24,  $P<0.001$ ), and more were early stage (48 vs. 21,  $P=0.002$ ). There was no significant difference in the number of late stage lung cancer (21 vs. 16,  $P=0.51$ ). The diagnostic false positive rate was 7.9% at baseline, 1.7% at year 1, 2.0% at year 2, 1.6% year 3, and 1.9% year 4. One limitation of this trial is that the sample size may be insufficient and the duration of follow-up may not be long enough to detect a reduction in mortality (Saghir 2012) The Multicentric Italian Lung Detection (MILD), a RCT that included 4,099 participants, examined whether screening high-risk individuals yearly or every two years with LDCT would reduce lung cancer mortality compared to usual care (no screening). Results from this trial suggest that after 5 years of follow-up, annual or biennial screening with LDCT did not reduce lung cancer mortality compared to usual care. The incidence of lung cancer was significantly higher in LDCT screening groups compared to the control group ( $P=0.025$ ), but not in the annual versus the biennial groups ( $P=0.24$ ). Due to recruitment issues the trial may be underpowered to detect differences in mortality. Additionally, at baseline more subjects in the control group were current smokers (Pastorino 2012). Conclusion: Results from the NLST suggest that screening high-risk patients with LDCT annually for three years may reduce lung-cancer mortality; however, despite these positive results there are many other questions that still need to be answered such as screening frequency and duration, and the effects of cumulative radiation exposure. Results from other RCTs have not shown a mortality benefit; however, these trials may be underpowered.

**Articles:** Low-dose CT screening for lung cancer was previously reviewed in 2001 and 2011. Since the 2011 review, two randomized controlled trial were identified that assessed the benefits and harms of screening for lung cancer using low-dose CT in high risk patients. The following studies were critically appraised: Saghir Z, Dirksen A, Ashraf H, et al. CT screening for lung cancer brings forward early disease. The randomized Danish Lung Cancer Screening Trial: status after five annual screening rounds with low-dose CT. *Thorax*. 2012; 67:296-301. See [Evidence Table](#) Pastorino U, Rossi M, Rosato V, et al. Annual or biennial CT screening versus observation in heavy smokers: 5-year results of the MILD trial. *Eur J Cancer Prev*. 2012; 21:308-315. See [Evidence Table](#)

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## Applicable Codes

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® or HCPC Codes	Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)
Diagnosis Codes	Description
Z87.891	Personal history of nicotine dependence
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.213	Nicotine dependence, cigarettes, with withdrawal
F17.218	Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17.219	Nicotine dependence, cigarettes, with unspecified nicotine-induced disorders

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
12/28/2001	05/03/2011 <sup>MDCRPC</sup> , 08/02/2011 <sup>MDCRPC</sup> , 09/06/2011 <sup>MDCRPC</sup> , 07/03/2012 <sup>MDCRPC</sup> , 11/06/2012 <sup>MDCRPC</sup> , 09/03/2013 <sup>MPC</sup> , 07/01/2014 <sup>MPC</sup> , 11/04/2014 <sup>MPC</sup> , 09/01/2015 <sup>MPC</sup> , 07/05/2016 <sup>MPC</sup> , 05/02/2017 <sup>MPC</sup> , 03/06/2018 <sup>MPC</sup> , 02/05/2019 <sup>MPC</sup> , 02/04/2020 <sup>MPC</sup> , 02/02/2021 <sup>MPC</sup> , 02/01/2022 <sup>MPC</sup> , 02/07/2023 <sup>MPC</sup>	12/07/2021

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
11/04/2014	MPC adopted the USPSTF guidelines for lung cancer screening
05/05/2015	Age limits were changed to align with Medicare: <ul style="list-style-type: none"> <li>• Ages 75 through 77</li> <li>• Ages 78 and over</li> </ul>
11/17/2015	Changed Medicare link
08/26/2021	Updated link under Medicare Local Coverage Article section
12/07/2021	MPC approved to adopt the modifications to the current Low Dose CT Cancer Screening to align with updated recommendations from the USPSTF. Requires 60-day notice, effective 03/01/2022.