MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Low-Dose Computed Tomography (LDCT) for Lung Cancer Screening**
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Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, annual lung cancer screening using low-dose computed tomography (CT) is considered **medically appropriate** for:
   A. Individuals who have not received a low-dose CT lung screening in the past 12 months, **AND**
   B. Have **NO** health problems that substantially limit life expectancy or the ability or willingness to undergo curative lung surgery; **AND**
   C. Individuals between 50 to 80 years of age; **AND**
   D. Has at least a 20 pack-years of smoking cigarettes; **AND**
   E. Currently smokes or quit smoking within the past less than or equal to 15 years.

II. Based upon our criteria and assessment 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 (CT) for Coronary Calcium Scoring

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINES

Lung cancer screening using low-dose CT should be discontinued when:

I. An individual has not smoked for more than 15 years; or

II. An individual develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.

DESCRIPTION

Low-dose CT (LDCT), also known as low-dose spiral CT scan, is a new form of CT that is used to diagnose lung cancer in symptomatic persons. Published data have indicated that a spiral CT with a low radiation dose 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 most commonly reported modality in the literature.

Spiral CT has several technical advantages over conventional CT, enhancing 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, and ability to administer without intravenous contrast; and
III. Reduction in cost when compared with high-resolution CT and minimal increase in cost when compared with 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 Image Checker 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 non-randomized 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. Risks involved with CT screening are increased radiation exposure and the unnecessary procedures (such as needle biopsy and surgery) performed after false-positive findings. Randomized, controlled trials are needed, to determine whether the use of this procedure improves survival and to assess the overall impact of various alternatives.

The National Lung Screening Trial (NLST) in 2011 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 three consecutive years with either a chest x-ray or LDCT. 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 three 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 the LDCT 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 three 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 LDCT for five 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.

The U.S. Preventive Services Task Force (USPSTF) published an updated recommendation statement on lung cancer screening. Based on new evidence, the USPSTF recommends yearly screening using a low-dose computed tomography (CT) scan for people aged 50 to 80 years old who are at high risk for lung cancer because of their smoking history. This is a B recommendation. Candidates for screening are people between 50 and 80 years old who have smoked at least 20 pack-years over their lifetime, and still smoke or have quit smoking within the last 15 years. By expanding who is eligible for screening, this updated USPSTF recommendation means more Black people and women will now be eligible for lung cancer screening.

The current National Comprehensive Cancer Network (NCCN) Lung Cancer Screening Guideline recommends that high-risk individuals be screened; however, low-risk individuals should not be screened. High-risk individuals are defined as greater than or equal to 50 years of age, with greater than or equal to 20 pack-years of smoking cigarettes, and, if a former smoker, quit within 15 years. This is a category 2A recommendation. In candidates for screening, shared patient/provider decision-making is recommended, including a discussion of benefits/risks. Risk factors include occupational exposure, radon exposure, personal cancer history of lymphomas, cancers of the head and neck, or smoking-related cancers, family history of lung cancer in first-degree relatives, or personal history of COPD or pulmonary fibrosis. All individuals who currently smoke cigarettes should be advised to quit smoking, and all individuals who formerly smoked should be advised to remain abstinent from smoking.

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: (1) annual screening with LDCT 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; (2) annual screening with LDCT should be offered over both annual screening with chest radiograph or no screening, but only in settings that can deliver the comprehensive care provided to NLST participants (Grade of recommendation: 2B). LDCT screening was not recommended 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; or for individuals with severe comorbidities that would preclude potentially curative treatment, limit life expectancy, or both (Grade of recommendation: 2C).

The American Lung Association (2012) recommended lung cancer screening with LDCT scans for people who meet the following criteria: current or former smokers, age 55 to 74 years old, with a smoking history of at least 30 pack-years and with no history of lung cancer. The American Lung Association emphasized that only CT scans are recommended, and chest x-rays should not be used for lung cancer screening. The American Lung Association recognized that, while LDCT 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 Association for Thoracic Surgery guidelines for cancer screening using LDCT scans for lung cancer survivors and other high-risk groups (2012) recommended annual lung cancer screening to begin at age 55 years for smokers and for former smokers with a 20 pack-years history of smoking that may continue to age 79 years (Level 1

evidence). Annual lung cancer LDCT scans should be performed for patients who have been treated for a primary bronchogenic carcinoma without recurrence at four years post- radiographic surveillance, and for patients 50 to 79 years of age with a 20 pack-years 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 five 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.

A study by Zhu 2020 looked at over 8,700 LDCT chest scans and identified 943 noncalcified nodules attached to the costal pleura, of these 897 were < 10 mm in size. There were 603 that were either lentiform, oval, semicircular or triangular in shape and had smooth margins. All of these nodules, that met these qualifications of shape, size and smooth margins, were benign. Follow-up with annual screening, rather than more immediate work-up, was recommended.

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: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s) **(NMN with 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)

ICD10 Codes

Code	Description
F17.210-F17.219	Nicotine dependence, cigarettes (code range)
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs
Z80.1 **(NMN)**	Family history of malignant neoplasm; trachea, bronchus and lung
Z87.891	Personal history of nicotine dependence

REFERENCES

Previously titled Spiral Computed Tomography (CT) for Lung Cancer Screening.

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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

Based upon our review, there is currently a National Coverage Determination (NCD) for Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (210.14). 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&] accessed 12/14/23.

Based upon our review, there is currently a Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N). Please refer to the following CMS website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274] accessed 12/14/23.