## **ACR Updates LDCT Lung Cancer Screening FAQs**

The Centers for Medicare and Medicaid Services (CMS) issued a national coverage decision (NCD) on Feb. 5, 2015, announcing a new benefit for low-dose computed tomography (LDCT) lung cancer screening for certain Medicare beneficiaries.

Beginning Jan. 4, 2016, Medicare contractors will accept claims for LDCT lung cancer screening retroactive to the Feb. 5, 2015, date of the NCD.

CMS posted claims billing instructions (Change Request Transmittal 185 and Transmittal 3374) for lung cancer screening with low-dose computed tomography, including details on beneficiary screening eligibility, shared decision-making and counseling visits, written order, radiologist, registry, and imaging center requirements. CMS has clarified that Medicare coinsurance and Part B deductible are waived for this preventive service. CMS further states that unless specifically covered in the NCD, in statute or regulations, preventive services are non-covered by Medicare.

The following two new G codes should be used for the shared decision-making visit (G0296) and LDCT lung cancer screening (G0297). Note that Medicare will deny G0296 and G0297 for claims that do not contain ICD-9 code V15.82 (ICD-10 Z87.891, personal history of tobacco use/personal history of nicotine dependence). Please note that CMS will be adding F17.2- (Nicotine dependence) to the approved list of ICD-10 codes on the National Coverage Determination (NCD) 210.14 for low-dose computed tomography (LDCT) lung cancer screening. Providers should be on the look-out for a revised Change Request. For more details, please refer to the December 2015 ACR Advocacy In Action article.

- G0296 Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan (service
  is for eligibility determination and shared decision making)
- G0297— Low-dose CT scan (LDCT) for lung cancer screening

CMS announced in their Feb. 5, 2015 press release that coverage is "effective immediately", full details of the LDCT lung cancer screening NCD can be found here.

Providers must meet all coverage criteria to be reimbursed by Medicare. The following frequently asked questions and answers, prepared by the ACR, address coverage and reimbursement requirements relating to patient eligibility, center eligibility, accreditation and lung cancer screening designation, radiologist requirements, clinical practice registry, and billing and payment.

For additional information on lung cancer screening coverage and reimbursement, visit the Lung Cancer Screening Resources page. For billing and payment questions, please email LCScoverage@acr.org.

# **Patient Eligibility**

Which patients are covered by Medicare for LDCT lung cancer screening?

#### Patients must:

- 1. Be age 55-77 years of age
- 2. Have no signs or symptoms of lung cancer
- 3. Have a 30-pack years or greater history of tobacco smoking
- 4. Be current smokers or have quit smoking within the last 15 years, AND
- Have a written order for LDCT from a qualified health professional following a lung cancer screening counseling that attests to shared decision-making having taken place before their first screening CT

Are cigar smokers or other non-cigarette smokers with other risk factors for lung cancer eligible for LDCT lung cancer screening?

No. Cigar smokers and other non-cigarette smokers are not eligible under the U.S. Preventive Services Task Force (USPSTF) recommendations and Medicare's national coverage determination for LDCT lung cancer screening. At this time, both the USPSTF grade B recommendation and the CMS NCD include language specific to cigarette smokers. While it is recognized that there are other risk factors for lung cancer, and that alone or in combination those risk factors, may equate to a similar lung cancer risk as the recommended screening population, there are no randomized trials based on these risk factors. It is possible that future recommendations could include other risk factors or individual patient risk assessment, however that is not the case at this time.

- CMS specifies "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."
- The USPSTF specifies "A "pack-year" means that someone has smoked an average of 1 pack of cigarettes
  per day for a year. For example, a person who has smoked a pack a day for 30 years has a 30 pack-year
  history of smoking, as does a person who smoked 2 packs a day for 15 years."

<u>Is a written order and shared decision-making visit required for the initial and subsequent visits for LDCT lung cancer screening?</u>

For the initial LDCT lung cancer screening service, a written order is required from a qualified health professional following a lung cancer screening counseling and with attestation to shared decision-making having taken place.

For the subsequent screening services, a written order is required which may be furnished during any appropriate visit from a qualified health professional.

What information is required to be included in the written order for the initial and subsequent visits for LDCT lung cancer screening?

For both the initial and subsequent lung cancer screening services, a written order is required to include:

- 1. Beneficiary date of birth
- 2. Actual number of pack years smoked
- 3. Current smoking status, and for former smokers, the number of years since quitting smoking
- 4. Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer), AND
- 5. National Provider Identifier (NPI) of the ordering practitioner

Are there any example patient order forms available for lung cancer screening?

Yes. Sample suggested patient order forms are available on the ACR webpage.

Are there any decision aid tools available for the shared decision making visit?

Yes. Patient information for decision aids as well as smoking cessation materials are available here. A shared decision making aid with risk calculator is available at shouldiscreen.com.

How do I bill for the shared decision-making visit?

Beginning Jan. 4, 2016, Medicare contractors are accepting claims for the shared decision-making visit retroactive to the date of the national coverage determination (NCD) (Feb. 5, 2015). (Change Request Transmittal 185 and Transmittal 3374)

The following G code should be used for the shared decision-making visit:

• G0296 — Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan (service is for eligibility determination and shared decision-making)

Note: The ACR asked CMS to clarify whether the shared decision-making visit could be billed on the same day as an E/M visit. CMS responded in the 2016 Medicare Physician Fee Schedule (MPFS) Final Rule that as long as the NCD requirement for the counseling and shared decision-making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M visit or an annual wellness visit with the -25 modifier. CMS also clarified that the shared decision-making visit would not be subject to coinsurance or deductibles. More details regarding this topic is addressed in the ACR 2016 MPFS comment letter to CMS.

Who can perform the shared decision-making visit?

CMS CAG clarified that, "As defined per the NCD for Lung Cancer Screening with LDCT, they would have to meet one of the definitions of physician or qualified non-physician practitioner as defined below:

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)."

On Feb. 1<sup>st</sup>, 2016, CMS further clarified to several professional organizations that "the National Coverage Determination (NCD) for Lung Cancer Screening with LDCT (210.14) is based on the recommendation of the United States Preventive Services Task Force (USPSTF) whose general focus is the primary care provider and setting. We recognize the NCD does not specifically state primary care physician or setting. Based on the NCD and applicable regulations, the physician or non-physician practitioner who furnishes the shared-decision making visit and orders the LDCT must be **treating** the beneficiary and use the results in the management of the beneficiary's specific medical problem to ensure improved health outcomes."

The ACR agrees with the NCD language that specifies that a physician or qualified non-physician practitioner must perform the shared decision making visit. As defined in §1861(r) of the Social Security Act (the Act), a "treating physician" is a physician, who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem. <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R80BP.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R80BP.pdf</a>

The ACR recommended to CMS a revision or clarification be included in their MLN Matters article that currently states "NOTE: For outpatient hospital settings, as in any other setting, services covered under this NCD must be ordered by a primary care provider within the context of a primary care setting and performed by an eligible Medicare provider for these services.", as this language may have unintended consequences and result in potential confusion.

## **Center Eligibility**

Which centers are eligible for LDCT lung cancer screening Medicare reimbursement?

#### Any center that:

- Uses LDCTs with volumetric CT dose index (CTDIvol) of ≤3.0 mGy 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
- 2. Utilizes a standardized lung nodule identification, classification and reporting system
- 3. Makes available smoking cessation interventions for current smokers, AND
- Collects and submits specific data elements to a CMS-approved national registry for each LDCT lung cancer screening provided.

# ACR Lung Cancer Screening Registry™

What is the status of the ACR's Clinical Practice Registry for LDCT lung cancer screening?

The ACR Lung Cancer Screening Registry™, was approved by the Centers for Medicare and Medicaid Services (CMS) to enable providers to meet quality reporting requirements to receive Medicare CT lung cancer screening payment.

Registry structure will be based on Lung-RADS™. Final data element specifications for the registry and measure definitions are provided below.

#### Timeline:

- Open for registration: Now!
- Data submission: Now! (and data may be submitted retroactively on exams performed starting January 1, 2015)
- First feedback reports: Fall 2015

## What radiology practices can do now?

- Determine which method you will use to submit data to the LCSR from the list below.
  - 1. Enter data manually using our on-line forms

- New! Upload a flat file (bar (I) delimited) configured according to the instructions in the LCSR User Guide (Section 4)
- 3. New! Transmit data electronically using web-based services. To request IT specifications please contact nrdr@acr.org.

Where can I locate additional information regarding the ACR lung cancer screening registry?

More information about the ACR lung cancer screening registry is available at the ACR Lung Cancer Screening Registry webpage. Click here for the registry information letter.

#### **Accreditation and Lung Cancer Screening Designation**

Are centers required to be accredited and designated in lung cancer screening for LDCT lung cancer screening coverage?

Centers are not required to be accredited and designated in LDCT for lung cancer screening coverage. However, the ACR recommends centers use both in establishing best practice and a quality lung cancer screening program.

Background: CMS provided a response to commenters within the LDCT lung cancer screening final decision that removed the imaging facility criteria previously requiring either past participation in lung cancer screening trials or advanced diagnostic imaging accreditation with training and experience in LDCT lung cancer screening. In place of these criteria, CMS is requiring that imaging facilities use standardized lung nodule identification, classification, and reporting systems and make available smoking cessation interventions for current smokers, based on the evidence reviewed. CMS believes these modifications strike an appropriate balance between maintaining appropriate and high quality access to these services, while reducing undue burden.

Does the ACR have a CT Accreditation for LDCT lung cancer screening and how long is the process in completing?

The ACR's CT accreditation has approved status from CMS under the Medicare Improvements for Patients and Providers Act (MIPPA) and takes approximately four to six months from start to finish. The ACR Lung Cancer Screening Center program meets the CMS threshold for radiation dose per the final NCD. This is a rapid process and can be turned around quickly. Since this program was launched, the College has seen enrollments increase. Over 900 facilities have qualified for an ACR Lung Cancer Screening designation since the program's inception. For a comparison of the ACR Lung Cancer Screening Center Designation and ACR Lung Cancer Registry, see learn more now.

## **Radiologist Requirements**

What are the radiology physician requirements?

According to CMS's proposed decision, radiologists must be:

- 1. Board certified or board eligible with the American Board of Radiology or equivalent organization, with documented training in diagnostic radiology and radiation safety
- 2. Have been involved with the supervision and interpretation of at least 300 chest CTs in the past three years
- 3. Have documented CME per the ACR guidelines and parameters, AND
- 4. Furnish LDCT lung cancer screening in a radiology imaging facility that meets the radiology imaging facility eligibility criteria specified in the CMS final coverage decision

## **Billing and Payment**

When can a center start billing Medicare for LDCT lung cancer screening and what codes should be used?

Beginning Jan. 4, 2016, Medicare contractors will accept claims for low-dose computed tomography (LDCT) lung cancer screening retroactive to the date of the national coverage determination (NCD) (Feb. 5, 2015). (Change Request Transmittal 185 and Transmittal 3374) CMS has clarified that Medicare coinsurance and Part B deductible are waived for this preventive service. CMS further states that unless specifically covered in the NCD, in statute or regulations, preventive services are non-covered by Medicare.

The following two new G codes should be used for the shared decision-making visit (G0296) and LDCT lung cancer screening (G0297). Note that Medicare will deny G0296 and G0297 for claims that do not contain ICD-9 code V15.82 (ICD-10 Z87.891, personal history of tobacco use/personal history of nicotine dependence). The ACR is verifying with CMS on the appropriate ICD-10 code(s) to report for a <u>current smoker</u> with a 30-pack year history of smoking to ensure there is no conflict with current ICD-10 reporting guidelines. Centers should continue to report Z87.891 as instructed by CMS and until further guidance is given.

- G0296 Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan (service is for eligibility determination and shared decision making)
- G0297 Low-dose CT scan (LDCT) for lung cancer screening

Note: <u>HCPCS code</u> S8032 established in October 2014 should be recognized (see ACR S-code article) by commercial payers through September 30<sup>th</sup>, 2016 (see <u>HCPCS Quarterly Updates</u>). Embedded in the "Other code effective October 1, 2016" zip file, S8032 is scheduled for deletion on September 30<sup>th</sup>, 2016. Some commercial payers have transitioned to the G0297 code. Please contact your private payer to clarify which code they recognize through September 30<sup>th</sup>, 2016 and stay on alert they transition to the G0297 code accordingly.

How much will Medicare and/or Managed Care pay for LDCT lung cancer screening and is there an additional reimbursement for the work tied to the data collection and submission to a CMS-approved registry?

The ACR recommends that the payment rate of CPT® code 71250 (Computed tomography, thorax; without contrast material) should serve as the reimbursement floor for LDCT lung cancer screening with additional RVUs assigned for the numerous quality criteria required of an effective lung cancer screening program and mandated in CMS's final coverage decision.

In the 2016 Medicare Physician Fee Schedule (MPFS) final rule, CMS indicated that LDCT would be valued at the same level as a non-contrast chest CT (CPT code 71250). Due to technical errors on the part of the Centers for Medicare and Medicaid Services (CMS) there was some delay in the release of CY 2016 Medicare Physician Fee Schedule (MPFS) reimbursement rates for the G-codes to be used in shared decision making (G0296 — Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan) and lung cancer screening G0297—Low-dose CT scan (LDCT) for lung cancer screening). These errors have been addressed in an <a href="Emergency Update">Emergency Update</a> to the CY 2016 Medicare Physician Fee Schedule Database.

For CY 2016 the MPFS global payment rate for G0297 will be roughly \$254.93, the professional component will be approximately \$51.56 and the Technical component will be approximately \$203.37. For G0296 the MPFS payment rate will be roughly \$28.64. These totals have been calculated by multiplying the total Relative Value Units for each code and multiplying them by the CY 2016 MPFS conversion factor (\$35.8043). The reimbursement rate under the Hospital Outpatient Prospective Payment System (HOPPS) for G0297 will be \$112.49 and for G0296 the payment rate will be \$69.65. These rates are calculated by multiplying the relative weight of the Ambulatory Payment Classification (APC) groupings of the two codes by the CY 2016 HOPPS conversion factor (\$73.725). The APC placement of G0297 is 5570 (Computed Tomography with Contrast) with a relative weight of 1.5258 and G0296 resides in APC 5822 (Level 2 Health and Behavior Services) with a relative weight of 0.9447.

For additional details on private payer reimbursement, the ACR published an article including a recommendation for valuation of the lung cancer screening S-code. Although the ACR is explicit in its payment recommendation, private payer reimbursement rates may vary.

<u>Do Medicare Advantage plans allow LDCT lung cancer screening coverage and payment? If so, how should this service be billed?</u>

The ACR recommends that radiology groups and practices verify billing instructions for LDCT lung cancer screening with their individual Medicare Advantage plans to address the flexibility afforded to these plans by CMS.

Since the ACR's recent lung cancer screening webinar, many practices have asked the College to clarify whether Medicare Advantage plans are required to await coding/billing instructions from CMS or if they are able to accept the S-code established in October 2014 for lung cancer screening (S8032 Low-dose computed tomography for lung cancer screening). Medicare Advantage plans generally must provide coverage of all Medicare-covered services, but they are afforded flexibility in how and what they pay for those services. Based on past precedent, CMS is giving Medicare Advantage plans latitude with respect to coding and billing instructions for lung cancer screening. As such, the ACR is encouraging imaging practices to check with each of their Medicare Advantage plans to determine if the S-code is accepted or if they are awaiting instructions from CMS.

How does Medicare Supplemental Insurance (Medigap) apply to lung cancer screening patient eligibility criteria?

For patients with primary Fee-For-Service Medicare coverage, Medigap policies cover the beneficiary portion of the Medicare approved payment (ie, co-payment). Medigap policies would cover lung cancer screening consistent with the Medicare National Coverage Determination (age 55-77).

Should a lung cancer screening exam or a diagnostic exam be reported for Lung-RADS category 1 and 2?

Lung-RADS category 1 and 2 are negative screenings and the 12-month LDCT is the next annual screening CT. An LDCT annual screening exam should be reported as the next management step for Lung-RADS category 1 and 2. However, interim CTs are considered diagnostic and should use diagnostic non-contrast chest CT code.

An example of report text for the results impression:

Lung-RADS category 1: Negative screen. Recommend continued annual low dose CT screening in 12 months. Lung-RADS category 2: Negative screen. Recommend continued annual low dose CT screening in 12 months.

Is it a requirement to notify the ordering provider and/or patient that they are due for their follow up scan?

No, it is not a requirement. However, a best practice for screening programs is to track patients with Lung-RADs 3s and 4s, and if they have not come back to their practice, to remind the referring physician and/or patient.

For example, a monthly data pull of all patients with Lung-RADs 3s and 4s, and verification of schedule for a followup test or appointment, and tracking the patients to ensure and encourage adherence; if they are not scheduled by the time window recommended in Lung-RADs, inform and alert the referring provider.

When should LOW DOSE protocols be utilized for follow up chest CTs?

Based on the ACR Lung-RADS LOW DOSE protocols are recommended for the 3 and 6 month diagnostic follow up exams (71250).

What codes should be reported for the annual LDCT lung cancer screening and the follow up chest CTs?

For Lung-RADS categories 1 and 2 with recommendations at a 12 month cycle, are considered an annual screening exam and reported with G0297. The HCPCS code G0297 is recognized by Medicare and some private payers (please contact your private payer to see if they recognize the S code or G code). For Lung-RADS categories 3 and 4 with recommendations at 3-6 month follow up, CPT code 71250 non-contrast chest CT (diagnostic) is reported. (see above Q&A for low dose protocols)

<u>Is it required to exclude patients from the LDCT lung cancer screening for persons who have had a CT within the last few years?</u>

Although this is a volunteer program, the ACR recommends the following per the <u>ACR Lung Cancer Screening</u> <u>Center Designation</u>:

Recommended Screening Population

- Majority of patients screened are between the ages of 55 and 80
- Have a smoking history of 30 pack years
- If no longer smoking, stopped smoking in 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.
- Persons who have undergone chest CT within 12 months should be excluded (initial screening)

## **Lung Cancer Screening Resources**

Additional ACR resources for lung cancer screening can be found on the ACR Lung Cancer Resources webpage. An ACR webinar on lung cancer screening can be viewed using this link to the presentation on YouTube. Webinar slides may be downloaded from the link located on the upper right hand corner of the Resources webpage.

Contact Us Screening Center Designation <u>lungcacreening@acr.org</u> 1-800-770-0145 x3712

# Registry

nrdr@acr.org 1-800-227-5463 x3535

Coverage / Payments LCScoverage@acr.org 1-800-227-5463 x4043

Education info@acr.org 1-800-227-5463 x4040

If you have any questions, please contact Anita McGlothlin at amcglothlin@acr.org or email questions directly to LCScoverage@acr.org.