This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

Helical computed tomography (CT) scanners are regulated by the FDA as Class II devices, and more than 200 different instruments have met all requirements of the 510(k) approval process. The complete list of commercially available helical CT scanners may be found on the FDA website using search Product Code JAK.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

No CMS National Coverage Determination (NCD) or Local Coverage Determination (LCD) was identified for low-dose helical CT for lung cancer screening. There is an NCD (220.1) and there are LCD’s with general guidelines for the use of computed tomography (CT) of the Thorax. These documents do not specific criteria for lung cancer screening.

Please access the Medicare Local Coverage Determination (LCD) for coverage criteria that may be available in your specific region at: http://www.cms.gov/mcd/search.asp?clickon=search

INITIAL COVERAGE CRITERIA

Low-dose Helical (spiral) Computed tomography (CT) for lung cancer screening is considered medically necessary and may be authorized when all of the following criteria are met: [ALL]
- Age 55 to 74 years; and
- Smoking history ≥ 30 pack-years; and
- Currently smoking or quit in the past 15 years; and
- Testing must be part of a structured, comprehensive screening and care program

**CONTINUATION OF THERAPY**

N/A

**COVERAGE EXCLUSIONS**

Low-dose Helical (spiral) computed tomography (CT) for lung cancer screening is considered not medically necessary and may not be authorized for any the following due to lack of sufficient evidence that the potential benefits outweigh the potential risks: [ALL]

- Age < 55 years or > 74 years; and
- Individuals who have a smoking history < 30 pack-years; and
- Individuals who have not smoked in the past 15 years; and
- When none of the initial coverage criteria have been met

**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

Helical (spiral) computed tomography (CT) is a radiographic technique that can provide high-quality, 3-dimensional images of the lungs during a single breath-hold with less radiation exposure than conventional high-resolution CT scanning. This imaging technique has been proposed for screening asymptomatic, high-risk individuals for early lung cancer lesions. During a helical computed tomography (CT) lung scan, the patient lies in a supine position on the examination table while the table moves through the scanner framework. The patient is asked to lie quietly during the scan and to hold his or her breath for a short period of time, usually 10 to 25 seconds. Low-dose scans are often used for screening purposes to minimize the amount of radiation exposure the patient receives. If a suspicious lesion is detected, a higher dose helical CT scan is performed to provide a higher resolution image. Although the images obtained with helical CT are more detailed when patients undergo scanning following intravenous administration of a contrast agent, a lung scan does not require use of contrast material or other preparation, and no sedation is necessary. Helical CT scans are performed in the out-patient setting.

**GENERAL INFORMATION**

Summary of Medical Evidence

The largest available randomized controlled trial (RCT) of helical computed tomography (CT) for lung cancer screening (the National Lung Screening Trial [NLST]) provides evidence that, compared with screening with chest x-ray, helical CT improves detection of early-stage lung cancer by 91%, reduces lung cancer mortality by 20%, and reduces overall mortality by 6% in patients who have been heavy smokers. The trial outcomes are outlined below:

The National Lung Screening Trial (NLST) was conducted to determine whether screening with low-dose CT could reduce mortality from lung cancer. 53,454 participants were enrolled from August 2002 through April
2004 who were at high risk for lung cancer at 33 U.S. medical centers. Participants were randomly assigned to undergo three annual screenings with either low-dose CT (26,722 participants) or single-view posteroanterior chest radiography (26,732). Data were collected on cases of lung cancer and deaths from lung cancer that occurred through December 31, 2009. The rate of adherence to screening was more than 90%. The rate of positive screening tests was 24.2% with low-dose CT and 6.9% with radiography over all three rounds. A total of 96.4% of the positive screening results in the low-dose CT group and 94.5% in the radiography group were false positive results. The incidence of lung cancer was 645 cases per 100,000 person-years (1060 cancers) in the low-dose CT group, as compared with 572 cases per 100,000 person-years (941 cancers) in the radiography group (rate ratio, 1.13; 95% confidence interval [CI], 1.03 to 1.23). There were 247 deaths from lung cancer per 100,000 person-years in the low-dose CT group and 309 deaths per 100,000 person-years in the radiography group, representing a relative reduction in mortality from lung cancer with low-dose CT screening of 20.0% (95% CI, 6.8 to 26.7; P = 0.004). The rate of death from any cause was reduced in the low-dose CT group, as compared with the radiography group, by 6.7% (95% CI, 1.2 to 13.6; P = 0.02). The trial found that screening with the use of low-dose CT reduces mortality from lung cancer.

The COSMOS study investigated whether estimation of the volume doubling time (VDT) or growth rate of tumors detected by low-dose CT scans could be used to determine which tumors may represent indolent cancers and thus potential over diagnosis. This study was a nonrandomized, single-center screening study involving 175 individuals with primary lung cancer enrolled between 2004 and 2005 who received LDCT annually for 5 years. Fifty-five cases of cancer were diagnosed at baseline, and 120 were diagnosed subsequently. VDT was estimated on the basis of change in tumor size with serial scans; a tumor with a VDT <400 days was considered to be fast-growing; 400 to 599 days as slow growing and >600 days as indolent. VDT correlated with lung cancer mortality rates (9.2 percent per year for fast-growing and 0.9 percent per year for slow-growing or indolent cancers). Ten percent of the cancers identified in the COSMOS cohort had a VDT of 600 days or more, and 25 percent a VDT of 400 or more days, and thus might represent over diagnosis. The study results concluded that slow-growing or indolent cancer comprised approximately 25% of incident cases, many of which may have been over diagnosed. To limit overtreatment in these cases, minimally invasive limited resection and nonsurgical treatments should be investigated.

Bach PB et al (2012) conducted a systematic review of the evidence regarding the benefits and harms of lung cancer screening using low-dose computed tomography (LDCT). A multisociety collaborative initiative (involving the American Cancer Society, American College of Chest Physicians, American Society of Clinical Oncology, and National Comprehensive Cancer Network) was undertaken to create the foundation for development of an evidence-based clinical guideline. Of 591 citations identified and reviewed, 8 randomized trials and 13 cohort studies of LDCT screening met criteria for inclusion. Primary outcomes were lung cancer mortality and all-cause mortality, and secondary outcomes included nodule detection, invasive procedures, follow-up tests, and smoking cessation. Critical appraisal using predefined criteria was conducted on individual studies and the overall body of evidence. Differences in data extracted by reviewers were adjudicated by consensus. Three randomized studies provided evidence on the effect of LDCT screening on lung cancer mortality, of which the National Lung Screening Trial was the most informative, demonstrating that among
53,454 participants enrolled, screening resulted in significantly fewer lung cancer deaths (356 vs 443 deaths; lung cancer–specific mortality, 274 vs 309 events per 100,000 person-years for LDCT and control groups, respectively; relative risk, 0.80; 95% CI, 0.73-0.93; absolute risk reduction, 0.33%; \( P = .004 \)). The other 2 smaller studies showed no such benefit. In terms of potential harms of LDCT screening, across all trials and cohorts, approximately 20% of individuals in each round of screening had positive results requiring some degree of follow-up, while approximately 1% had lung cancer. There was marked heterogeneity in this finding and in the frequency of follow-up investigations, biopsies, and percentage of surgical procedures performed in patients with benign lesions. Major complications in those with benign conditions were rare. The reviewers concluded that low-dose computed tomography screening may benefit individuals at an increased risk for lung cancer, but uncertainty exists about the potential harms of screening and the generalizability of results.  

Sighir et al (2012) performed a randomized controlled trial to report lung cancer findings and mortality rates at the end of screening in the Danish Lung Cancer Screening Trial. 4104 men and women, healthy heavy smokers/former smokers were randomised to five annual low-dose CT screenings or no screening. Two experienced chest radiologists read all CT scans and registered the location, size and morphology of nodules. Nodules between 5 and 15 mm without benign characteristics were rescanned after 3 months. Growing nodules (>25% volume increase and/or volume doubling time<400 days) and nodules >15 mm were referred for diagnostic workup. In the control group, lung cancers were diagnosed and treated outside the study by the usual clinical practice. Participation rates were high in both groups (screening: 95.5%; control: 93.0%; \( p<0.001 \)). Lung cancer detection rate was 0.83% at baseline and mean annual detection rate was 0.67% at incidence rounds (p=0.535). More lung cancers were diagnosed in the screening group (69 vs. 24, p<0.001), and more were low stage (48 vs 21 stage I-IIB non-small cell lung cancer (NSCLC) and limited stage small cell lung cancer (SCLC), p=0.002), whereas frequencies of high-stage lung cancer were the same (21 vs 16 stage IIIA-IV NSCLC and extensive stage SCLC, p=0.509). At the end of screening, 61 patients died in the screening group and 42 in the control group (p=0.059). 15 and 11 died of lung cancer, respectively (p=0.428). The authors concluded that CT screening for lung cancer brings forward early disease, and at this point no stage shift or reduction in mortality was observed. More lung cancers were diagnosed in the screening group, indicating some degree of over diagnosis and need for longer follow-up.  

Pasterino et al reported five year results from the MILD trial. The screening program started with a pilot study on 1035 volunteers in Milan in 2000 and was followed up in 2005 by a randomized trial comparing annual or biennial LDCT with observation, named Multicentric Italian Lung Detection. This included 4099 participants, 1723 randomized to the control group, 1186 to biennial LDCT screening, and 1190 to annual LDCT screening. Follow-up was stopped in November 2011, with 9901 person-years for the pilot study and 17 621 person-years for Multicentric Italian Lung Detection. Forty-nine lung cancers were detected by LDCT (20 in biennial and 29 in the annual arm), of which 17 were identified at baseline examination; 63% were of stage I and 84% were surgically resectable. Stage distribution and resection rates were similar in the two LDCT arms. The cumulative 5-year lung cancer incidence rate was 311/100 000 in the control group, 457 in the biennial, and 620 in the annual LDCT group (P=0.036); lung cancer mortality rates were 109, 109, and 216/100 000 (P=0.21), and total mortality rates were 310, 363, and 558/100 000, respectively (P=0.13). Total mortality in the pilot study was
similar to that observed in the annual LDCT arm at 5 years. The results showed that there was no evidence of a protective effect of annual or biennial LDCT screening. Furthermore, a meta-analysis of the four published randomized trials showed similar overall mortality in the LDCT arms compared with the control arm.\textsuperscript{16}

Croswell et al (2010) conducted a randomized, controlled trial of low-dose CT versus chest radiography for the ongoing National Lung Screening Trial to quantify the cumulative risk that a person who participated in a 1- or 2-year lung cancer screening examination would receive at least 1 false-positive result, as well as rates of unnecessary diagnostic procedures. Participants included current or former smokers, aged 55 to 74 years, with a smoking history of 30 pack-years or more and no history of lung cancer (n = 3190). Random assignment to low-dose CT or chest radiography with baseline and 1 repeated annual screening and 1-year follow-up after the final screening were included. Randomization was centralized and stratified by age, sex, and study center. False-positive screenings, defined as a positive screening with a completed negative work-up or 12 months or more of follow-up with no lung cancer diagnosis. By using a Kaplan-Meier analysis, a person's cumulative probability of 1 or more false-positive low-dose CT examinations was 21\% (95\% CI, 19\% to 23\%) after 1 screening and 33\% (CI, 31\% to 35\%) after 2. The rates for chest radiography were 9\% (CI, 8\% to 11\%) and 15\% (CI, 13\% to 16\%), respectively. A total of 7\% of participants with a false-positive low-dose CT examination and 4\% with false-positive chest radiography had a resulting invasive procedure. Screening was limited to 2 rounds. Follow-up after the second screening was limited to 12 months. The false-negative rate is probably an underestimate. The authors concluded that risks for false-positive results on lung cancer screening tests are substantial after only 2 annual examinations, particularly for low-dose CT. Further study of resulting economic, psychosocial, and physical burdens of these methods is warranted. National Cancer Institute.\textsuperscript{10}

Another randomized controlled trial called the DANTE trial (2009) was performed to explore the effect of screening with low-dose spiral computed tomography (LDCT) on lung cancer mortality. Secondary endpoints are incidence, stage at diagnosis, and resectability. Male subjects, aged 60 to 75 years, smokers of 20 or more pack-years, were randomized to screening with LDCT or control groups. All participants underwent a baseline, once-only chest X-ray and sputum cytology examination. Screening-arm subjects had LDCT upon accrual to be repeated every year for 4 years, whereas controls had a yearly medical examination only. A total of 2,811 subjects were randomized and 2,472 were enrolled (LDCT, 1,276; control, 1,196). After a median follow-up of 33 months, lung cancer was detected in 60 (4.7\%) patients receiving LDCT and 34 (2.8\%) control subjects (P = 0.016). Resectability rates were similar in both groups. The results showed that more patients with stage I disease were detected by LDCT (54 vs. 34\%; P = 0.06) and fewer cases were detected in the screening arm due to intercurrent symptoms. However, the number of advanced lung cancer cases was the same as in the control arm. Twenty patients in the LDCT group (1.6\%) and 20 controls (1.7\%) died of lung cancer, whereas 26 and 25 died of other causes, respectively. The mortality benefit from lung cancer screening by LDCT might be far smaller than anticipated.\textsuperscript{15}

\textit{Cost Effectiveness}
Goulart et al (2012) performed an economic analysis of LDCT screening using data from the 2009 National Health Interview Survey, CMS, and the National Lung Screening Trial (NLST). The analysis included a budget impact model, an estimate of additional costs per lung cancer death avoided attributed to screening, and a literature search of cost-effectiveness analyses of LDCT screening. They conducted a one-way sensitivity analysis, reporting expenditures in 2011 U.S. dollars, and took the health care payer and patient perspectives. LDCT screening will add $1.3 to $2.0 billion in annual national health care expenditures for screening uptake rates of 50% to 75%, respectively. However, LDCT screening will avoid up to 8100 premature lung cancer deaths at a 75% screening rate. The prevalence of smokers who qualify for screening, screening uptake rates, and cost of LDCT scan were the most influential parameters on health care expenditures. The additional cost of screening to avoid one lung cancer death is $240,000. Previous cost-effectiveness analyses have not conclusively shown that LDCT is cost-effective. The authors concluded that LDCT screening may add substantially to the national health care expenditures. Although LDCT screening can avoid more than 8000 lung cancer deaths per year, a cost-effectiveness analysis of the NLST will be critical to determine the value of this intervention and to guide decisions about its adoption.

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes:

There is a Hayes Medical Technology Directory report entitled: Low-Dose Helical (Spiral) Computed Tomography for Lung Cancer Screening (2013). This report outlines that the National Lung Screening Trial (NLST), provides evidence that, compared with screening with chest x-ray, helical CT improves detection of early-stage lung cancer by 91%, reduces lung cancer mortality by 20%, and reduces overall mortality by 6% in patients who have been heavy smokers. The other available RCTs appear too small to detect significant improvements in mortality rates but three of these four smaller RCTs found that screening with helical CT increased detection of early-stage lung cancer compared with no screening or screening with chest x-ray. The benefits of screening with helical CT were partially offset by a much higher rate of false-positive findings, which was 23% with helical CT versus 7% with chest x-ray. This higher rate of false-positive findings resulted in significantly increased use of invasive procedures for confirmatory diagnostic testing, which significantly increased the incidence of moderate and severe complications that occurred during confirmatory testing. These risks do not appear to completely offset the benefit of screening with helical CT, which resulted in prevention of one lung cancer death for every 320 patients screened. Lung cancer screening with helical computed tomography (CT) is recommended in patients who meet the following criteria: age 55 to 74 years, smoking history ≥ 30 pack-years, currently smoking or quit in the past 15 years. Lung cancer screening with helical CT is NOT recommended in patients who are age < 55 years or > 74 years, patients who have a smoking history < 30 pack-years, and patients who have not smoked in the past 15 years. Since the risks involved may outweigh the benefits in patients who do not have a smoking history of at least 30 pack-years, screening of these patients cannot be recommended until further study has established the risk-benefit ratio of screening with helical CT for these patients. Additional studies are also needed to optimize protocols for screening and confirmatory testing to maintain or enhance the benefits of screening while minimizing the harms.
Cochrane:

A Cochrane systematic review was performed (2004) to determine whether screening for lung cancer using regular sputum examinations or chest radiography or CT chest reduces lung cancer mortality. Selection criteria included controlled trials of screening for lung cancer using sputum examinations, chest radiography or CT chest. Seven trials were included (6 randomised controlled studies and 1 non-randomised controlled trial) with a total of 245,610 subjects. There were no studies with an unscreened control group. Frequent screening with chest x-rays was associated with an 11% relative increase in mortality from lung cancer compared with less frequent screening (RR 1.11, CI: 1.00-1.23). A non-statistically significant trend was observed to reduced mortality from lung cancer when screening with chest x-ray and sputum cytology was compared with chest x-ray alone (RR 0.88, CI:0.74-1.03). Several of the included studies had potential methodological weaknesses. There were no controlled studies of spiral CT. The review concluded that the current evidence does not support screening for lung cancer with chest radiography or sputum cytology. Frequent chest x-ray screening might be harmful. Further, methodologically rigorous trials are required. 13

UpToDate:

In a report entitled Lung Cancer Screening the following is summarized: Lung cancer screening is a rapidly evolving field, with potential to significantly reduce the burden of lung cancer. A large randomized trial (NLST) of annual low-dose CT screening in patients with a 30 pack-year history of smoking, including those who quit smoking in the preceding 15 years, demonstrated a decrease in lung cancer and all-cause mortality. Other large randomized trials are ongoing and guidelines from professional organizations are undergoing revisions. 8

Professional Organizations

American Association for Thoracic Surgery (AATS): The AATS has prepared an evidence-based guideline that relies primarily on the results of the National Lung Screening Trial (NLST), which found a 20% reduction in lung cancer mortality for older patients who have an extensive history of smoking. In its guideline, the AATS has recommended annual low-dose helical CT for patients aged 55 to 79 years who have a ≥ 30 pack-year smoking history. The AATS has also recommended this screening for patients aged 50 to 55 years if they have a 20 to 29 pack-year smoking history combined with a ≥ 5% additional risk for developing lung cancer over the next 5 years. Specific indicators of risk include chronic obstructive pulmonary disease, occupational or environmental exposure to carcinogens, a history of thoracic radiation therapy, and a personal or family history of lung cancer. The AATS guideline warns that lung cancer screening requires the participation of a team of qualified subspecialists and that lung cancer screening guidelines will likely require refinement in the future. 6

American Cancer Society: The ACS has issued lung cancer screening guidelines in 2013 based on the results of the National Lung Screening Trial (NLST). This guideline recommends that clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about screening
with apparently healthy patients aged 55 years to 74 years who have at least a 30-pack-year smoking history and who currently smoke or have quit within the past 15 years. A process of informed and shared decision-making with a clinician related to the potential benefits, limitations, and harms associated with screening for lung cancer with low-dose computed tomography should occur before any decision is made to initiate lung cancer screening. Smoking cessation counseling remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer. Screening should not be viewed as an alternative to smoking cessation.  

**American College of Chest Physicians (ACCP) / American Cancer Society (ACS) / American Society of Clinical Oncology (ASCO) / National Comprehensive Cancer Network (NCCN):** The ACCP, ACS, ASCO, and NCCN collaborated to review the evidence concerning helical CT for lung cancer screening. In their guideline, they concluded that moderate quality evidence supports a weak recommendation to approve annual helical CT for lung cancer screening in current and former smokers aged 55 to 74 years who have a smoking history of ≥ 30 pack-years and who have smoked in the past 15 years. This recommendation is only valid for patients who have access to a structured, comprehensive screening and care program equal to that provided to participants in the National Lung Screening Trial (NLST). A particular concern expressed in the joint guideline was that, during screening with helical CT, the NLST found that the incidence of false-positive results was much higher than the incidence of lung cancer. Therefore, subsequent diagnostic testing puts many patients with benign lesions at risk for unnecessary radiation exposure, biopsy, and surgery. 

**American Lung Association:** Based on the NLST findings, the American Lung Association recommends lung cancer screening with low-dose CT scans for people who meet certain criteria, which include the following: current or former smokers (aged 55 to 74 years), with a smoking history of at least 30 pack-years (that is, an average of a pack a day for 30 years) and with no history of lung cancer.  

**American Thoracic Society (ATS):** The ATS has endorsed the guideline prepared by the ACCP, ACS, ASCO, and NCCS that is described above. The guideline include 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. 

**National Comprehensive Cancer Network (NCCN):** The 2013 NCCN guidelines for lung cancer screening recommend helical low-dose CT scan screening for those at high risk; they recommend no routine screening for moderate- or low-risk individuals. High risk was defined by the NCCN as age 55 to 74 years with a 30 pack-
year history of smoking and, if no longer smoking, smoking cessation within 15 years (category 1 evidence), or a 20 pack year history of smoking with one additional risk factor (other than secondhand smoke exposure), category 2B evidence. Routine screening is not recommended for individuals with moderate or low risk. The guidelines also indicate that lung cancer screening with CT should be part of a program of care and not performed in isolation as a stand-alone test.  

**Coding Information**

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**Resource References**


18. Advanced Medical Review: Policy reviewed by MD Board certified in Internal Medicine, Pulmonary Disease. May 13, 2013.