Clinical Policy Title: Lung cancer screening

Clinical Policy Number: 07.01.02

Effective Date: July 1, 2016
Initial Review Date: April 27, 2016
Most Recent Review Date: April 27, 2016
Next Review Date: April 2017

Policy contains:
- Lung cancer screening.
- Low-dose computed tomography (LDCT).

Related policies:

None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of lung cancer screening with low-dose computed tomography (LDCT) scanning, also known as spiral CT or helical CT scanning, to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Annual screening for lung cancer with LDCT criteria:
- Ages 55–80 years.*
- Asymptomatic (no signs or symptoms of lung disease).
- Tobacco-smoking history of at least 30 pack-years (1 pack-year = smoking 1 pack per day for 1 year; 1 pack = 20 cigarettes).
- Current smoker or one who has quit smoking within the past 15 years.
- A written order for LDCT lung cancer screening.
- For the initial LDCT lung cancer screening service, a written order must be provided during a lung cancer screening counseling visit.
For subsequent LDCT lung cancer screenings, a written order may be provided during any appropriate visit.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other indications for lung cancer screening with LDCT scanning are not medically necessary.

Chest X-rays (CXR) should not be used for cancer screening. (Wender et al. 2013).

Positron emission tomography (PET) is considered experimental and investigational for lung cancer screening because its effectiveness for this indication has not been established.

Alternative covered services:

Monitoring by treating provider and smoking cessation program.

Background

Lung cancer is the third most common cancer and the leading cause of cancer death in the United States. In 2012, the American Cancer Society estimates that there were about 226,000 people newly diagnosed with lung cancer and 160,000 deaths. The most important risk factor for lung cancer is smoking, which results in approximately 85 percent of all U.S. lung cancer cases. Although the prevalence of smoking has decreased, approximately 37 percent of U.S. adults are current or former smokers. The incidence of lung cancer increases with age and occurs most commonly in persons aged 55 years or older. Increasing age and cumulative exposure to tobacco smoke are the two most common risk factors for lung cancer.

Lung cancer has a poor prognosis, and nearly 90 percent of persons with lung cancer die of the disease. However, early-stage non-small cell lung cancer (NSCLC) has a better prognosis and can be treated with surgical resection.

Most lung cancer cases are NSCLC, and most screening programs focus on the detection and treatment of early-stage NSCLC. Although chest radiography and sputum cytologic evaluation have been used to screen for lung cancer, LDCT has greater sensitivity for detecting early-stage cancer.

Although lung cancer screening is not an alternative to smoking cessation, the U.S. Preventive Services Task Force (USPSTF) found adequate evidence that annual screening for lung cancer with LDCT in a defined population of high-risk persons can prevent a substantial number of lung cancer-related deaths.
Direct evidence from a large, well-conducted, randomized, controlled trial (RCT) provides moderate certainty of the benefit of lung cancer screening with LDCT in this population. The magnitude of benefit to the person depends on that person’s risk for lung cancer because those who are at highest risk are most likely to benefit. Screening cannot prevent most lung-cancer-related deaths, and smoking cessation. Combination therapy with counseling and medications is more effective at increasing cessation rates than either component alone. The U.S. Food and Drug Administration has approved several forms of nicotine replacement therapy (gum, lozenge, transdermal patch, inhaler, and nasal spray), as well as bupropion and varenicline. More information on the treatment of tobacco dependence is available in the U.S. Public Health Service Reference Guide “Treating Tobacco Use and Dependence: 2008 Update.”

The sensitivity of chest radiography for detecting lung cancer varies depending on the size and location of the lesion, image quality of the scan and skill of the radiologist who interprets the scan. LDCT has emerged as a test with higher sensitivity and specificity for lung cancer than chest radiography. In 2004, the USPSTF found inadequate evidence to recommend for or against screening for lung cancer with LDCT, chest radiography, sputum cytologic evaluation or a combination of these tests (I statement). Since then, many RCTs have been done and published, resulting in more data on the benefits and harms of screening. Recent data from the National Lung Screening Trial (NLST) showed a sensitivity of 93.8 percent and specificity of 73.4 percent for LDCT and a sensitivity of 73.5 percent and specificity of 91.3 percent for chest radiography. Sputum cytologic evaluation is now rarely used for lung cancer screening, and no studies reported on the test characteristics of this screening method.

A computed tomography (CT or CAT) scan X-ray produces detailed cross-sectional images of the lungs. It is better than a regular X-ray at finding lung tumors and showing them clearly. That is why CT scans are used for lung cancer screening.

One drawback of a CT scan is that it finds a lot of abnormalities that turn out not to be cancer but that still need to be checked out to be sure. This may lead to additional scans or even more-invasive tests such as needle biopsies or even surgery to remove a portion of lung in some people. A small number of people who do not have cancer or have very early-stage cancer have died from these tests. There is also a risk that comes with increased exposure to radiation, even though a low dose is used for lung screening.

To weigh the benefits and risks before issuing current guidelines, experts at the American Cancer Society reviewed several studies that looked at low-dose CT screening. The most significant was the NLST. This study included more than 50,000 people aged 55 to 74 who were current or former smokers with at least a 30-pack-year history of smoking (equal to smoking a pack a day for 30 years, or two packs a day for 15 years) and who had not quit more than 15 years ago. The NLST found that people who got low-dose CT had a 16 percent lower chance of dying from lung cancer than those who got chest X-rays. However, some other trials have not found a benefit from screening.
Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 23, 2016. Search terms were: “lung cancer,” “screening,” “mass screening,” “tomography,” “x-ray computed” and “early detection of cancer.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The U.S. Preventive Services Task Force (USPSTF) recommends annual screening for lung cancer with LDCT in adults aged 55 to 80 years who have a 30-pack-year smoking history and 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.

The USPSTF used modeling studies to predict the benefits and harms of screening programs that use different screening intervals, age ranges, smoking histories and times since quitting. A program that annually screens adults aged 55 to 80 years who have a 30-pack-year smoking history and currently smoke or have quit within the past 15 years is projected to have a reasonable balance of benefits and harms. The model assumes that persons who achieve 15 years of smoking cessation during the screening program discontinue screening. This model predicts the outcomes of continuing the screening program used in the NLST through age 80 years.

The USPSTF found insufficient evidence on the harms associated with incidental findings. Overdiagnosis of lung cancer occurs, but its precise magnitude is uncertain. A modeling study performed for the USPSTF estimated that 10 percent to 12 percent of screen-detected cancer cases are overdiagnosed — that is, they would not have been detected in the patient’s lifetime without screening. Radiation harms, including cancer resulting from cumulative exposure to radiation, vary depending on the age at the start...
of screening, the number of scans received and the person's exposure to other sources of radiation, particularly other medical imaging.

The NLST, the largest RCT to date with more than 50,000 patients, enrolled participants aged 55 to 74 years at the time of randomization who had a tobacco use history of at least 30 pack-years and were current smokers or had quit within the past 15 years. The USPSTF recommends extending the program used in the NLST through age 80 years. Screening should be discontinued once the person has not smoked for 15 years.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Kawahara M. (2004)</td>
<td><strong>Key points:</strong></td>
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<td></td>
<td>• More frequent screenings (every 4 or 6 months) showed increased mortality from lung cancer, compared with annual screening. A mass screening</td>
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<td>conducted in 1990 was effective in a case-control study. The results of lung cancer screening by low-dose spiral computed tomography were reported from</td>
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<td>the Milan group and the Mayo Clinic. Computed tomography depicted peripheral early lung cancer, especially adenocarcinoma. These results are consistent</td>
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<td>with previous reports from other groups. Screening with imaging becomes more sensitive with automated computerized methods.</td>
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<td></td>
<td>• A high percentage of stage IA lung cancers were detected by screening with low-dose helical computed tomography. The characteristics of the nodules</td>
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<td>detected by low-dose spiral computed tomography have been clarified. There have been many controversial discussions about cost effectiveness and overdiagnosis.</td>
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<td>There is still no evidence that screening tests reduce the rate of cancer-specific mortality. Several studies of screening for lung cancer are under way.</td>
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<td>Moizs M. et al. (2014)</td>
<td><strong>Key points:</strong></td>
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<td>• Volunteers without thoracic complaints above the age of 40 years (n = 963) were screened for lung cancer using digital chest radiography and low-dose</td>
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<td>computed tomography.</td>
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<td>• Two lung cancers were found among the participants screened with digital chest radiography (0.2%). After informed consent, 173 individuals with</td>
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<td>normal chest radiography findings (n = 943) took the opportunity to voluntarily participate in LDCT screening for lung cancer. After 3 or 12 months, 65</td>
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<td>individuals had follow-up control examinations based on the size and characteristics of the detected lesions. Among them, one participant was found to have</td>
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<td>lung cancer using low-dose computed tomography.</td>
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<td>• These results indicate that low-dose computed tomography-based lung cancer screening as a public health screening procedure can enhance the success of</td>
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<td>screening with 50% (from 0.2% to 0.3%). The cost-benefit ratio can be raised if chest radiography is performed prior to the LDCT examination.</td>
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Veronesi G. et al. (2008)

Difficulties encountered managing nodules detected during a computed tomography lung cancer screening program.

**Key points:**

- The main challenge of screening a healthy population with LDCT is to balance the excessive use of diagnostic procedures with the risk of delayed cancer detection. Evaluated the pitfalls, difficulties, and sources of mistakes in the management of lung nodules detected in volunteers in the Cosmos single-center screening trial.
- During the first year of screening, 106 patients underwent lung biopsy and 91 lung cancers were identified (70% were stage I). Diagnosis was delayed (false-negative) in 6 patients (stage IIB in 1 patient, stage IIIA in 3 patients, and stage IV in 2 patients), including 2 small cell cancers and 1 central lesion. Surgical biopsy revealed benign disease (false-positives) in 15 cases (14%). Positron emission tomography sensitivity was 88% for prevalent cancers and 70% for cancers diagnosed after first annual screening. No needle biopsy procedures were performed in this cohort of patients.
- LDCT screening is effective for the early detection of lung cancers, but nodule management remains a challenge. Computed tomography-positron emission tomography is useful at baseline, but its sensitivity decreases significantly the subsequent year. Multidisciplinary management and experience are crucial for minimizing misdiagnoses.

**Glossary**

**Computed tomography (CT) scan** — Uses X-rays to make detailed cross-sectional images of the body. Instead of taking one picture like a regular X-ray, a CT scanner takes many pictures as it rotates around the patient as he or she lies on a table. A computer then combines these pictures into images of slices of the part of the body being studied. CT scans are more likely to show lung tumors than routine chest X-rays do. They can also show the size, shape and position of any lung tumors and can help find enlarged lymph nodes that might contain cancer that has spread from the lung.

**Epidermal growth factor receptor (EGFR)** — Inhibitors used for the treatment of metastatic colorectal cancer and KRAS wild-type colon cancer.

**Kirsten rat sarcoma (KRAS)** — A group of genes named for the laboratory settings in which they were first characterized.

**Non-small cell lung cancer (NSCLC)** — Lung cancer starts when cells of the lung become abnormal and begin to grow out of control. As more cancer cells develop, they can form into a tumor and spread to other areas of the body.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


Clinical trials:


CMS National Coverage Determinations (NCDs):

210.14 Lung Cancer Screening with Low Dose Computed Tomography (LDCT) Effective 2/5/2015. Implementation Date 1/4/2016. CMS Medicare Coverage Database website. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=364&ndcver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC A%7cCAL%7cNCD%7cMEDC6C%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Final&s=All&KeyWord=Lung+Cancer+Screening+with+Low+Dose+Computed+Tomography+(LDCT)&KeyWordLookUp=Title&KeyWordSearchType=Exact&q=true&bc=IAAAABAAAAAAA%3d%3d&. Accessed February 22, 2016.
Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>Personal history of nicotine dependence</td>
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