

Purpose

To decrease morbidity and mortality from lung cancer by identifying and offering LDCT screening to persons at high-risk for lung cancer who may benefit from the early detection with annual low-dose computed tomography (LDCT), through a patient-centric shared decision making process with careful consideration of patient preferences and potential benefits and harms.

Key Points/Recommendations

Patient eligibility

- 1) Age 55-80 (55-77 for Medicare)
- 2) Current smokers and former smokers who guit within 15 years
- 3) ≥30 pack years of smoking

Lung Cancer screening counseling

Counseling should include:

- Shared decision making regarding screening.
- Discussion of potential benefits (early detection of lung cancer).
- Discussion of potential harms (potential complications from diagnosis and/or treatment and radiation exposure).
- Consideration of patients' health and life expectancy, i.e. those in ill health with reduced life expectancy may not benefit.
- Smoking cessation for all current smokers emphasizing that screening is not a substitute for quitting smoking given the many other health risks of smoking.

Screening Follow-up

- For patients electing screening, counsel on the importance of adherence to annual lung cancer screening, impact of co morbidities and ability or willingness to undergo diagnosis and treatment.
- Annual screening should be offered until the patient reaches thresholds based on age, poor health or has passed 15 years in quitting smoking, or their preference changes.
- Follow-up care when lung nodule(s) are detected is based on size and, characteristics of the lung nodule [i.e., solid or part solid nodules; ground glass opacity (GGO); ground-glass nodule (GGN); nonsolid nodule (NS); multiple GGOs, GGNs or NSs].
- Ordering physician and radiologist assume a shared responsibility for arranging further screening and diagnostic workup and will consider referral to a comprehensive multi-disciplinary lung cancer screening program when appropriate.*

Screening facilities

Lung cancer screening should only be done at accredited facilities where the patient has access to a team of specialists that can provide the appropriate care and follow up. Imaging and screening facilities should implement patient tracking systems as soon as they become available.

*If there are results that require immediate follow up, a direct communication between the two physicians should occur, a plan for follow up established and the appropriate orders placed. These orders should be executed in an efficient and timely fashion. Optimally, it is the radiologist's responsibility to send both the patient and primary care physician reminders for follow-up imaging when due. If the patient returns to screening, it is the responsibility for the screening facility to log when the patient will be due for their next screening exam and obtaining the order. The PCP will be responsible for placing the order in a timely fashion. The radiology facility will be responsible for ultimately obtaining the order prior to performing the study.

Guidelines are intended to be flexible. They serve as reference points or recommendations, not rigid criteria. Guidelines should be followed in most cases, but there is an understanding that, depending on the patient, the setting, the circumstances, or other factors, care can and should be tailored to fit individual needs. Approved Mar 2016. Next scheduled review by Mar 2018



Important points to discuss with patients

Presented below are talking points that may be considered in discussions with patients considering lung cancer screening.

Bolded text draws attention to the specific points to document in Medicare patients

- Discuss the concept of lung cancer and the relationship with cigarette smoking. This is a great
 opportunity to bring focus and attention to smoking cessation or smoking abstinence in current or
 former smokers. [Medicare documentation requires counseling on the importance of maintaining
 cigarette smoking abstinence if former smoker, or the importance of smoking cessation if current
 smoker, and furnishing information about tobacco cessation interventions when appropriate].
- Discuss the National Lung Cancer Screening Trial (NLST), which compared annual low dose CT scans with annual chest X-rays for three years in a large number (>53,000) current or former smokers aged 55-74, with at least a 30 pack year history of smoking.
 - As a consequence of NLST, eligible patients are aged 55-80 (77 for Medicare) have at least a 30 pack year history, and are either actively smoking or quit within the last 15 years.
 [Medicare requires specific calculation of cigarette smoking pack-years, and if a former smoker, the number of years since quitting]
 - There is no evidence that lung cancer screening benefits patients other than studied in NLST, although this may change in the future.
- Discuss that in the NLST there was a lower rate of death from both lung cancer, and from all causes of death. The benefits were modest, but considered significant. There were also some risks from lung cancer screening, and prior to ordering a lung cancer screening CT scan, it is important for these benefits and risks to be discussed. [Medicare requires lung cancer screening counseling and shared decision making, as outlined below, documented in the patient medical record]
 - o The Benefits:
 - A 20% reduction in lung cancer mortality among screened patients and a 6% reduction in overall mortality
 - o The Risks:
 - Radiation Exposure: The low dose CT of the Chest requires radiation exposure. The risk of the radiation is quite low in patients who are eligible for screening.
 - Psychologic Distress: The CT of the Chest is a very detailed image of your lungs. By nature of age and smoking history, patients who are eligible for lung cancer screening, some sort of abnormal finding on the CT scan of your chest is <u>common</u>. It is important that:
 - Anyone willing to be screened should be aware that finding of some abnormality on the CT scan is <u>VERY COMMON</u> (terms such as lump, nodule, shadow, lesion, thickening, swelling, and infiltrate). Any psychologic distress that might ensue from an abnormality being found should be lessened by understanding how common they are.
 - The abnormalities on the CT scan are UNLIKELY to represent a cancer. In fact, in the NLST 96% of nodules were found to be benign (not cancer). These are



often referred to as "False Positive" findings, which is a finding which raises the concern of a lung cancer, but ultimately is not a lung cancer. This is a natural part of the screening process.

- Procedural Risks: In patients who have some abnormality on the CT scan, your physician will make recommendations. In some instances a surgery or an invasive diagnostic procedure would be recommended. In other situations additional CT scans to follow the abnormality over time would be recommended.
- Discuss the fact that lung cancer screening is not always indicated, even among patients who are eligible by age and smoking history. These include:
 - o Patients who are unwilling or not able to undergo therapy.
 - o Patients who are unwilling or not able to adhere with annual screening.
 - o Patients who have symptoms of concern for lung cancer
 - Medicare requires a statement that the patient has no signs or symptoms of lung cancer, and documentation of counseling on the importance of adherence to annual lung cancer screening, the impact of comorbidities, and ability or willingness to undergo diagnosis and treatment.



Summary of USPSTF and CMS Recommendations

	<u> </u>
United States Preventive Services Task Force*	Annual screening in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. (Grade B)
Centers for Medicare & Medicaid**	 Age 55 - 77 years; Asymptomatic (no signs or symptoms of lung cancer); Tobacco smoking history of at least 30 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 Receives a written order for LDCT lung cancer screening that meets the following criteria: For the initial LDCT lung cancer screening service: a beneficiary must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit, furnished by a physician or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist). A lung cancer screening counseling and shared decision making visit includes the following elements (and is appropriately documented in the beneficiary's medical records): 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. For subsequent LDCT lung cancer screenings: the beneficiary must receive a written order for LDCT lung cancer screening, which m

^{*}U.S. Preventive Services Task Force, Screening for lung cancer: U.S. Preventive Services Task Force Recommendation Statement, Ann Intern Med; 2013.

Available at: http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.pdf

Available at: http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.pdf.

**Decision Memo for Screening for Lung Cancer with Low Dose computed Tomography (LDCT) (CAG-00439N). Available at: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAld=274.



Resources for Physicians

Monroe County Medical Society Community-wide Guideline for Treating Tobacco Use and Dependence

Provides physicians and other clinicians with the evidence based tools necessary to systematically provide these effective treatments in outpatient setting.

American Cancer Society

- Screening Guidelines
 - Patients should be asked about their smoking history.
 - Patients who meet ALL of the following criteria may be candidates for lung cancer screening:
 - o 55 to 74 years old
 - o In fairly good health (people who do not have symptoms of the disease)
 - Have at least a 30 pack-year smoking history (Someone who smoked a pack of cigarettes per day for 30 years has a 30 pack-year smoking history, as does someone who smoked 2 packs a day for 10 years and then a pack a day for another 10 years.)
 - Are either still smoking or have quit smoking within the last 15 years
 - Doctors should talk to these patients about the benefits, limitations, and potential harms of lung cancer screening.
 - Screening should only be done at facilities that have the right type of CT scan and that have a great deal of
 experience in LDCT scans for lung cancer screening. The facility should also have a team of specialists that can
 provide the appropriate care and follow-up of patients with abnormal results on the scans.
- <u>Summary Chart of Eligibility Criteria for the National Lung Screening Trial</u> can serve as the basis for initiating a discussion with patients about lung cancer screening
- Testing for Lung Cancer in People at High Risk a reproducible patient information sheet to help facilitate shared decision making

American College of Radiology

Pack year calculator

eviCore National/Med Solutions

Clinical criteria for medical necessity review of outpatient diagnostic imaging

eviCore healthcare – main page with links to current health plan-specific radiology criteria arranged by CPT code

National Cancer Institute

• <u>Lung Cancer Screening (PDQ)</u> – subjects covered include: overview of evidence of benefit and no benefit associated with screening, description of evidence, harms of screening

Shared Decision-Making Aids

- American College of Radiology Shared decision making tool based on USPSTF criteria
- <u>Bach Model</u> Presents 10-year absolute risk estimates for an individual being diagnosed with lung cancer. (constructed from data derived from the β-Carotene and Retinol Efficacy Trial, a multicenter randomized, controlled study of β-carotene and vitamin A supplementation in over 14,000 heavy smokers (mostly men) and over 4000 asbestos-exposed men.
- <u>Brock University</u> Gives an exact percent risk in the next 6 years and includes a few other factors such as weight, race, and education. It does not discuss the risk reduction achieved from screening.
- <u>Hoggart Model</u>- A risk model for lung cancer using prospective cohort data from a general population which predicts individual incidence in a given time period.
- <u>LLP Model</u> An individual risk prediction model to estimate the probability that an individual with a specified combination of risk factors would develop lung cancer within a 5-year period. (developed using 579 lung cancer cases and 1157 age- and sex-matched population-based controls from a case-control study that was a part of the Liverpool Lung Project
- <u>Memorial Sloan Kettering</u> Provides lung screening assessment for 1,000 people like the patient over the next 6 yrs in the following categories: 1) Out of 1,000 people like the patient who are NOT screened, number who will be diagnosed with and die from lung cancer 6.4; 2) Out of 1,000 people like the patient who ARE screened, number who will die from lung cancer 5.2; 3) Out of 1,000 people like the patient who ARE screened, the number of lives



that will be saved - 1.3; 4) Number of people like the patient that would need to be screened in order for ONE similar to the patient to benefit.

- <u>Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial</u> A lung cancer risk-prediction model based on data from the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial was more sensitive than The National Lung Screening Trial enrollment criteria for selecting individuals who were subsequently diagnosed with lung cancer.
- <u>Spitz Model</u> Presents one-year probabilities of lung cancer and compare with baseline incidence rates. (based on a sample of 1851 lung cancer cases and 2001 age-, sex-, race-, and smoking-status (never, former, or current smokers) matched controls from an ongoing lung cancer case control study at the University of Texas MD Anderson Cancer Center in Houston, Texas)

Resources for Patients

American Cancer Society

- Lung cancer detection and early prevention
- Guide to Quitting Smoking

American College of Radiology

- What is lung cancer screening
- · Benefits and Harms of Screening
- Lung cancer screening compared to other tests
- Causes of lung cancer
- · Reducing risk of lung cancer

American Lung Association

• How to Quit Smoking

Dartmouth-Hitchcock Medical Center Lung Cancer Screening Program

<u>Helping you decide about Lung Cancer Screening</u> - explains the benefits and harms of lung cancer screening with low-dose CT scans.

National Cancer Institute

- <u>Lung Cancer Screening (PDQ)</u> subjects covered include: What is screening; General Information About Lung Cancer; Lung Cancer Screening; Risks of Lung Cancer Screening
- Patient and Physician Guide: National Lung Screening Trial explains benefits and harms of low-dose CT

National Comprehensive Cancer Network

Lung Cancer Screening - describes who should be screened and tests used for screening

Radiology Info.org

Radiology Information for patients produced by the Radiological Society of North America and the American College of Radiology

http://www.radiologyinfo.org/en/info.cfm?pg=screening-lung



References

Monroe County Medical Society Community-wide Guideline for Follow-up and Management of Indeterminate Lung Nodules Detected Incidentally on Nonscreening CT

MCMS COMMUNITY PRINCIPLES\Follow-up Outpatient DX testing, Lab, Imaging Studies\PRINCIPLES AND DEFINITIONS\FINAL\Community Principles and Definitions 03 19 13 FINAL.pdf

Marcus PM, Fagerstrom RM, Prorok PC, et al.: Screening for lung cancer with helical CT scanning. Clinical Pulmonary Medicine 9 (6): 323-9, 2002. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21714641.

Brenner DJ, Ellisto CD, Estimated radiation risks potentially associated with full-body CT screening. Radiology. 2004 Sep;232(3):735-8. Epub 2004 Jul 23. Available at: http://www.ncbi.nlm.nih.gov/pubmed/15273333

1998-2015 Mayo Foundation for Medical Education and Research. Available

at: http://www.mayoclinic.org/medical-professionals/clinical-updates/general-medical/screening-lung-cancer-evolving-challenge

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2014;160:330-338. Available at: http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening

RadiologyInfo.org, produced by the American College of Radiology and the Radiological Society of North America. Available at: http://www.radiologyinfo.org/en/info.cfm?pg=screening-lung

National Cancer Institute. National Lung Screening Trial Primary Findings. Available at: http://www.cancer.gov/types/lung/research/nlst-qa

American Cancer Society Lung Cancer Screening Guidelines. Wender R, Fontham ETH, Ermilo Barrera, Jr E, et al. American Cancer Society, CA Cancer J Clin 2013;63:106–117. Available at: http://onlinelibrary.wiley.com/doi/10.3322/caac.21172/full

Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N). Centers for Medicare & Medicaid Services, 2015. Available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274

National Lung Screening Trial Research Team, Aberle DR, Adams AM, et al. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening, N Engl J Med. 2011;365(5):395-409. Available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1102873

Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement, U.S. Preventive Services Task Force. Ann Intern Med. 2014;160:330-338. Available at: http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/lung-cancer-screening?ds=1&s=lung cancer