LUNG CANCER SCREENING WITH LOW DOSE COMPUTED TOMOGRAPHY (LDCT) (NCD 210.14)

Guideline Number: MPG195.04

Approval Date: January 09, 2019

Overview

Lung cancer is the third most common cancer and the leading cause of cancer deaths in the United States. Computed tomography (CT) is an imaging procedure that uses specialized x-ray equipment to create detailed pictures of areas inside the body. Low dose computed tomography (LDCT) is a chest CT scan performed at settings to minimize radiation exposure compared to a standard chest CT. Screening for lung cancer with LDCT is not currently covered under the Medicare program.

The Centers for Medicare & Medicaid Services (CMS) under §1861(ddd) of the Social Security Act (the Act), has the authority to add coverage of “additional preventive services” through the Medicare national coverage determination (NCD) process if certain statutory requirements are met: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Guidelines

Nationally Covered Indications

Effective for claims with dates of service on or after February 5, 2015, CMS has determined that the evidence is sufficient to add coverage under Medicare Part B a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, 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;
• Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
• Asymptomatic (no signs or symptoms of lung cancer);
• Current smoker or one who has quit smoking within the last 15 years; and
• Receive a written order for lung cancer screening with LDCT. Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary’s medical records, and must contain the following information:
  o Beneficiary date of birth;
  o Actual pack – year smoking history (number);
  o National Provider Identifier (NPI) of the ordering practitioner; and
  o Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer);
  o Current smoking status, and for former smokers, the number of years since quitting smoking.
Counseling and Shared Decision Making Visit

Before the beneficiary’s first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision making visit that meets all of the following criteria, and is appropriately documented in the beneficiary’s medical records:

• Must be 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), and

• Must include all of the following elements:
  o 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;
  o Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
  o 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;
  o 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
  o If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

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;
• Furnish lung cancer screening with LDCT in a radiology imaging facility that meets the radiology imaging facility eligibility criteria described below;
• 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.

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 (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;
• Makes available smoking cessation interventions for current smokers;
• Utilizes a standardized lung nodule identification, classification and reporting system; 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>
<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>
<tr>
<td>Smoking history</td>
<td>Current status (current, former, never)</td>
</tr>
<tr>
<td></td>
<td>If former smoker, years since quitting</td>
</tr>
<tr>
<td></td>
<td>Pack-years as reported by the ordering practitioner</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>Initial screen or subsequent screen</td>
</tr>
</tbody>
</table>
Written Orders for Subsequent Annual Lung Cancer Screenings with LDCT
For subsequent annual lung cancer LDCT screenings, the beneficiary must receive a written order for lung cancer LDCT screening. The written order may be furnished during any appropriate visit with 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 Section 1861(aa)(5) of the Social Security Act).

If a physician or qualified non-physician practitioner elects to provide a lung cancer screening counseling and shared decision making visit before a subsequent annual lung cancer LDCT screening, the visit must meet all of the criteria described above for a counseling and shared decision making visit.

Nationally Non-Covered Indications
Unless specifically covered in this NCD, any other NCD, in statute or regulations, preventive services are non-covered by Medicare.

Other
Part B deductible and Medicare coinsurance are waived for this preventive service.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: New HCPCS codes G0296 and G0297 are in the January 1, 2016 HCPCS and OPPS updates with a retro effective date of February 5, 2015.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0296</td>
<td>Counseling visit to discuss need for lung cancer screening using low dose CT scan (LDCT) (service is for eligibility determination and shared decision making)</td>
</tr>
<tr>
<td>G0297</td>
<td>Low dose CT scan (LDCT) for lung cancer screening</td>
</tr>
</tbody>
</table>

QUESTIONS AND ANSWERS

1. Q: Is eligible radiology imaging facilities required to submit data?
   A: Yes, eligible radiology imaging facilities furnishing lung cancer screening with LDCT are required to collect and submit data to a CMS-approved registry for each lung cancer LDCT screening performed.

2. Q: Are there specific reading radiologist and radiology imaging facility eligibility criteria?
   A: Yes, both must meet all of the eligibility criteria designated by CMS.

3. Q: What is the correct diagnosis code to submit on the claim?
   A: On or after date of service 10/01/2015 with ICD-10 F17.210, F17.211, F17.213, F17.218, F17.219 or Z87.891.

4. Q: Is this a preventive service?
   A: Yes, therefore no coinsurance and Part B deductible for this preventive service.

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support claims.
support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 210.14 Lung Cancer Screening with Low Dose Computed Tomography (LDCT)

CMS Articles

<table>
<thead>
<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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</thead>
<tbody>
<tr>
<td>A55816 (IDTFs and Low Dose CT Scan for Lung Cancer Screening for HCPCS Code G0297) Palmetto</td>
<td>NC, SC, VA, WV, AL, GA, TN</td>
<td>NC, SC, VA, WV, AL, GA, TN</td>
</tr>
</tbody>
</table>

CMS Claims Processing Manual
Chapter 18; § 220 Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

CMS Transmittals
Transmittal 185, Change Request 9246, Dated 08/21/2015 (Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT))
Transmittal 1658, Change Request 9540, Dated 04/29/2016 (Coding Revisions to National Coverage Determinations)
Transmittal 3374, Change Request 9246, Dated 10/15/2015 (Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT))
Transmittal 3425, Change Request 9486, Dated 12/18/2015 (January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS))
Transmittal 3669, Change Request 9888, Dated 12/02/2016 (HCPCS Code Update for Preventive Services)
Transmittal 3901, Change Request 10338, Dated 11/03/2017 (Update to Pub 100-04, Chapter 18 Preventive and Screening Services - Screening for Lung Cancer with Low Dose Computed Tomography (LDCT))

MLN Matters
Article MM9246, Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)
Article MM9486, January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)

UnitedHealthcare Commercial Policies
Preventive Care Services

Others
American College of Radiology (ACR) Lung Cancer Screening Registry (LCSR), ACR Website
Lung Cancer Screening Registries, CMS Website
Lung Cancer Screening Registry Active Registrants as of January 28, 2016, ACR Website
The ABCs of the Annual Wellness Visit (AWV), Article ICN 905706 January 2015, CMS Website
The ABCs of the Initial Preventive Physical Examination (IPPE), Article ICN 006904 January 2015, CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>01/09/2019</td>
<td>• Annual review</td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services
are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.