Medicare Coverage of Lung Cancer Screening with Low Dose CT

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NAS Workshop, 06/20/2016

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Medicare Construct

• Established by the Social Security Act of 1965, Title XVIII
  • §1862(a)(1) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—
    • (A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member
    • (E) in the case of research conducted pursuant to §1142, which is not reasonable and necessary

• Defined benefit program
  • Beneficiaries
  • Providers
  • Settings
Medicare Population

• Age ≥ 65 years
• Disabled individuals
• Patients with end stage renal disease
Medicare Coverage of Preventive Services

CMS authority to add preventive services established by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Section 101).

May add using national coverage determination (NCD) process if the service meets all of the following:

• Reasonable and necessary for the prevention or early detection of illness or disability.
• Recommended with a grade of A or B by the United States Preventive Services Task Force.
• Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

• “Secretary [HHS] may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination”
Lung and Bronchus Cancer (2009-2013)

New Cases of Lung and Bronchus Cancer

Deaths from Lung and Bronchus Cancer

Lung and bronchus cancer is most frequently diagnosed among people aged 65-74.

The percent of lung and bronchus cancer deaths is highest among people aged 65-74.

Stage of Diagnosis and Survival (2006-2012)

Percent of Cases by Stage

- Localized (16%)
- Confined to Primary Site
- Regional (22%)
- Spread to Regional Lymph Nodes
- Distant (57%)
- Cancer Has Metastasized
- Unknown (5%)
- Unstaged

National Lung Screening Trial (2011)

- Randomized trial LDCT vs chest radiology annually x3
- “Eligible participants were between 55 and 74 years of age at the time of randomization, had a history of cigarette smoking of at least 30 pack years, and, if former smokers, had quit within the previous 15 years.”
- N= 53,454
- “Screening with the use of low-dose CT reduces mortality from lung cancer.”
Lung Cancer Screening Trials

- Narrow window of evidence of benefit
- NLST was positive; DANTE and DLSCT were negative
- Different comparison, age, smoking history, definition of positive

<table>
<thead>
<tr>
<th>Study</th>
<th>Age (inclusion criterion)</th>
<th>Smoking history (inclusion criterion)</th>
<th>Positive result LDCT (false positive rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DANTE; n = 2472 CTx5 vs no screening</td>
<td>mean age = 64.6; (60-74 years)</td>
<td>mean = 47 pack-years; (≥ 20 pack-years)</td>
<td>non-calcified nodule ≥ 10 mm, etc; (291/351, 83%)</td>
</tr>
<tr>
<td>DLSCT; n = 4104 CTx5 vs no screening</td>
<td>91% 50-64 years; (50-70 years)</td>
<td>mean = 36 pack-years; (≥ 20 pack-years)</td>
<td>nodule ≥ 5 mm; (542/611, 89%)</td>
</tr>
<tr>
<td>NLST; n = 53454 CTx3 vs CXR</td>
<td>73% 55-64 years; (55-74 years)</td>
<td>mean = 56 pack-years; (≥ 30 pack-years)</td>
<td>non-calcified nodule ≥ 4 mm; (17497/18146, 96 %)</td>
</tr>
</tbody>
</table>


The USPSTF recommends annual screening for lung cancer with low-dose computed tomography 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.

(B recommendation)
MEDCAC

- Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), April 30, 2014
  - Low confidence that there is adequate evidence that the benefits outweigh the harms of lung cancer screening with LDCT in the Medicare population
  - Low confidence that the harms of lung cancer screening with LDCT if implemented in the Medicare population will be minimized
  - High confidence that clinically significant evidence gaps remain regarding the use of LDCT for lung cancer screening in the Medicare population outside a clinical trial
  - Concerns about over-diagnosis, false positive results and diagnostic evaluation of nodules in older adults
  - Translational / implementation issues

Stakeholder Engagement

Multi-society, multi-disciplinary meetings


Medicare National Coverage Determination
Screening for Lung Cancer with LDCT

• Annual screening for lung cancer with LDCT, as an additional preventive service benefit under the Medicare program only if all of the following eligibility criteria are met.

• Beneficiary Eligibility Criteria
  • For purposes of Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following 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.

• Counseling and Shared Decision Making Visit
NCD Lung Cancer Screening with LDCT (cont.)

• Reading Radiologist Eligibility Criteria

• For purposes of Medicare coverage of lung cancer screening with LDCT, the reading radiologist must meet all of the following 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 described below.
NCD Lung Cancer Screening with LDCT (cont.)

• Radiology Imaging Facility Eligibility Criteria

• For purposes of Medicare coverage, lung cancer screening with LDCT must be furnished in a radiology imaging facility that meets all of the following eligibility criteria:
  • Performs LDCT with volumetric CT dose index (CTD\text{vol}) of $< 3.0$ mGy (milligray) for standard size patients (defined to be 5' 7" and approximately 155 pounds) with appropriate reductions in CTD\text{vol} for smaller patients and appropriate increases in CTD\text{vol} 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:
NCD Lung Cancer Screening with LDCT (cont.)

- Minimum data elements

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Minimum Required Data Elements</th>
</tr>
</thead>
<tbody>
<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 or symptoms of lung cancer</td>
</tr>
<tr>
<td>System</td>
<td>Lung nodule identification, classification and reporting system</td>
</tr>
</tbody>
</table>
| Smoking history         | 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. |
| Effective radiation dose| CT Dose Index (CTDvol).        |
| Screening               | Screen date                    |
|                         | Initial screen or subsequent screen |

Information regarding CMS-approved registries is posted on the CMS website at:  
http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Lung-Cancer-Screening-Registries.html
Counseling & Shared Decision Making Visit

- First formal Medicare SDM coverage requirement
  - 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;
  - If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)  
Evidence-based Decision Aids

• Several evidence-based decision aids and support tools have been developed and published since our NCD requiring SDM and use of decision aid, including but not limited to:
  
  
  
  
  
  • Volk R, Linder S, Cinciripini P. Lung Cancer Screening Decision Aid Development and Testing (NCT02282969)
  
  • Studts J, Byrne MM. Development and Feasibility Testing of a Lung Cancer Screening Decision Aid (LuCaS-DA) (NCT02790866)
AHRQ Lung Cancer Screening Tools

Is lung cancer screening right for me?

A Decisionmaking Tool for You and Your Health Care Professional

If you have smoked for many years, you may want to think about lung cancer screening (testing) with low-dose computed tomography (LDCT). Before making a decision, you should think about the possible benefits and harms of lung cancer screening.

### What are the possible benefits and harms of lung cancer screening with LDCT?

**BENEFIT:** Greater chance of not dying from lung cancer.
- If 1,000 people are not screened for lung cancer with LDCT, 21 will die from lung cancer.
- If 1,000 people are screened once a year with LDCT for 5 years, 8 will die from lung cancer.
- This means that LDCT screening 3 fewer people will die from lung cancer.

**BENEFIT:** Greater chance of not dying from any cause (not just lung cancer).
- If 1,000 people are not screened for lung cancer with LDCT, 70 will die from any cause.
- If 1,000 people are screened once a year with LDCT for 5 years, 70 will die from any cause.
- This means that LDCT screening 3 fewer people will die from any cause.

**HARM:** False alarms and unneeded additional testing.

- A false alarm happens when a person has a positive screening test but does not actually have lung cancer.
- If 1,000 people are screened every year for 3 years, about 365 will have a false alarm.
- Of those 365 people with a false alarm, 11 will have an invasive procedure such as a biopsy to rule out the false alarm.
- Of those 11 people, less than 1 will have a major complication as a result of the procedure, such as bleeding in the lung, a collapsed lung, or an infection.
- If you have a positive screening test, but your follow-up imaging tests and biopsy do not show cancer, you might still get yearly scans in the future. So it is important for you and your health care professionals to think about lung cancer screening every year.

**HARM:** Radiation Exposure.

This includes radiation from screening plus radiation from additional testing. High doses of radiation increase a person’s chance of developing cancer.

**HARM:** Overdiagnosis.

Screening may find lung cancer that would not have caused harm or disease in the future.

*For people enrolled in a Medicare Advantage plan with the Comprehensive Medicare Plan.

### What is important to you when deciding?

**What else should you consider when deciding about lung cancer screening?**

**Insurance Coverage**

- Private insurance plans cover lung cancer screening for people age 55 through 80 with no out-of-pocket costs.
- Medicare covers lung cancer screening with no out-of-pocket costs for people age 55 to 77 who meet other criteria.

**What else should you consider when deciding?**

- Your health care professional can provide you with smoking cessation counseling.

**What is your decision about lung cancer screening?**

- You should get written advice from your health care professional and go to the Imaging Center located in your local area.

Accessed 06/2016.

Next Steps

- Post coverage analysis – SDM, LDCT
  
  | G0296 (SDM) | 1023 | G0297 (LDCT) | 8971 |

- Registry data (real world data)
- Administrative data (outcomes)
- Refine coverage criteria and SDM visit

Thank you