Lung Cancer Screening Webinar on Coverage and Payment

Hosted by the American College of Radiology and supported by the Radiology Business Management Association (RBMA) and the Lung Cancer Alliance (LCA)
Questions

• As a reminder, to ask a question use the Webinar Now control panel on the upper right side of your screen.

• Click the “+” located next to “Questions”. Then type your question in the [Enter a question for staff] box. Then hit enter or click send.

• Questions will be answered contingent upon remaining time. However, any additional questions can be sent to LCScoverage@acr.org
Featured Speakers

Ella Kazerooni, MD, MS, FACR
Professor of Radiology, Director Division of Cardiothoracic Radiology and Associate Chair for Clinical Affairs in the Department of Radiology
University of Michigan Medical School / Health System

Geraldine McGinty, MD, MBA, FACR
Assistant Professor of Radiology at Weill Cornell Medical College
Assistant Attending Radiologist at the NewYork-Presbyterian Hospital / Weill Cornell Campus
Outline

- Background
- CMS Coverage Decision 2/5/15
  - Shared Decision Making
  - Smoking Cessation
- ACR Lung Cancer Screening Registry
  - Structured Reporting & Management (LungRADS)
- Coding and Valuation
Lung Cancer Screening Background

- Leading cause of cancer death in both men & women
- More people die from lung cancer annually than cancers of the breast, colon and prostate combined
- Large population at risk
- 85% of all lung cancer attributed to smoking
National Lung Cancer Screening Trial

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team

20% lung cancer mortality reduction
6.7% all cause mortality reduction

screen 320 individuals to save 1 from lung cancer death

8 yrs & 53,454 subjects randomized to annual x 3 LDCT vs. CXR
National Lung Cancer Screening Trial

Cost-Effectiveness of CT Screening in the National Lung Screening Trial

William C. Black, M.D., Ilana F. Gareen, Ph.D., Samir S. Soneji, Ph.D., JoRean D. Sicks, M.S., Emmett B. Keeler, Ph.D., Denise R. Aberle, M.D., Arash Naeim, M.D., Timothy R. Church, Ph.D., Gerard A. Silvestri, M.D., Jeremy Gorelick, Ph.D., and Constantine Gatsonis, Ph.D. for the National Lung Screening Trial Research Team


cost $81,000 per QALY gained

modest changes in assumptions would greatly alter this figure

determination of whether screening outside the trial will be cost-effective will depend on how screening is implemented
Screening for Lung Cancer

This topic page summarizes the U.S. Preventive Services Task Force (USPSTF) recommendations on screening for lung cancer.

Current Recommendation

Release Date: December 2013

- The USPSTF recommends annual screening for lung cancer with low-dose computed tomography in adults ages 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 recommendation.

http://www.uspreventivesservicestaskforce.org/uspstf/uspslung.htm
Implications of USPSTF Grade B Recommendation

- Grade “B” grade indicates either:
  - *high certainty* that the net benefit is *moderate* or
  - *moderate certainty* the net benefit is *moderate to substantial*, and
  - that the particular service should be offered or provided

- Patient Protection & Affordable Health Care Act (PPACA) requires private insurers to cover *without a co-pay* all medical exams/procedures that receive a grade “B” or higher

- Does not specify that Medicare provides full national coverage

- Fall 2013 CMS received 2 requests for a national coverage decision
Lung Cancer Screening

- Screening is a public health recommendation
- Many sites have or are considering developing screening programs
- CMS MEDCAC panel held 4/30/2014
- Can the efficacy of what has been done in clinical trials be translated into effectiveness in clinical practice?
Lung Cancer Screening

- **Benefits:** reduced lung cancer mortality
  - Smoking cessation
  - Detection of other smoking related conditions

- **Harms:** detection and treatment related
  - Inappropriate screening
  - Radiation exposure
  - Unnecessary diagnostic testing and procedures
  - Procedure related complications
ACR: Lung Cancer Screening Activities

- ACR-STR Practice parameter for the performance and interpretation CT for lung cancer screening
- LungRADS structured reporting and management tool
- ACR Designated Lung Cancer Screening Centers under the CT accreditation program
- ACR Lung Cancer Screening Registry
ACR to Host Lung Cancer Screening Webinar on Coverage and Payment

Medicare and private insurer coverage and provider reimbursement for low-dose CT lung cancer screening will be addressed April 6 at a free webinar, sponsored by the American College of Radiology and supported by the Radiology Business Management Association and the Lung Cancer Alliance.

To register for the fee webinar, read here.

Practice Parameters and Technical Standards

- ACR-STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography (CT)
- Annals of Internal Medicine — Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement

Patient Information

CT Lung Cancer Screening

- National Cancer Institute – SEER Stat Fact Sheet: Lung and Bronchus Cancer
- National Comprehensive Cancer Network (NCCN) Guidelines for Patients
- RadiologyInfo.org - Lung Cancer Screening

Smoking Cessation

- American Cancer Society – Guide to Quitting Smoking
- American Lung Association – How to Quit Smoking

Lung Cancer Advocates

- Lung Cancer Alliance

Screening Decision Aid (with risk calculator)

- Decision Aid Tool

Quality Assurance

- Apply for ACR Lung Cancer Screening Center Status
- ACR Computed Tomography Accreditation
- Lung CT Screening Reporting and Data System (Lung-RADS™)
- CT Quality Control Manual
- ACR Dose Index Registry®
- AAPM Protocols for Lung Cancer Screening
- Lung Cancer Screening Practice Registry - Final data elements now available
CMS - Lung Cancer CT Screening

CMS February 5, 2015 National Coverage Decision

Beneficiary eligibility criteria:

- 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:

- 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.
Shared decision making (SDM) is a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.

SDM honors both the provider's expert knowledge and the patient's right to be fully informed of all care options and the potential harms and benefits. This process provides patients with the support they need to make the best individualized care decisions, while allowing providers to feel confident in the care they prescribe.

http://www.informedmedicaldecisions.org/what-is-shared-decision-making/
Shared Decision Making: Web Resource

Should I Screen

http://www.shouldiscreen.com/

Shared decision making aid with a risk calculator

Web based, publically available

We can help you.

Deciding whether or not to go through lung cancer CT screening is not easy. Here is up to date information provided by doctors to help you make an informed choice.

**BENEFITS AND HAZARDS OF SCREENING**

Find out about lung cancer CT screening and how it can help you decrease your chances of having lung cancer.

**LUNG CANCER RISK CALCULATOR**

Do you want to know if you should be screened? Use our calculator to see your personalized lung cancer risk.
Shared Decision Making Materials

National Comprehensive Cancer Center

http://www.nccn.org/patients/guidelines/lung_screening/

- Patient education materials
- Web based booklet
- May be printed
Patient Education Materials

NCCN Guidelines for Patients®
Lung Cancer Screening

Available online at NCCN.org/patients

Promotional materials provided with support from

[Image of a man with hands clasped]
Smoking Cessation and Lung Cancer Screening

- The best way to reduce lung cancer is to stop smoking!

- Included in the ACR-STR Practice Parameter for LCS CT and the ACR Lung Cancer Screening Designated Center Program as a required element
  - “Must have a mechanism in place to refer patients for smoking cessation counseling or to provide smoking cessation materials”

- Resources
  - American Cancer Society – Guide to Smoking Cessation
    http://www.cancer.org/healthy/stayawayfromtobacco/guidetoquittingsmoking/index
  - American Lung Association – How to Quit Smoking
    http://www.lung.org/stop-smoking/how-to-quit/
  - Look for local resources, including through your state health department
Smoking in the U.S.

- Large population at risk due to cigarette smoking and second hand smoke exposure
  
  - ≈ 60 million current smokers (19.3% of U.S. adults in 2010; 3 million fewer than 20.9% in 2005)
  
  - ≈ 30 million former smokers
  
  - Tobacco: leading cause of preventable death & illness; responsible for 1 in 5 deaths

![About 443,000 U.S. Deaths Attributable Each Year to Cigarette Smoking*](chart)
Second Hand Smoke in U.S.


- > 126 million are exposed to SHS
- 3,400 lung cancer deaths / year
- 46,000 heart disease deaths / year
- Declining: 84% in 1988-94 to 46% in 1999-2004
- 74% of population covered by smoke free policies in work places and restaurants/bars
ACR Lung Cancer Screening Registry

- Approved by CMS as a qualified registry March 5, 2015

- ACR National Radiology Database Registries (NRDR) aid facilities with quality improvement programs & efforts to improve patient care by comparing facility data to others regionally and nationally and are approved by CMS as a Qualified Clinical Data Registry (QCDR) for Physician Quality Reporting System (PQRS)

- NRDR registries include:
  - Dose Index Registry (DIR)
  - CT Colonography Registry (CTC)
  - National Mammography Database (NMD)
  - National Oncologic PET Registry (NOPR)
  - General Radiology Improvement Database (GRID)

Go to acr.org/nrdr for more information
ACR Lung Cancer Screening Registry

- Major data categories:
  - Appropriateness of screening
  - Screening test itself
    - CT radiation exposure
    - LungRADS™ structured reporting category
  - Outcomes at 12 months from the screening CT event

- Contracting to begin in May 2015

- Target launch June 2015

http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Lung-Cancer-Screening-Registry
ACR LungRADS™ Released at AMCLC 2014

- Modeled after the ACR’s 20 year experience with BIRADS, now it’s fifth edition
- Structured reporting and management tool for lung cancer screening CT interpretation
- Practice audit component

http://www.acr.org/Quality-Safety/Resources/LungRADS
Lung Cancer CT Screening & False Positives

- 40% of NLST subjects had at least one FP over the 3 years
- Uncertainty about best management protocol for FPs
- Among patients with a positive screen who underwent a diagnostic procedure, approximately 1.4% experienced a complication
ACR LungRADS®

- Structured reporting and management
- 0-4 Categories
- 2 Modifiers:
  - S: Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)
  - C: Prior diagnosis of lung cancer who return to screening
- Facilitates practice audit
  - Total # of screens
  - Distribution of screens across categories
  - Positive screen rate
  - PPVs
# ACR LungRADS™

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<th>Primary Category</th>
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<tbody>
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<td>-</td>
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<td>4A, 4B</td>
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<td>4B</td>
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Fundamental question:
What is a positive screen?
NLST: Positive CT Screen Definition

- Nodule $\geq 4$ mm
- Independent of nodule consistency
- Positive screen rates:
  - 27.3% baseline
  - 27.9% T1 screen
  - 16.8% T2 screen
Size Threshold for a Positive Lung Cancer Screening CT

Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer
A Cohort Study
Claudia I. Henschke, PhD, MD; Rowena Yip, MPH; David F. Yankelevitz, MD; and James P. Smith, MD, for the International Early Lung Cancer Action Program Investigators*


effect of alternative thresholds for defining a positive result on the rates of positive results and cancer diagnoses
# Size Threshold for a Positive Lung Cancer Screening CT

- 21,136 individuals with baseline CT performed between 2006 and 2010

<table>
<thead>
<tr>
<th>Size</th>
<th>(+) Screen Rate</th>
<th>Work Up Reduction</th>
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<tbody>
<tr>
<td>≥ 5 mm</td>
<td>16.0%</td>
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<tr>
<td>≥ 6 mm</td>
<td>10.2%</td>
<td>36%</td>
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<tr>
<td>≥ 7 mm</td>
<td>7.1%</td>
<td>56%</td>
</tr>
<tr>
<td>≥ 8 mm</td>
<td>5.1%</td>
<td>68%</td>
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<tr>
<td>≥ 9 mm</td>
<td>4.0%</td>
<td>75%</td>
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</table>

9 month delay in cancer dx 0%, 5%, 5.9%, 6.7%
Examined performance of CT with nodules > 4 mm NLST (+) screen threshold

Largest nodule was ≤ 7 mm in 64% of (+) screens (11598/18141)

Going from 5 to 8 mm
- missed or delayed cancer increased from 1.0% to 15.8%
- false positives reduced from 65.8% to 10.5%

“Raising the nodule size threshold for a (+) screen would substantially reduce false-positive CT screenings and medical resource utilization with a variable impact on screening outcomes.”
2011 IASLC/ATS/ERS
International Multidisciplinary Classification of Lung Adenocarcinoma

AAH

AIS

MIA

INVASIVE
Non Solid Nodules

2011 IASLC/ATS/ERS
International Multidisciplinary Classification of Lung Adenocarcinoma

- **Preinvasive Lesions:**
  - Atypical adenomatous hyperplasia (AAH)
    - localized small proliferation of atypical Type II pneumocytes and/or Clara cells lining the alveolar walls and respiratory bronchioles
  - Adenocarcinoma in situ (AIS)
    - ≤ 3 cm solitary adenocarcinoma with pure lepidic growth
    - complete resection achieves 100% disease-specific survival
Non Solid Nodules & ACR

2011 IASLC/ATS/ERS
International Multidisciplinary Classification of Lung Adenocarcinoma

- Minimally invasive adenocarcinoma (MIA)
  - $\leq 3$ cm with predominantly lepidic pattern and $\leq 5$ mm invasion at the largest dimension
  - does not invade lymphatics, blood vessels, or pleura
  - contains no necrosis
  - complete resection achieves nearly 100% disease-specific survival

- Invasive adenocarcinoma
ACR LungRADS®

- **Nodule size**
  - baseline, growth v stability

- **Nodule consistency**
  - solid, part solid, non solid (aka ground glass nodule)
  - calcification, fat

- **Benign & benign behavior vs. clinically active cancer** *(what is cancer?)*

- **Reduces false positives from > 1 in 4, to 1 in 10**
Classifying Screen-Detected Lung Nodules

- **solid**
- **part solid**
- **non solid**
  aka GGO or GGN
## NEGATIVE SCREEN: ACR LungRADS™

<table>
<thead>
<tr>
<th>Category</th>
<th>Category Descriptor</th>
<th>Category</th>
<th>Findings</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>No nodules and definitely benign nodules</td>
<td>1</td>
<td>no lung nodules, nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules</td>
<td>Continue annual screening with LDCT in 12 months</td>
</tr>
<tr>
<td>Benign Appearance or Behavior</td>
<td>Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth</td>
<td>2</td>
<td>solid nodule(s): &lt; 6 mm, new &lt; 4 mm, part solid nodule(s): &lt; 6 mm total diameter on baseline screening, non solid nodule(s) (GGN): &lt; 20 mm OR ≥ 20 mm and unchanged or slowly growing</td>
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<tr>
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</tr>
<tr>
<td>Probably Benign</td>
<td>Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer</td>
<td>3</td>
<td>solid nodule(s):</td>
<td>6 month LDCT</td>
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<td></td>
<td>≥ 6 to &lt; 8 mm at baseline OR new 4 mm to &lt; 6 mm</td>
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<td></td>
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<td></td>
<td>part solid nodule(s)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>≥ 6 mm total diameter with solid component &lt; 6 mm OR new &lt; 6 mm total diameter</td>
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<td></td>
<td>non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new</td>
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</tbody>
</table>
| Suspicious | Findings for which additional diagnostic testing and/or tissue sampling is recommended | solid nodule(s):  
≥ 8 to < 15 mm at baseline OR  
growing < 8 mm OR  
new 6 to < 8 mm  
part solid nodule(s):  
≥ 6 mm with solid component ≥ 6 mm to < 8 mm OR  
with a new or growing < 4 mm solid component  
endobronchial nodule | 3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component |
| 4A |  |  |  |
| 4B | solid nodule(s)  
≥ 15 mm OR  
new or growing, and ≥ 8 mm  
part solid nodule(s) with:  
a solid component ≥ 8 mm OR  
a new or growing ≥ 4 mm solid component | chest CT with or without contrast, PET/CT and/or tissue sampling depending on the probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component |
| 4X | Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy |  |  |
2180 consecutive high-risk patients undergoing clinical CT screening between 1/2012-05/2014 reclassified using ACR LungRADS

- no clinical follow-up in 577 patients (26%)

ACR Lung-RADS:

- Reduced positive screen rate from 27.6% to 10.6%
- No false negatives in the 152 patients with >12-month follow-up reclassified as benign
- Increased PPV for malignancy from 6.9% to 17.3%

http://www.jacr.org/article/S1546-1440(14)00473-6/abstract
Reclassified NLST CT screening exams using LungRADS
26,722 LDCT arm subjects (26,309 baseline; 48,671 post-baseline)

<table>
<thead>
<tr>
<th></th>
<th>BASELINE</th>
<th>POST BASELINE</th>
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<tbody>
<tr>
<td></td>
<td>LungRADS</td>
<td>(NLST)</td>
</tr>
<tr>
<td>FPR (1-Specificity)</td>
<td>12.9%</td>
<td>(26.6%)</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>86.1%</td>
<td>(93.8%)</td>
</tr>
<tr>
<td>PPV</td>
<td>6.9%</td>
<td>(3.8%)</td>
</tr>
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</table>

*Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and Ella Kazerooni, MD Annals of Internal Medicine February 2015
False negative LungRADS screens were nodules with no growth and/or pure nonsolid nodules (5 year survival 64% TPs vs. 73% FNs)

Compared to the original NLST criteria
- FPRs with LungRADS were ½ at baseline and ¼ post-baseline
- Sensitivity was 8% and 15% lower at baseline and post-baseline
- PPV was 2-3 fold higher for LungRADS
Lung Cancer Screening Economics and Payment Policy

Geraldine McGinty, MD, MBA, FACR
Weill Cornell Medical College
Chair, ACR Commission on Economics
@DrGMcGinty
What happens now?

• ACR met with coverage and payment groups at CMS in February
• Coverage group will issue a change request to payment group
• Expect this process to take several months
• What did we discuss with CMS
  • G code to allow payment in 2015
  • Screening typically pays lower than diagnostic
  • This is different to 71250 (non contrast chest CT)
    • Lower resolution imaging
    • Quality activities
    • Structured reporting
    • Responsibility for follow up
  • Detailed work and expense descriptions sent to CMS
• How does shared decision making visit get done/paid for
  • Access a concern
  • Should be able to add it to other visits
• Cost sharing for follow up care is a concern
• “S” code created in October 2014
• Don’t have to use G code if created
• Variable payment rates
• Not hearing about requirements to use registry
  • Encourage you to use it for all cases
• Some payers telling you to use 71250
  • We are pushing back on this
    • Need to track screening cases
So what do I do right now?

- Hold your claims
- Hold your registry data
- Medicare WILL pay for it but we cannot say at what rate
- Do not bill MC beneficiaries, it is a covered service
- Advocate for **fair** reimbursement with payers to ensure access and treat those patients the same in terms of outcomes tracking
Questions?
Thank you for attending today’s webinar!

Contact us:

- Coverage/Payment: LCScoverage@acr.org
- Registry: nrdr@acr.org
- Screening Center Designation: lungcancerscreening@acr.org
- Resources: http://www.acr.org/Quality-Safety/Resources/Lung-Imaging-Resources