BlueCross BlueShield of Louisiana

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Screening for Lung Cancer Using Computed Tomography Scanning

Policy # 00185
Original Effective Date: 02/23/2006
Current Effective Date: 09/02/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider low-dose computed tomography (CT) scanning, no more frequently than annually, as a screening technique for lung cancer to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for low-dose computed tomography (CT) scanning, no more frequently than annually, as a screening technique for lung cancer in individuals will be considered when ALL of the following criteria are met:

- Between 55 and 80 years of age; and
- History of cigarette smoking of at least 30 pack-years; and
- If former smoker, quit within the previous 15 years.

Patient selection criteria are based on the National Lung Screening Trial (NLST) and the U.S. Preventive Services Task Force (USPSTF) 2013 recommendation.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers low-dose computed tomography (CT) scanning as a screening technique for lung cancer in all other situations to be **investigational.***

The use of low-dose computed tomography (CT) scanning as a screening technique for lung cancer when patient selection criteria are not met is considered to be **investigational.***

Note: This policy does not apply to individuals with signs and/or symptoms of lung disease. In symptomatic individuals, a diagnostic work-up appropriate to the clinical presentation should be undertaken, rather than screening.

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Background/Overview

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 CT scans. 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 radiographs failed to demonstrate that screening improved health outcomes. More recently, there has been interest in low-dose 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 with 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 10 to 20 seconds, or during 1 breath hold in most patients. The radiation exposure for this examination is greater than for that of a chest radiograph but less than for a conventional CT scan.

There are also growing applications of computer-aided *detection* or *diagnosis* (CAD) technologies that may have an impact on the use of CT scanning or chest radiographs for lung cancer screening. Computer-aided *detection* points out possible findings to the radiologist who then decides if the finding is abnormal. Computer-aided detection 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. Both of these technologies may be expected to offer more benefit when used by relatively inexperienced readers and may help to standardize diagnostic performance.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In March 2001, the FDA approved the RapidScreen™‡ RS-2000 system as a CAD system intended to identify and mark regions of interest on digitized chest radiographs. In February 2004, 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.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD).

Rationale/Source

An initial literature search was performed in 2006. The policy was updated regularly with literature reviews. The following is a summary of the literature on screening for lung cancer with chest radiographs or low-dose CT scanning.

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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.

Overdiagnosis: This bias occurs when screening identifies nonlethal cancer (sometimes called pseudodisease). 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 radiograph as a screening technique were published in the 1980s. The studies found that, although patients undergoing screening with chest radiograph had a higher incidence of earlier stage lung cancers, more resectable lung cancer, and improved 5-year survival rate compared with the control group, there were no statistically significant differences in mortality attributable to lung cancer between the 2 groups.

Findings from an additional randomized controlled trial (RCT) that evaluated the effectiveness of screening with chest radiographs, the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial, have recently been published. Enrollment for the study was completed in 2001. Approximately 155,000 individuals were randomly assigned to receive selected screening interventions, including chest radiographs, or usual care. Smokers received chest radiographs 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, 5991 (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 nonsmokers. Results of subsequent screenings were published in 2010. 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 1 positive screen. In 2011, the investigators published the main outcome data related to lung cancer screening. The rate of lung cancer mortality did not differ significantly in the 2 groups. Over 13 years of follow-up, there were a total of 1213 lung cancer deaths in the intervention group and 1230 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 to 1.22). There was also no benefit of screening with chest radiographs when the analysis was limited to individuals who met criteria for the 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, previously described. 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 D*etection*
Computer-aided detection may increase the sensitivity of chest radiographs. An RCT evaluating CAD-assisted chest radiography was published by Mazzone et al in 2013. 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 patients stand as though they were receiving a chest radiograph, but no radiograph was taken. The primary study end point 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. Each radiograph was evaluated without and then with CAD findings; the OnGuard CAD system was used. Computer-aided detection 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). Computer-aided detection 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 Computed Tomography
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, 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. Following are descriptions of the major randomized trials evaluating CT screening:

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National Lung Screening Trial: The NSLT sponsored by the National Institutes of Health was launched in 2002. 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 radiograph 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, the absolute risk reduction was 0.33% and the number needed to screen (NNS) for 3 years with a low-dose CT to prevent 1 death from lung cancer was 303. The authors reported an NNS of 320 based on per-protocol data from participants who underwent at least 1 screen. Overall mortality, a secondary outcome, was also significantly reduced in the low-dose CT screening group. There were a total of 1877 deaths (7.0%) in the low-dose CT group and 2000 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 5556).

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 4764 of 5043 (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 1 positive screening test.

During follow-up, 1060 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. A total of 367 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.

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

	Low-Dose CT (N=17,702), n (% of total sample)	**Chest Radiography (N=4953), n (% of total sample)**
Imaging exam	10,246 (57.9)	3884 (78.4)
Chest radiography	2547 (14.4)	1613 (32.6)
Chest CT	8807 (49.8)	3003 (60.6)
FDG PET/PET-CT	1471 (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)

CT: computed tomography; FDG: fluorodeoxyglucose; PET: positron emission tomography.

Selected data from Table 4 of the August 2011 publication on complication rates after the most invasive screening-related diagnostic procedures are shown next. 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.)

	Low-Dose CT, n (% of total sample)	**Chest Radiography, n (% of total sample)**
Lung cancer confirmed	649 (3.7)	279 (5.2)
At least 1 complication	184 (1.0)	65 (1.3)
At least 1 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)	4674 (94.4)
At least 1 complication	61 (0.3)	16 (0.3)
At least 1 major complication	12 (0.1)	4 (0.1)
Death within 60 days after invasive diagnostic procedure[a]	6 (<0.1)	0 (0)

CT: computed tomography.
[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.

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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; 1040 in the low-dose CT group and 929 in the radiography group (Of the 1040 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, NLST 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 NNS to prevent 1 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, eg, 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. The estimated doses from low-dose CT screening were 5.2±0.9 mGy to the lung, based on the protocol used in NLST. (This would be equivalent to at least 250 standard chest radiographs.) 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 to 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 (DLCST): Between 2004 and 2006, a total of 4104 current or former smokers were randomized to screening with annual low-dose CT for 5 years or no screening; lung cancer mortality was the primary outcome measure. After 5 annual rounds of screening, the mean annual participation rate was 95.5% in the screening group and 93.0% in the control group. 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 4013 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 next), 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 2811 male current or former smokers to receive 5 yearly spiral CT-screening exams or physical examination alone. All participants had baseline chest radiographs. The study was initiated in 2001, and recruitment was completed in 2006. Three-year findings were published in 2009. After a median of 33 months' follow-up, significantly more lung cancer was detected in the CT screening group compared with 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 3206 current or former smokers to receive 4 yearly low-dose CT scans or no screening. Participants will be followed up by cancer registry for lung cancer incidence and mortality and contacted by telephone 4 years after randomization. At baseline, 1406 underwent CT screening, and 426 (30%) tested positive (nodule at or >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. The screening intervention consisted of a CT scan at baseline and 1 and 3 years after baseline. Recruitment occurred between 2004 and 2006. Of the 7557 participants who underwent the first round of screening, 196 (2.6%) had positive scans, and 177 (2.3%) were referred for workup. Seventy of the 177 were diagnosed with lung cancer; this represents 39.5% of participants worked up after a positive scan and 0.9% of screened individuals. The 70 individuals had 72 lung cancers; 46 (64%) of these were classified as stage 1. The primary outcome of the trial is lung cancer mortality reduction after 10 years. Mortality results are expected in 2015 or 2016.

A total of 1466 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. 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 1288 (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 4052 heavy smokers age 50 to 69 years old to screening with 5 annual CT scans or a control group that is not being screened. Baseline screening findings were reported in 2012. A total of 2029 participants received a first-round CT scan. The baseline scan was negative for 1488 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%). Of these 22 cancers, 18 (82%) were stage I, one was stage II, and 3 were stage III. There was 1 interval cancer.

Systematic reviews and modelling studies
In 2012, Bach et al published a systematic review of literature on CT screening for lung cancer. The study identified 8 RCTs and 13 cohort studies; 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.

In 2013, 2 studies funded by the Agency for Healthcare Research and Quality were published. Humphrey et al conducted a systematic review of evidence for the update of USPSTF recommendations on lung cancer screening. 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.

Also in 2013, a study modelling benefits and harms of various approaches to screening was published. The modelling 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 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 1 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
The evidence on CT screening for lung cancer includes several RCTs, some of which are still ongoing. The largest RCT, the 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 CT scans compared with chest radiographs. There is considerable uncertainty regarding the

optimal length and interval of screening. Thus, screening for lung cancer with low-dose CT annually may be considered medically necessary for high-risk patients who meet criteria and investigational otherwise.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	71250, 71260, 71270
HCPCS	S8032
ICD-9 Diagnosis	V15.82, V76.0
ICD-9 Procedure	87.41, 87.44, 87.49

Policy History

Original Effective Date: 02/23/2006
Current Effective Date: 09/02/2014

12/07/2005	Medical Director review
12/20/2005	Medical Policy Committee review
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee review
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee review. No change to coverage.
02/04/2010	Medical Director review

Screening for Lung Cancer Using Computed Tomography Scanning

Policy # 00185
Original Effective Date: 02/23/2006
Current Effective Date: 09/02/2014

02/17/2010	Medical Policy Committee review. Title changed to "Screening for Lung Cancer Using CT Scanning or Chest Radiographs." Added statement saying that radiographs with or without computer-assisted detection or diagnosis as a screening technique for lung cancer is considered investigational.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Low-dose CT scans for lung cancer screening changed from investigational to eligible for coverage for three consecutive years with criteria and is investigational when criteria are not met and in all other situations. Investigational statement on chest radiographs removed and title changed accordingly. Note added to the coverage section that the policy does not apply to symptomatic individuals.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding revised
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. "For 3 consecutive years" removed from the statements in the Eligible for Coverage section. Upper age limit for screening changed to 80 years. U.S. Preventive Services Task Force 2013 recommendation added to statement on patient selection criteria.
10/01/2014	Coding update- New code S8032-Low-dose computed tomography for lung cancer screening- will be added to policy to pend for review

Next Scheduled Review Date: 06/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.