Lung Cancer Screening Guidelines with low-dose computed tomography (LDCT): USPSTF and CMS
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Kentucky Cancer Consortium and Kentucky LEADS Component 3
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USPSTF: http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening
CMS: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

Criteria	**USPSTF**	**CMS**
Age	55-80	55-77
Smoking History	30 pack year smoking history	At least 30 pack years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes)
Smoking Status	Current or quit within the past 15 years	Current or one who has quit within the last 15 years
Frequency	Annual screening	Annual screening
Asymptomatic		No signs or symptoms of lung cancer
Discontinue	Once a person has not smoked for 15 years OR Develops a health problem that substantially limits life expectancy or the ability/willingness to have curative lung surgery	
Insurance Coverage	ACA (includes all kynect plans, Medicaid Expansion, private health insurance plans that are not grandfathered)	Medicare

Criteria	USPSTF	CMS
Provider Recommendation		Written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit, 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). Must contain the following information, which must also be appropriately documented in the beneficiary's medical records: • 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.
Smoking Cessation	Current smokers should be informed of their continuing risk for lung cancer and offered cessation treatments. Screening with LDCT should be viewed as an adjunct to tobacco cessation interventions. Combination therapy with counseling and medications is more effective at increasing cessation rates than either component alone.	Incorporated into shared decision making visit: 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

Criteria	USPSTF	CMS
Shared Decision Making	Shared decision making is important for persons within the population for whom screening is recommended. The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms.	Required for the first screening and may elect to do in subsequent screenings. <u>Must include the following</u>: • 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.

Criteria	USPSTF	CMS
Database/Registry	In the context of substantial uncertainty about how best to manage individual lesions, as well as the magnitude of some of the harms of screening, the USPSTF encourages the development of a registry to ensure that appropriate data are collected from screening programs to foster continuous improvement over time. The registry should also compile data on incidental findings and the testing and interventions that occur as a result of these findings.	All CMS-approved registries must have the capacity and capability to collect data from any Medicare-eligible imaging facility/department that furnishes lung cancer screening with LDCT, with a catchment area that includes all 50 States, United States Territories, and the District of Columbia. CMS will evaluate each entity interested in participating as a CMS-approved registry to determine if they are capable of meeting the registry and data collection requirements outlined in this national coverage determination, including: a. Establishment of a steering committee and a governance board for oversight of the registry; b. Registry management plan, including identification of key personnel; c. Operational plan and framework that describes mechanisms for collection and submission of data from imaging facilities to the registry; d. Registry catchment area; e. Mechanisms for the submission of registry data to CMS electronically; f. Mechanisms to collect information (e.g.; HICN) in order to permit linkage of registry data with external databases (e.g. Medicare claims data sets); g. Description of data management and data quality review methods, including validation; h. Use of CMS-approved standardized data dictionary; i. Mechanisms for submitting a list of facilities participating in the registry to CMS; and j. Quality assurance plan. To apply to function as a CMS-approved registry, interested entities must submit a letter of interest along with detailed supporting information about how the interested entity is able to meet the requirements outlined in this national coverage determination via email to caginquiries@cms.hhs.gov.

Criteria	USPSTF	CMS
Quality Standards	Supports adherence to quality standards for LDCT and establishing protocols to follow up abnormal results, such as those proposed by the National Comprehensive Cancer Network. A mechanism should be implemented to ensure adherence to these standards.	Provides specifics related to radiologist and imaging facility. See below
Reading Radiologist eligibility criteria		• Board certification or board eligibility with the American Board of Radiology or equivalent organization; • Documented training in diagnostic radiology and radiation safety; • Involvement in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years; • Documented participation in continuing medical education in accordance with current American College of Radiology standards; and • Furnish lung cancer screening with LDCT in a radiology imaging facility that meets the radiology imaging facility eligibility criteria below.

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<tr><th>Criteria</th><th>USPSTF</th><th>CMS</th></tr>
<tr><td>Radiology imaging facility criteria</td><td></td><td>

Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy (milligray) for standard size patients (defined to be 5’ 7” and approximately 155 pounds) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients;
Utilizes a standardized lung nodule identification, classification and reporting system;
Makes available smoking cessation interventions for current smokers; and
Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved registry must include, at minimum, all of the following elements:

<table>
<tr><th>Data Type</th><th>Minimum Required Data Elements</th></tr>
<tr><td>Facility</td><td>Identifier</td></tr>
<tr><td>Radiologist (reading)</td><td>National Provider Identifier (NPI)</td></tr>
<tr><td>Patient</td><td>Identifier</td></tr>
<tr><td>Ordering Practitioner</td><td>National Provider Identifier (NPI)</td></tr>
<tr><td>CT Scanner</td><td>Manufacturer, Model</td></tr>
<tr><td>Indication</td><td>Lung cancer LDCT screening – absence of signs/symptoms of lung cancer</td></tr>
<tr><td>System</td><td>Lung nodule identification classification and reporting system</td></tr>
<tr><td>Smoking History</td><td>Current status (current, former, never). If former smoker, years since quitting. Pack-years as reported by the ordering practitioner. For current smokers, smoking cessation interventions available</td></tr>
<tr><td>Effective Radiation Dose</td><td>CT Dose Index (CTDIvol)</td></tr>
<tr><td>Screening</td><td>Screen date: initial screen or subsequent screen</td></tr>
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Criteria	USPSTF	CMS
Research Needs and Gaps	• Socioeconomically disadvantaged populations • Implementation in diverse community settings • Use of biomarkers to focus LDCT in highest risk people and discriminating between benign and malignant as well as aggressive tumors	