Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/24**
(See policy history boxes for previous effective dates)

Title: Screening for Lung Cancer Using Computed Tomography Scanning or Chest Radiographs

Description/Background

There is interest in screening and early identification of lung cancer because the disease, when identified clinically, tends to have a poor prognosis. Two proposed screening methods are chest radiographs and low-dose computed tomography (CT) scans. These techniques can be used with or without computer-assisted detection (CAD). Due to biases inherent in screening studies, randomized trials that evaluate reduction in lung cancer morbidity and mortality are required to demonstrate the efficacy of screening.

Given the poor prognosis of lung cancer, there has been longstanding research interest in developing screening techniques for those at high risk. Previous studies of serial sputum samples or chest x-rays failed to demonstrate that screening improved health outcomes. More recently, there has been interest in low-dose computed tomography (CT) scanning as a screening technique, using either spiral (also referred to as helical) or electron beam (also referred to as ultrafast) CT scanning. Compared to conventional CT scans, these scans allow for the continuous acquisition of images, thus shortening the scan time and radiation exposure. A complete CT scan can be obtained within 20 seconds, or during one breath hold, in the majority of patients. The radiation exposure for this examination is greater than for that of a chest x-ray but less than for a conventional CT scan.

There are also growing applications of computer-assisted *detection* or *diagnosis* (CAD) technologies that may have an impact on the use of CT scanning or chest radiographs for lung cancer screening. Computer-assisted *detection* points out possible findings to the radiologist who then decides if the finding is abnormal. Computer-assisted *diagnosis* uses a computer algorithm to analyze features of a lesion to determine the level of suspicion and is intended to enhance the reader's diagnostic performance. These technologies may be expected to offer more benefit when used by relatively inexperienced readers and may help to standardize diagnostic performance.

Regulatory Status:

In March 2001, the U.S. Food and Drug Administration (FDA) approved the RapidScreen RS-2000 system as a computer-aided detection (CAD) system intended to identify and mark regions of interest on digitized chest radiographs. In February 2004, the FDA approved the R2 Technology ImageChecker CT system as a technique to assist in the detection of lung nodules on multidetector CT scans of the chest. The R2 Technology ImageChecker also received FDA clearance for the Temporal Comparison software module in June 2004 and for the CT-LN 1000 in July 2004. The Temporal Comparison software module provides the ability to automatically track lung nodule progression or regression over time. The ImageChecker CT-LN 1000 is used for the detection of solid nodules in the lungs. Other systems that have been developed include iCAD's Second Look CT lung and Siemens' syngo LungCARE CT. FDA product code: MYN.

Medical Policy Statement

The safety and effectiveness of low-dose CT scanning of the lung as a screening tool for lung cancer have been established. It is a useful therapeutic option for patients meeting patient selection guidelines.

Routine chest radiographs, including computer-aided detection (CAD) analysis of the x-ray, for the purpose of screening patients for lung cancer is experimental/investigational. They have not been shown to improve long-term patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

Low-dose computed tomography (CT) scanning, no more frequently than annually, may be appropriate as a screening technique for lung cancer in individuals who meet ALL of the following criteria (which are based on the results of the National Lung Screening Trial (NLST):

- Between 50 and 80 years of age
- History of cigarette smoking of at least 20 pack-years (a "pack-year" is calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked. One pack year is the equivalent of 365.24 packs of cigarettes or 7,305 cigarettes).
- 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.

Exclusions:

- Low-dose CT scanning as a screening technique for lung cancer in all other situations where the above selection guidelines are not met.
- Routine chest radiographs when used as a screening technique for ruling out lung cancer.

Policy Guidelines (for informational purposes only):

The upper age limit for screening differs among the screening guidelines. National organizations' recommendations regarding the upper age limit for screening are as follows:

- U.S Preventive Services Task Force (USPSTF) 2013 recommendation:[1, 2] 80 years old (based on analysis evaluating 5 independent micro-simulation models)
- National Comprehensive Cancer Network (NCCN) 2014 guideline:[3] 74 years-old (based on NSLT)
- American College of Chest Physicians (ACCP) and American Society of Clinical Oncology (ASCO) 2012 joint statement:[4] 74 years-old (based on NSLT)
- American Association for Thoracic Surgery (AATS) 2012 guideline:[5] 79 years-old (based on several factors including that the average life expectancy is 78.6 years and that age is a risk factor for lung cancer)
- American Cancer Society (ACS) 2013 guideline:[6] 74 years-old (based on NSLT)

Screening setting
The national organizations with recommendations on lung cancer screening all include a recommendation that the low-dose CT screening of eligible patients occurs in settings that use a multi-disciplinary approach and involve participation of a sub-specialty qualified medical team.

Chest Radiographs
Evidence from randomized controlled trials does not support the use of chest radiography as a screening technique for lung cancer. Chest radiography and sputum cytology are not considered to be valid methods for lung cancer screening at the present time.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

71250 71271 G0296

Other codes (investigational, not medically necessary, etc.):

0174T 0175T

Rationale

An initial literature search on this topic was performed by BCBSA in 2001. The policy was updated regularly with literature searches. The following is a summary of the literature on screening for lung cancer with chest x-rays or low-dose computed tomography (CT) scanning.

High-quality, randomized trials that examine the effect of screening on lung cancer morbidity and mortality are necessary to determine the true impact of this technology on health outcomes. While survival from time of screening is commonly reported in screening trials, the apparent increase in survival may be confounded by one or more biases associated with screening:

- Lead-time bias: Lead-time refers to the length of time between when a cancer is detected by screening and when the first signs or symptoms would have appeared. If screening identifies lung cancer earlier, survival could be longer due to the lead-time rather than because of effective early treatment.
- Length-time bias: This bias refers to the greater likelihood that screening will detect slow-growing indolent cancers (which take longer to become symptomatic) than faster-growing, more aggressive cancer. Patients with screen-detected cancer may appear to live longer because the cancers are more indolent.
- Over-diagnosis: This bias occurs when screening identifies non-lethal cancer (sometimes called pseudo-disease). When this type of cancer is identified and removed, the patient appears to have benefited from screening, although the cancer would not have been fatal if left undetected.

Chest Radiographs

Several randomized trials of chest x-ray as a screening technique were published in the 1980s. The studies found that, although patients undergoing screening with chest x-ray had a higher incidence of earlier stage lung cancers, more resectable lung cancer, and improved five-year survival rate compared with the control group, there were no statistically significant differences in mortality attributable to lung cancer between the two groups.[7]

More recently, findings from an additional randomized controlled trial (RCT) that evaluated the effectiveness of screening with chest x-rays, the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial, have recently been published. Enrollment for the study was completed in 2001.[8] Approximately 155,000 individuals were randomly assigned to receive selected screening interventions, including chest radiographs, or usual care. Smokers received chest x-rays at baseline and annually for 3 years; never-smokers were screened at entry and annually for 2 years. Baseline results were reported in 2005. Of the 77,465 patients randomly assigned to the intervention arm, 5,991 (8.9%) radiographs were suspicious for lung cancer. Of these, 206 patients underwent biopsy, and 126 cancers were diagnosed. Among these cancers, 44% were stage I. Rates of lung cancer for the initial screening ranged from 0.63% for current smokers to 0.04% in non-smokers. Results of subsequent screenings were published in 2010.[9] Positivity rates were 7.1%, 6.6%, and 7.0%, respectively, for the first, second, and third yearly follow-up chest radiographs. Over the entire screening period, 18.5% of screened individuals had at least one positive screen. In 2011, the investigators published the main outcome data related to lung cancer screening.[10] The rate of lung cancer mortality did not differ significantly in the two groups. Over 13 years of follow-up, there were a total of 1,213 lung cancer deaths in the intervention group and 1,230 lung cancer deaths in the usual care group. Cumulative lung cancer mortality rates (per 10,000 person-years of observation) were 14.0 in the intervention group and 14.2 in the control group (rate ratio [RR]: 0.99, 95% confidence interval [CI]: 0.87-1.22). There was also no benefit of screening with chest x-rays when the analysis was limited to individuals who met criteria for the National Lung Screening Trial (NLST, discussed in a subsequent section of the policy). In this subset of study participants (n=30,321), there were 316 lung cancer deaths in the intervention group and 334 lung cancer deaths in the usual care group (RR: 0.94, 95% CI: 0.81 to 1.10). The authors concluded that annual screening with chest radiographs did not reduce lung cancer mortality compared with usual care.

A 2013 Cochrane review, of evidence on lung cancer screening identified only 1 trial comparing screening with chest radiographs to no screening; this was the PLCO trial, described above.[11] The Cochrane review identified 5 RCTs comparing more intensive

screening with chest radiographs (with or without sputum cytology) to less intensive screening. A pooled analysis of data from 4 of these studies did not find a statistically significant difference in the risk of mortality with more intensive versus less intensive screening.

Computer-aided detection

Computer-aided detection **(CAD)** may increase the sensitivity of chest radiographs. An RCT evaluating CAD-assisted chest radiography was published by Mazzone and colleagues in 2013.[12] The study included individuals between the ages of 40 and 75 years who (1) were a current or former smoker with at least a 10 pack-year history or (2) had a first degree relative with a history of lung cancer or (3) had a diagnosis of chronic obstructive pulmonary disorder (COPD). A total of 1424 individuals were randomized, 710 to 3 annual CAD chest radiography screenings and 713 to placebo screening. The placebo intervention consisted of having the patient stand as though they were receiving a chest radiograph but no radiograph was taken. The primary study endpoint was development of symptomatic advanced stage lung cancer. After adjudication, 3 symptomatic advanced lung cancer events were identified, all in the control group. The number of events was too small for a meaningful statistical analysis of differences in primary outcome.

Several previous studies evaluated whether CAD improves diagnostic accuracy. For example, a 2010 retrospective study conducted in Europe evaluated chest radiographs from 46 individuals who had histologically proven lung cancer and 65 control patients who had no nodules larger than 5 mm in diameter identified at a CT screening that occurred within 6 weeks of the radiograph.[13] Each radiograph was evaluated without and then with CAD findings; the OnGuard CAD system was used. CAD was not found to improve observer performance. The average sensitivity of the reviewers (2 radiologists and 4 residents) was similar without (49%) and with (51%) use of the CAD system. Observers correctly identified 27 lesions without CAD, and with CAD assistance, 3 additional malignancies were identified.

In addition, in 2009, a retrospective study identified radiographs with missed cancerous nodules and evaluated them with a CAD system (OnGuard 3.0, Riverain Medical).[14] CAD correctly marked overlooked nodules in 46 of 89 (52%) patients, and there was a mean of 3.9 false positive results per image.

Low-Dose Spiral CT

Randomized controlled trials

Findings from a large RCT in the United States that evaluated the impact of screening with low-dose CT on lung cancer morbidity and mortality, the National Lung Screening Trial (NLST), were published in 2011. In addition, several smaller European RCTs are ongoing. There is insufficient evidence to determine whether CAD technology may improve the accuracy of CT scanning interpretation.[15, 16] Following are descriptions of the major randomized trials evaluating CT screening:

National Lung Screening Trial

The National Lung Screening trial sponsored by the National Institutes of Health (NIH) was launched in 2002.[3] By April 2004, a total of 53,454 current or former smokers from 33 sites in the United States had been randomly assigned to screening in 3 consecutive years with either a chest x-ray or low-dose spiral CT. Study eligibility included age between 55 and 74 years, a history of cigarette smoking of at least 30 pack-years and, for former smokers, quitting within the past 15 years. Individuals with a previous diagnosis of lung cancer or who had signs and/or symptoms suggestive of lung cancer were excluded. There was no study-wide diagnostic follow-up algorithm; individuals who had positive test findings were managed according to

protocols at their local center. A total of 95% of participants in the low-dose CT group and 93% in the radiography group adhered to the screening protocol.

In October 2010, the independent safety and monitoring board determined that sufficient data were available to conclude that there was a statistically significant reduction in the primary outcome, lung cancer mortality. Consequently, the trial was terminated, and study results that occurred through December 31, 2009 were analyzed and reported. During a median 6.5-year follow-up, a total of 356 of 26,722 (1.33%) participants in the low-dose CT group and 443 of 26,732 (1.66%) participants in the radiography group died of lung cancer, representing a relative risk reduction of 20% (95% CI: 6.8% to 26.7%, p=0.004) (Using intention-to-treat analysis (ITT), the absolute risk reduction was 0.33% and the number needed to screen (NNS) for 3 years with a low-dose CT to prevent one death from lung cancer was 303. The authors reported an NNS of 320 based on per-protocol data from participants who underwent at least one screen. Overall mortality, a secondary outcome, was also significantly reduced in the low-dose CT screening group. There were a total of 1,877 deaths (7.0%) in the low-dose CT group and 2,000 deaths (7.5%) in the radiography group—relative risk reduction 6.7% (95% CI: 1.2% to 13.6%, p=0.02); absolute risk reduction of 0.46% and the NNS of 219 (95% CI: 111 to 5,556).

Over all 3 screenings, the frequency of positive tests was 24.2% in the low-dose CT group and 6.9% in the radiography group. Of these, 17,497 of 18,146 (96.4%) in the low-dose CT group and 4,764 of 5,043 (94.5%) in the radiography group were false positives. The remaining 649 tests (3.6% of total positive tests) in the low-dose CT scan group and 279 (5.5% of total positive tests) in the radiography group were confirmed lung cancers. During the screening phase, a total of 39.1% of participants in the low-dose CT group and 16.0% of those in the radiography group had at least one positive screening test.

During follow-up, 1,060 lung cancers were identified in the low-dose CT group and 941 lung cancers were identified in the radiography group. The difference in the cancer rates between groups was statistically significant, with a rate ratio of 1.13 (95% CI: 6.8 to 26.7, p=0.004). In addition to the screen-detected cancers, 44 cancers in the low-dose CT group and 137 in the radiography group were diagnosed after a negative screen. Three hundred sixty-seven cancers in the low-dose CT group and 525 cancers in the radiography group were diagnosed among participants who either missed screening or who had completed their 3 screenings.

Selected data from Table 3 of the August 2011 publication[3] on rates of follow-up diagnostic procedures after a positive screening result in the NSLT are shown below. Data represent all 3 screening rounds and include only cases for which diagnostic information is complete (over 97% of cases).

Table 3. Rates of Follow-up Diagnostic Procedures

	Low-dose CT (N=17,702) n (% of total sample)	**Chest Radiography (N=4,953) n (% of total sample)**
Imaging exam	10,246 (57.9)	3,884 (78.4)
• Chest radiography	2,547 (14.4)	1,613 (32.6)
• Chest CT	8,807 (49.8)	3,003 (60.6)
• FDG PET*/PET-CT	1,471 (8.3)	397 (8.0)
Percutaneous cytologic exam or biopsy	322 (1.8)	172 (3.5)

Bronchoscopy	671 (3.8)	225 (4.5)
Surgical procedure	713 (4.0)	239 (4.8)
• Mediastinoscopy or mediastinotomy	117 (0.7)	55 (1.1)
• Thoracoscopy	234 (1.3)	53 (1.1)
• Thoracotomy	509 (2.9)	184 (3.7)

*Positron emission tomography; (FDG, fluorodeoxyglucose)

Selected data from Table 4 of the August 2011 publication on complication rates after the most invasive screening-related diagnostic procedures are shown below. The data are from all 3 screening rounds and include only cases for which diagnostic information is complete (over 97% of cases). The frequencies of each major complication were not reported; rather the article included the total number of patients with any major complication. (Percent of total sample was calculated).

Table 4. Complication Rates

	Low-dose CT n (% of total sample)	Chest Radiography n (% of total sample)
Lung cancer confirmed	649 (3.7%)	279 (5.2%)
At least one complication	184 (1.0%)	65 (1.3%)
At least one major complication	75 (0.4%)	24 (0.5%)
Death within 60 days after invasive diagnostic procedure	10 (0.1%)	10 (0.2%)
Lung cancer not confirmed	17,053 (96.3%)	4,674 (94.4%)
At least one complication	61 (0.3%)	16 (0.3%)
At least one major complication	12 (0.1%)	4 (0.1%)
Death within 60 days after invasive diagnostic procedure[a]	6 (<0.1%)	0 (0%)

[a]This does not include deaths among individuals who had follow-up diagnostic procedures but no invasive procedures: a total of n=5 in the low-dose CT group and n=4 in the radiography group.

Note: Major complications were defined as the following: acute respiratory failure, anaphylaxis, bronchopulmonary fistula, cardiac arrest, cerebral vascular accident/stroke, congestive heart failure, death, hemothorax requiring tube placement, myocardial infarction, respiratory arrest, wound dehiscence, bronchial stump leak requiring tube thoracostomy or other drainage for more than 4 days, empyema, injury to vital organ or vessel, prolonged mechanical ventilation over 48 hours postoperatively, thromboembolic complications requiring intervention, chylous fistula, brachial plexopathy, lung collapse, and infarcted sigmoid colon.

Cancer stage was reported for cancers with a known stage; 1,040 in the low-dose CT group and 929 in the radiography group (Of the 1,040 confirmed lung cancers in the low-dose CT group, 416 (40%) were stage 1A, and 104 (10%) were stage 1B. Over half of the confirmed lung cancers identified by a positive screen (329 of 635, 52%) were stage 1A. In the radiography group, 90 of 275 confirmed cancers identified by a positive screen (32.7%) were stage 1A.

In summary, the National Lung Screening Trial was a large well-conducted trial. It 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 in low-dose CT group. There was a high rate of follow-up imaging tests but relatively low rates 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.

In 2004, Brenner assessed the radiation risks associated with low-dose CT screening.[17] The estimated doses from low-dose CT screening were 5.2 mGy + 0.9 to the lung, based on the protocol used in the National Lung Screening Trial. (This would be equivalent to at least 250 standard chest x-rays.) Brenner concluded that the radiation-related lung cancer risks for a single examination at age 55 ranges from approximately 1 per 10,000 to approximately 5 per 10,000, depending on gender and whether the person is a current or former smoker. The study estimated that there would be a 1.8% increase (95% CI: 0.5% to 5.5%) in the number of lung cancers associated with radiation from screening if 50% of all current and former smokers in the U.S. aged 50–75 years received annual CT screening. The risks of screening could be reduced by scanning less frequently or beginning screening at a later age.

Several smaller European trials that evaluate spiral CT screening are ongoing. Findings may ultimately be pooled with those from other RCTs in Europe and the United States. Each study includes a somewhat different screening population and screening regimen.

Danish Lung Cancer Screening Trial

Between 2004 and 2006, a total of 4,104 current or former smokers were randomized to screening with annual low dose CT for 5 years or no screening; lung cancer mortality is the primary outcome measure.[18] After five annual rounds of screening, the mean annual participation rate was 95.5% in the screening group and 93.0% in the control group.[19]The mean lung cancer detection rate was 0.83% at baseline and 0.67% for each of the 4 follow-up rounds. After a median follow-up of 4.8 years, a total of 69 lung cancers were diagnosed in the screening group and 24 in the control group; the difference between groups was statistically significant, $p<0.001$). The number of early stage cancers diagnosed was significantly higher in the screening than the control group (48 vs. 21, $p=0.002$). However the number of late stage cancers diagnosed was similar in the 2 groups (21 vs. 16, $p=0.509$). As of the end of March 2010, 103 of 4,013 study participants had died, 61 (3%) in the screening group and 42 (2%) in the control group ($p=0.059$ for overall mortality). Fifteen patients (0.73%) in the screening group and 11 patients (0.54%) in the control group died of lung cancer, $p=0.428$). This trial did not have adequate power to examine mortality outcomes on its own, the power calculation for mortality assumed that data would be combined with that of the NELSON study (described below), another European screening trial.

Detection and Screening of Early Lung Cancer by Novel Imaging Technology and Molecular Essays (DANTE) Trial

This trial, conducted in Italy, randomly assigned 2,811 male current or former smokers to receive 5 yearly spiral CT screening exams or physical examination alone. All participants had baseline chest radiographs.[20] Three-year findings were published in 2009.[21] After a median of 33 months' follow-up, significantly more lung cancer was detected in the CT screening group compared to control (4.7% vs. 2.8%, respectively, $p=0.016$). More stage-1 disease was

detected by CT screening; the rate of advanced lung cancer detection was similar in the 2 groups.

ITALUNG Trial
Another Italian study randomly assigned 3,206 current or former smokers to receive four yearly low-dose CT scans or no screening.[22] Participants will be followed up by cancer registry for lung cancer incidence and mortality and contacted by telephone four years after randomization. At baseline, 1,406 underwent CT screening and 426 (30%) tested positive (nodule at or greater than 5 mm). Twenty individuals were found to have lung cancer; 406 of 426 (95%) of positive screens were false-positive.

Netherlands-Leuvens Longkanger Screenings Onderzoek (NELSON) Trial
This study, conducted in the Netherlands and Belgium, randomly assigned current or former smokers to CT screening or no screening.[23, 24] The screening intervention consisted of a CT scan at baseline and at 1 and 3 years after baseline. For the 3 screening rounds, and 2 years additional follow-up, the sensitivity of low-dose CT screening was 84.6% (95% CI, 79.6% to 89.2%), and the specificity was 98.6% (95% CI, 98.5% to 98.8%). (25) A total of 187 of 7155 participants (3%) were diagnosed with screening-detected lung cancer, and another 49 were diagnosed with interval cancers, 34 in the first year after screening and 15 in the second year. The primary outcome of the trial is lung cancer mortality reduction after 10 years. Mortality results are expected in 2015 or 2016.[26]

A total of 1.466 participants in the NELSON trial participated in a related quality-life-study; 733 were randomized to the screening arm and 733 to the control arm.[27] They were given questionnaires before randomization, 2 months after the first screening round, and 2 years after baseline (6 months after the second screening round). The questionnaire response rate was 1,288 (88%) at baseline and 931 (79%) 2 years later. No statistically significant differences between the screened and control groups were found in scores on any quality-of-life measures at 2 years. The authors interpreted this finding as suggesting that lung cancer screening did not negatively impact quality of life.

German Lung Cancer Screening Intervention trial (LUSI)
This study randomized 4,052 heavy smokers age 50-69 years old to screening with 5 annual CT scans or a control group that is not being screened.[28] Baseline screening findings were reported in 2012. A total of 2,029 participants received a first-round CT scan. The baseline scan was negative for 1,488 of participants (73%). The remaining 540 suspicious screens led to 31 biopsies (biopsy rate 1.5%) and 22 confirmed lung cancers (cancer detection rate 1.1%).

Systematic Reviews
In 2012, Bach and colleagues published a systematic review of literature on CT screening for lung cancer.[29] The study identified 8 RCTs and 13 cohort study; the NLST was the largest RCT. Across studies, approximately 20% of participants in each round of screening had positive findings resulting in follow-up, and about 1% had lung cancer. There was heterogeneity across studies in the rate of positive findings and the type and frequency of follow-up investigations. The authors noted that the NLST trial was the only study to date that has found a significant lung cancer mortality benefit associated with low-dose CT screening. Other studies were described as too small, too poorly designed, or else the final results were not yet available. Another systematic review, published in 2014 by Fu et al, identified 9 RCTs evaluating CT screening in current and former smokers.[30] NLST remains the study with the largest sample size, by far. In a meta-analysis of 4 RCTs, the pooled lung cancer specific mortality favored low-dose CT over chest radiography or usual care (odds ratio, 0.84; 95% CI,

0.74 to 0.96). As previously noted, a number of the European trials are ongoing and do not yet have final mortality data.

A pair of studies funded by the Agency for Healthcare Research and Quality was published in 2013. Humphrey et al conducted a systematic review of evidence for the update of the USPSTS recommendation on lung cancer screening.[31] The review identified 4 trials focusing on low-dose CT screening in current and former smokers; the 4 trials consisted of the NLST and 3 European trials. The authors did not pool study findings. They noted that the 3 European trials were underpowered, and follow-up was not long enough to evaluate screening effectiveness.

In addition, a study modeling benefits and harms of various approaches to screening was published.[2] The modeling study evaluated models that varied screening programs by age of the participants, pack-years, years since quitting, and frequency of screening. The authors found that several possible approaches to screening and did not identify an approach that was clearly the “best” in terms of trade-offs between benefits and harms. One approach that was supported by the study was annual screening between the ages of 55 and 80 years for individuals with at least 30 pack-years of smoking and no more than 15 years since quitting for former smokers. This program is similar to the NLST eligibility criteria, except the maximum screening age is 80 years rather than 74. Using this approach, the analysis estimated that 37 eligible individuals would need to be screened to prevent one death from lung cancer. The published modeling study did not report on models in which screening ended at age 74 years (or 75), but the lead author stated in personal communication that these models had been tested and were inferior in terms of numbers of deaths prevented.

SUMMARY OF EVIDENCE

The evidence on computed tomography (CT) screening for lung cancer includes several randomized controlled trials (RCTs), some of which are still ongoing. The largest RCT, the National Lung Screening Trial (NLST) was a multicenter trial published in 2011. This was a high-quality trial that reported a decrease in both lung cancer mortality and overall mortality in a high-risk population screened with 3 annual low-dose computed tomography (CT) scans compared to chest radiographs. There is considerable uncertainty regarding the optimal length and interval of screening. Thus, screening for lung cancer with low-dose CT annually for 3 years may be considered medically necessary for high-risk patients who meet criteria of the NLST and investigational otherwise.

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Medical Societies and Academic Medical Centers

In response to requests by BCBSA, input was received through 2 Physician Specialty Societies and 3 Academic Medical Centers in late 2011. All of the reviewers agreed with the medically necessary policy statement, with the exception that one reviewer did not think the criterion limiting CT scanning to once a year for 3 years should be included. The reviewers were split on the issue of whether screening with CT scanning should be considered investigational for all other asymptomatic individuals who did not meet criteria in the medically necessary statement. No studies were cited in support of screening other individuals with low-dose CT, but several reviewers mentioned the 2011 version of the National Comprehensive Cancer Network (NCCN) guideline.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network (NCCN)[3]

The Version 2.2024 lung cancer screening guideline from the National Comprehensive Cancer Network has the following recommendations regarding screening with low-dose CT:

Risk Assessment	Risk Status		Screening
• Cigarette smoking history[d] • Radon exposure[e] • Occupational exposure[f] • Cancer history[g] • Family history of lung cancer in first-degree relatives • Disease history (chronic obstructive pulmonary disease [COPD] or pulmonary fibrosis) • Cigarette smoking exposure[h] (second-hand smoke) • Risk calculator to enhance determination of risk status[i,j]	High risk[i,l,m] • Age ≥50 y (category 1) and • ≥20 pack-year history of smoking cigarettes (category 1)	In candidates for screening, shared patient/provider decision-making is recommended, including a discussion of benefits/risks[c,j]	Low-dose CT (LDCT)[n] (category 1)
Patients not eligible for lung cancer screening: • Symptoms of lung cancer (see NCCN Guidelines for Non-Small Cell Lung Cancer) • Previous lung cancer (see Surveillance in the NCCN Guidelines for Non-Small Cell Lung Cancer) • Functional status and/or comorbidity that would prohibit curative intent treatment[k] (see Principles of Surgery in the NCCN Guidelines for Non-Small Cell Lung Cancer)	Low risk • Age <50 y and/or •<20 pack-year history of smoking cigarettes		Lung cancer screening not recommended

[a] It is recommended that institutions performing lung cancer screening use a multidisciplinary approach for nodule management that includes the specialties of thoracic radiology, pulmonary medicine, and thoracic surgery. Some institutions also include medical oncology, radiation oncology, and/or pathology.

[b] Lung cancer screening with LDCT is appropriate to consider for patients at high risk for cancer who are potential candidates for definitive treatment. Chest x-ray is not recommended for lung cancer screening.

[c] Although age and smoking history are used for risk assessment, other potential risk factors for lung cancer (eg, occupational exposure, radon exposure, cancer history, family history, lung disease history) may be discussed during shared decision-making.

[d] 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.

[e] Documented sustained and substantially elevated radon exposure increases the risk for lung cancer in patients who also have a history of heavy smoking. Many state websites have information more specific to local areas, including areas of known elevated radon.

[f] Agents that are identified specifically as carcinogens targeting the lungs include: arsenic, asbestos, beryllium, cadmium, chromium, coal smoke, diesel fumes, nickel, silica, soot, and uranium.

[g] There is increased risk of developing new primary lung cancer among survivors of lymphomas, cancers of the head and neck, or smoking-related cancers.

[h] Individuals exposed to second-hand smoke have a highly variable exposure to the carcinogens, with varying evidence for increased risk after this variable exposure. Therefore, second-hand smoke is not independently considered a risk factor sufficient for recommending lung cancer screening.

[i] NCCN encourages providers to consider using risk calculators, if possible, because additional candidates at high risk for lung cancer may be identified for lung screening.

[j] Shared decision-making aids may assist in counseling patients about the risks and benefits of screening.

[k] Curative intent treatment includes surgery and stereotactic body radiation therapy (SBRT), also known as stereotactic ablative body radiotherapy (SABR). Ablative techniques, such as radiofrequency ablation (RFA), are additional alternatives for curative intent treatment. SBRT or ablation may be used for medically inoperable patients with cardiac disease or severe COPD. See also the NCCN Guidelines for Non-Small Cell Lung Cancer. l Although randomized trial evidence supports screening up to age 77 years, there is uncertainty about the upper age limit to initiate or continue screening. One can consider screening beyond age 77 years as long as patient functional status and comorbidity allow consideration for curative intent therapy. m Black and African American individuals with less smoking exposure have a similar risk for lung cancer as white individuals with more smoking exposure. This increased risk for Black/African Americans should be considered in shared decision-making and risk assessment.
[n] All screening and follow-up chest CT scans should use a CT dose index volume (CTDIvol) threshold of 3 mGy or less for a patient of average size, unless evaluating mediastinal abnormalities or lymph nodes, where standard-dose CT with IV contrast might be appropriate (LCS-A). Parameters should be adjusted for patients of smaller or larger size. There should be a systematic process for appropriate follow-up. See ACR-STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography (CT)

American College of Radiology (ACR)

In 2022, The American College of Radiology (ACR) published a low-dose CT for lung cancer screening FAQs for patients between the ages of 50 and 77 years with at least a 20 year pack-history of smoking.[32] The statement also described the ACR Lung Cancer Screening Center designation to increase the likelihood that lung cancer screening will take place at sites that offer high-quality low dose CT screening programs.

American Cancer Society (ACS)[6]

In January 2013 (updated 2023 per website), American Cancer Society (ACS) website published guidelines on lung cancer screening with low-dose CT. They state that patients who meet all of the following criteria, which are based on National Lung Screening Trial (NLST) criteria, may be candidates for screening: ·

- 50 to 80 years old; and
- currently smoke or have quit in the past 15 years; and
- At least a 20 pack-year smoking history; AND

American College of Chest Physicians

In 2021, the ACCP released new clinical guidelines on Screening for Lung Cancer: CHEST Guideline and Expert Panel Report. The guideline contains 16 evidence-based recommendations and an update of the evidence base for the benefits, harms, and implementation of low-dose chest computed tomography (CT) screening.

Of the 16 recommendations, the guidelines presented in the report include the following:

1. For asymptomatic individuals age 55 to 77 who have smoked 30 pack years or more and either continue to smoke or have quit within the past 15 years, we recommend that annual screening with low-dose CT should be offered (Strong Recommendation, Moderate-Quality Evidence).
2. For asymptomatic individuals who do not meet the smoking and/or age criteria in Recommendation #1, are age 50 to 80, have smoked 20 pack years or more and either continue to smoke or have quit within the past 15 years, we suggest that annual screening with low-dose CT should be offered (Weak Recommendation, Moderate-Quality Evidence).We suggest that low-dose CT screening programs develop strategies to maximize compliance with annual screening exams and evaluation of screen detected findings.
3. For asymptomatic individuals who do not meet the smoking and/or age criteria in Recommendations #1 and 2 but are projected to have a high net benefit from lung cancer screening based on the results of validated clinical risk prediction calculations and life expectancy estimates, or based on life-year gained calculations, we suggest that annual screening with low-dose CT should be offered (Weak Recommendation, Moderate-Quality Evidence).

4. For individuals who have accumulated fewer than 20 pack years of smoking or are younger than age 50 or older than 80, or have quit smoking more than 15 years ago, and are not projected to have a high net benefit from lung cancer screening based on clinical risk prediction or life-year gained calculators, we recommend that low dose CT screening should not be performed (Strong Recommendation, Moderate-Quality Evidence).
5. For individuals with comorbidities that substantially limit their life expectancy and adversely influence their ability to tolerate the evaluation of screen detected findings, or tolerate treatment of an early stage screen detected lung cancer, we recommend that low-dose CT screening should not be performed (Strong Recommendation, Low-Quality Evidence).
6. ACCP suggests that low-dose CT screening programs develop strategies to determine whether patients have symptoms that suggest the presence of lung cancer, so that symptomatic patients do not enter screening programs but instead receive appropriate diagnostic testing, regardless of whether the symptomatic patient meets screening eligibility criteria (Ungraded Consensus-Based Statement).
7. ACCP suggests that low-dose CT screening programs develop strategies to provide effective counseling and shared decision-making visits prior to the performance of the LDCT screening exam (Ungraded Consensus-Based Statement).
8. ACCP suggests that screening programs define what constitutes a positive test on the low-dose CT based on the size of a detected solid or part-solid lung nodule, with a threshold for a positive test that is either 4 mm, 5 mm, or 6 mm in diameter (Weak Recommendation, Low-Quality Evidence).

American Association for Thoracic Surgery (AATS)

In 2012, the American Association for Thoracic Surgery (AATS) published guidelines for lung cancer screening. The guidelines recommend “annual lung cancer screening with low-dose computed tomography screening for North Americans from age 55 to 79 years with a 30 pack-year history of smoking. Long-term lung cancer survivors should have annual low-dose computed tomography to detect second primary lung cancer until the age of 79 years. Annual low-dose computed tomography lung cancer screening should be offered starting at age 50 years with a 20 pack-year history if there is an additional cumulative risk of developing lung cancer of 5% or greater over the following 5 years. Lung cancer screening requires participation by a subspecialty-qualified team.”[5]

In 2021, AATS issued a guideline and consensus statement: CHEST Guideline and Expert Panel Report provides a summary of recommendations:

- For asymptomatic individuals age 55 to 77 who have smoked 30 pack years or more and either continue to smoke or have quit within the past 15 years, we recommend that annual screening with low-dose CT should be offered (Strong Recommendation, Moderate-Quality Evidence).
- For asymptomatic individuals who do not meet the smoking and/or age criteria in Recommendation #1, are age 50 to 80, have smoked 20 pack years or more and either continue to smoke or have quit within the past 15 years, we suggest that annual screening with low-dose CT should be offered (Weak Recommendation, Moderate-Quality Evidence).
- For asymptomatic individuals who do not meet the smoking and/or age criteria in Recommendations #1 and 2 but are projected to have a high net benefit from lung cancer screening based on the results of validated clinical risk prediction calculations and life expectancy estimates, or based on life-year gained calculations, we suggest

that annual screening with low-dose CT should be offered (Weak Recommendation, Moderate-Quality Evidence).

- For individuals who have accumulated fewer than 20 pack years of smoking or are younger than age 50 or older than 80, or have quit smoking more than 15 years ago, and are not projected to have a high net benefit from lung cancer screening based on clinical risk prediction or life-year gained calculators, we recommend that low dose CT screening should not be performed (Strong Recommendation, Moderate-Quality Evidence).
- For individuals with comorbidities that substantially limit their life expectancy and adversely influence their ability to tolerate the evaluation of screen detected findings, or tolerate treatment of an early stage screen detected lung cancer, we recommend that low-dose CT screening should not be performed (Strong Recommendation, Low-Quality Evidence).

U.S. Preventive Services Task Force Recommendations

On March 9, 2021, the USPSTF published updated recommendations on screening for lung cancer. [1] The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 50 to 80 years who have a 20 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 recommendation was given a “B” recommendation, defined as “high certainty that the net benefit is substantial or the ability or willingness to have curative lung surgery”.

Government Regulations
National/Local:

National Coverage Determination (NCD) for Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (210.14). Implementation date: 1/4/16.

CAG-00439R, decision summary: Screening for lung cancer with LDCT. Date published February 10, 2022

For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following eligibility criteria:

- Age 50 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 20 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and
- Receive a written order for lung cancer screening with LDCT. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary’s medical records, and must contain the following information:
  - Beneficiary date of birth;
  - Actual pack – year smoking history (number);
  - Current smoking status, and for former smokers, the number of years since quitting smoking;
  - Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and
  - National Provider Identifier (NPI) of the ordering practitioner.

Counseling and Shared Decision Making Visit
Before the beneficiary's first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision-making visit that meets all of the following criteria, and is appropriately documented in the beneficiary's medical records:

- Must be furnished by a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Social Security Act), and
- Must include all of the following elements:
    - Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
    - Shared decision making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;
    - Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
    - Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and
    - If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

Written Orders for Subsequent Annual Lung Cancer Screenings with LDCT
For subsequent annual lung cancer LDCT screenings, the beneficiary must receive a written order for lung cancer LDCT screening. The written order may be furnished during any appropriate visit with a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Social Security Act).
If a physician or qualified non-physician practitioner elects to provide a lung cancer screening counseling and shared decision making visit before a subsequent annual lung cancer LDCT screening, the visit must meet all of the criteria described above for a counseling and shared decision making visit.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/15/03	5/15/03	4/1/03	Joint policy established
6/21/05	6/21/05	5/23/05	Routine maintenance
5/1/07	2/10/07	2/10/07	Routine maintenance
3/1/09	12/908	12/31/08	Routine maintenance
7/1/11	4/19/11	5/3/11	• Policy title changed from "Spiral CT Scanning for Lung Cancer Screening" to "Screening for Lung Cancer Using CT Scanning or Chest Radiographs (Spiral or Helical CT)." • Added codes 0174T and 0175T to policy, in addition to NOC code 76497.
11/1/12	8/21/12	8/21/12	Routine update. Policy status unchanged. This policy replaces the policy, "Computer Aided Detection and Algorithm Analysis of Digital Image Data for Malignant Pulmonary Lesion Detection."
5/1/14	2/18/14	2/28/14	Policy status changed to established for specified indications. References and new Hayes rating added. Removed NOC code from policy.
1/1/15	10/24/14	11/3/14	Added new code, S8032 – Low-dose computed tomography for lung cancer screening for services beginning 10/1/14.
2/5/15	2/17/15	2/17/15	Updated Medicare section to reflect CMS coverage determination to cover this screening service effective 2/5/15. Updated rationale and references.
5/1/16	2/16/16	2/16/16	Routine maintenance. Updated references. Added G0296 & G0297 payable for Medicare.
5/1/17	2/21/17	2/21/17	Routine maintenance, S8032 deleted. CMS/MDHHS sections updated.
5/1/18	2/20/18	2/20/18	Routine maintenance.
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance. Updated references. No change in policy status.

5/1/21	2/16/21		Routine maintenance. Code G0297 deleted. No change in policy status.
7/1/21	4/20/21		MPS adjusted to align with USPSTF changes in age and amount of pack per year smoking history.
7/1/22	4/19/22		Added code 71271 to policy**,** no change in policy status, routine policy maintenance.
7/1/23	4/18/23		Routine policy maintenance, updated supplemental section. No change in policy status. Vendor managed: AIM, Chest Imaging. (ds)
7/1/24	4/16/24		Routine policy maintenance, updated supplemental section. No change in policy status. Vendor managed: Carelon (71250). (ds)

Next Review Date: 2nd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SCREENING FOR LUNG CANCER USING CT SCANNING OR CHEST RADIOGRAPHS (SPIRAL OR HELICAL CT)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.