MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**LOW-DOSE COMPUTED TOMOGRAPHY (LDCT) FOR LUNG CANCER SCREENING**
Policy Number	**6.01.19**
Category	**Technology Assessment**
Effective Date	**10/18/01**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and review of the peer-reviewed literature, annual lung cancer screening using Low Dose CT is considered **medically appropriate** for high risk individuals who have not received a Low Dose CT lung screening in the past 12 months, have no signs or symptoms suggestive of underlying lung cancer, and are able and willing to undergo curative lung surgery. High-risk individuals are defined as aged 55 to 80 years with a history of 30 pack years of smoking cigarettes (e.g., have smoked at least a pack per day for 30 years), who are either:
   A. a current smoker; or
   B. have quit smoking within the past 15 years.

II. Based upon our criteria and review of the peer-reviewed literature, computer aided detection (CAD) has not been medically proven to be effective to improve the accuracy of CT scanning in screening for lung cancer and, therefore, is considered **investigational**.

Refer to Corporate Medical Policy #6.01.13, Computed Tomography (EBCT, Spiral CT, MDCT) to Detect Coronary Artery Calcification (Coronary Calcium Scoring).

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

I. Lung cancer screening using Low Dose CT should be discontinued when:
   A. An individual has not smoked for more than 15 years; or
   B. An individual develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Low dose computed tomography (LDCT) is a new form of CT, also known as low-dose spiral CT scan, is used to diagnose lung cancer in symptomatic persons. Published data has indicated that a low radiation dose spiral CT is capable of detecting abnormalities, including those suggestive of lung cancer, in asymptomatic, high-risk individuals. Electron beam CT (EBCT) is also used; however, spiral CT is the modality most commonly reported in the literature.
Spiral CT has several technical advantages over conventional CT, which enhances its clinical role. Imaging can be performed during a 20-second breath hold. The X-ray tube rotates continuously around the patient while the table and patient slowly move through the scanner. Each rotation takes 0.7-1 second therefore large volumes can be covered during a single scan. A volume data set is obtained as the tube-detector system traces a helical or spiral path. If the scan is performed during a single breath hold, it will be virtually free of misregistration artifacts. Radiation exposure is comparable to that absorbed during mammography. The entire examination is performed in less than 10 minutes.

The outcomes proposed for measuring the efficacy of spiral CT are:
I. Detection of smaller and presumably earlier stage tumors than chest x-ray;
II. Reduction in mortality of lung cancer patients, exposure to a lower dose of radiation than high resolution CT, no intravenous contrast needed; and
III. Less expensive than high resolution CT and minimally more expensive than chest x-ray.

RATIONALE

Spiral CT systems such as the LightSpeed Plus CT System (General Electric Medical Systems) are approved by the U.S. Food and Drug Administration (FDA). In February 2004, the FDA approved the R2 Technology ImageChecker CT software system as a technique to assist in the detection of lung nodules on multi-detector CT scans of the chest.

While spiral CT is proposed as an alternative to chest x-ray and high resolution CT in the screening of lung cancer, published clinical trials do not provide evidence to support the efficacy of spiral CT over conventional screening methods in reducing mortality from lung cancer. Studies support that spiral CT scanning is more sensitive than chest x-rays in identifying lung lesions. However, there is inadequate data to indicate whether early identification of lung cancer will lead to decreased cancer mortality. Because no lung cancer mortality data exists for spiral CT, there is insufficient evidence to advocate mass screening with spiral CT for individuals at elevated risk of lung cancer.

To be a valuable screening tool, it is not sufficient that spiral CT accurately detect malignant pulmonary nodules at an earlier stage. The technology must also demonstrate potential to prolong lung cancer survival time and to reduce disease-associated mortality. At this time, the available evidence from clinical research trials does not indicate clinically significant benefits or cost-effectiveness associated with spiral CT detection of lung cancer by routine screening.

Results from the International Early Lung Cancer Action Project (ELCAP) reported that of 31,657 asymptomatic patients who underwent a baseline and then annual CT scan for detection of lung cancer, a diagnosis of lung cancer was found in 484 patients (1.53% of the study population). Participants were enrolled at multiple sites worldwide, including the U.S., Japan and Europe. The study did not use a comparison group, such as screening with chest x-ray, to clearly demonstrate that there is any benefit from annual CT exams, and was non-randomized. Risks involved with CT screening are increased radiation exposure and the extent of evaluation of false-positive scans including needle biopsy and surgery to further evaluate a positive finding. Randomized controlled trials are needed to determine whether the use of this procedure improves survival and to assess the overall impact of various alternatives. One such trial, the National Lung Screening Trial, is in progress.

The National Lung Screening Trial (NLST) was a large well-conducted trial comprising a total of 53,454 current or former smokers from 33 sites in the United States who were randomly assigned to screening in 3 consecutive years with either a chest x-ray or low-dose spiral CT. Eligible participants included were aged 55 to 74 years, had a history of cigarette smoking of at least 30 pack-years, and either continued to smoke or had quit. Individuals with a previous diagnosis of lung cancer or who had signs and/or symptoms suggestive of lung cancer were excluded. The trial results found a statistically significantly lower rate of lung cancer mortality with 3 annual CT screens compared to chest radiographs; the number needed to screen (NNS) to prevent one lung cancer death was 320 (95% CI: 193 to 934). The

study also found a statistically significant but modestly lower overall mortality rate in low-dose CT group. There was a high rate of follow-up imaging tests but a relatively low rate of invasive tests. There were few major complications reported after invasive testing, although major complications that did occur were not well-characterized. The rates of other potential complications, in particular radiation-induced cancers, are not yet known. Findings of the trial cannot be generalized to other populations, e.g., younger individuals or lighter smokers. The NLST evaluated the utility of a series of 3 annual CT screens; the efficacy of other screening regimens is not known.

The Danish Lung Cancer Screening Trial randomized a total of 4,104 current or former smokers to screening with annual low-dose CT for 5 years or no screening during 2004 and 2006; lung cancer mortality was the primary outcome measure. Among the 2,052 individuals who received baseline CT scans, 179 (8.7%) had positive findings; a large proportion of these findings (162 of 179, 91%) were false positive. Seventeen individuals (0.8%) were found to have lung cancer; 10 cases were stage 1 disease.

On December 31, 2013, the U.S. Preventive Services Task Force (USPSTF) published its recommendation statement on lung cancer screening. The Task Force recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 55 to 80 years with a smoking history of 30 pack-years, who currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. (B recommendation). The USPSTF concluded with moderate certainty that annual screening for lung cancer with LDCT is of moderate net benefit in asymptomatic persons who are at high risk for lung cancer based on age, total cumulative exposure to tobacco smoke, and years since quitting smoking. The moderate net benefit of screening depends on limiting screening to persons who are at high risk, the accuracy of image interpretation being similar to that found in the NLST (National Lung Screening Trial), and the resolution of most false-positive results without invasive procedures.

The National Comprehensive Cancer Network Lung Cancer Screening Guideline (2014) recommends that high risk individuals should be screened; however moderate- and low-risk individuals should not currently be screened. High risk individuals are defined as between aged 55 to 74 years with a history of smoking tobacco 30 pack years and if a former smoker, quit within 15 years. This is a category I recommendation because individuals are selected based on the NLST inclusion criteria; individuals age 50 years or older, with a 20 or more packs per year history of smoking tobacco and one additional risk factor. Risk factors include exposure to high radon levels; occupational exposure to silica, cadmium, asbestos, arsenic, beryllium, chromium, diesel fumes or nickel; personal history of lung cancer, lymphoma, or head and neck cancer; family history of lung cancer; or personal history of COPD or pulmonary fibrosis. This is a category 2B recommendation because these individuals are selected based on lower level evidence and some panel members would not recommend LDCT for these individuals.

A collaborative initiative of the American Cancer Society (ACS), the American College of Chest Physicians (ACCP), and the American Society of Clinical Oncology (ASCO) developed the following recommendations: for smokers and former smokers aged 55 to 74 years who have smoked tobacco for 30 pack-years or more, and either continue to smoke or have quit within the past 15 years, annual screening with low-dose computed tomography (LDCT) are suggested to be offered over both annual screening with chest radiograph or no screening, but only in settings that can deliver the comprehensive care provided to National Lung Screening Trial (NLST) participants. (Grade of recommendation: 2B.) For individuals who have accumulated fewer than 30 pack years of smoking are either younger than 55 years or older than 74 years, or quit smoking more than 15 years ago, as well as, for individuals with severe comorbidities that would preclude potentially curative treatment, limit life expectancy, or both, LDCT screening is not recommended. (Grade of recommendation: 2C.)

The American Lung Association (2012) recommends lung cancer screening with low-dose CT scans for people who meet the following criteria: current or former smokers (aged 55 to 74 years), with a smoking history of at least 30 pack-years (that is, an average of a pack a day for 30 years) and with no history of lung cancer. The American Lung Association emphasizes that only CT scans are recommended and that chest X-rays should not be used for lung cancer screening. The Lung Association recognizes that while low dose CT scans may save lives, screening for lung cancer should not be recommended for everyone as many known and unknown risks may be associated with the screening and subsequent medical evaluation.

The American Cancer Society Interim Guidance on Lung Cancer Screening(2012) recommend that adults between the ages of 55-74 *who meet the eligibility criteria of the NLST* and are concerned about their risk of lung cancer may consider screening for early lung cancer detection. With their physician or other primary provider, individuals interested in screening should weigh the currently known benefits of LDCT screening with the currently known limitations and risks and make a shared decision as to whether they should be screened for lung cancer.

The American Association for Thoracic Surgery guidelines for cancer screening using low-dose computed tomography scans for lung cancer survivors and other high risk groups (2012) recommends annual lung cancer screening to begin at age 55 years for smokers and former smokers with a 20 pack-year history of smoking which may continue to age 79 years (Level 1 evidence). Annual lung cancer low-dose CT should be performed in patients who have been treated for a primary bronchogenic carcinoma without recurrence 4 years post- radiographic surveillance or in patients aged 50-79 years with a 20 pack-year smoking history and other factors (e.g., COPD with FEV1 of 70% or less than predicted, environmental and occupational exposures, prior cancer or thoracic radiation, or genetic or family history) that produce a cumulative risk of developing lung cancer of 5% or more over the following 5 years (Level 2 evidence).

The use of computer-aided detection (CAD) software may assist in lung cancer screening. However, there is insufficient evidence to determine whether CAD technology may improve the accuracy of CT scanning interpretation. While CAD systems have been shown to detect additional lung nodules compared to the results of human readers alone, the issue is how many detected nodules are lung cancers. The effectiveness of CAD in detecting lung cancer has not been fully investigated. High-quality randomized trials examining the effect of CAD systems for CT scans on lung cancer morbidity and mortality are necessary to determine the true impact of this technology on health outcomes.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key; NMN = Not Medically Necessary*

CPT Codes

Code	Description
71250	Computerized tomography, thorax; without contrast material (NMN with V16.1, Z80.1)

HCPCS Codes

Code	Description
G0296	Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)
G0297	Low dose CT scan (LDCT) for lung cancer screening

ICD10 Codes

Code	Description
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs
Z80.1	Family history of malignant neoplasm; trachea, bronchus and lung

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*Key Article

KEY WORDS

EBCT, Electron beam computed tomography, Helical CT, Low-dose CT, Spiral CT.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT). Please refer to the following CMS website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

There is currently a National Coverage Determination (NCD) for Lung Cancer Screening with Low Dose Computed Tomography (LDCT). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=364&ncdver=1&bc=AAAAgAAAAAAAAA%3d%3d&