

LCA Advocates for Lung Cancer Screening in the IDTF Setting

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On August 15th, 2018 the Lung Cancer Alliance (LCA) and other key stakeholders held a conference call with the Centers for Medicare and Medicaid Services Coverage and Analysis Group (CMS CAG) regarding their continued and erroneous lung cancer screening denials by local Medicare Administrative Contractors (MACs) when performed in the Independent Diagnostic Testing Facility (IDTF) setting. CMS CAG confirmed that all MACs deny reimbursements to IDTFs for low dose CT lung cancer screening. These denials continue to be a major barrier and access issue for Medicare patients who may be forced to pay out of pocket for a screening benefit that is covered at 100% with no patient co-pays when performed at other settings.

LCA urged CMS to remedy this issue through a Change Request Transmittal (MM9246), instructions to their MACs, as per their June 2017 clarification and MLN Matters article, affirming that lung cancer screening is available in ALL facilities including IDTFs when criteria are met.

While we do not believe it was CMS's intent to prohibit coverage of lung cancer screening in the IDTF setting, CMS national are complacent, continue to remain silent, and allow Medicare contractors to deny across the board for all lung cancer screenings performed in this type of imaging facility. MACs assert that lung cancer screenings are not eligible for coverage in the IDTF setting, as they have deemed this imaging exam to be a "therapeutic intervention." CMS national agreed with this MAC assertion in their February 2018 letter which cites local MAC articles:

*"IDTFs are enrolled for diagnostic testing only and are not permitted to perform therapeutic activities (IOM 100-04, Chapter 35). IDTFs may perform the low dose CT scan associated with this benefit (when all requirements for coverage, including a physician's order, are met; see Change Request 9246), **but since the code G0297 also includes a therapeutic activity (must make available smoking cessation interventions for current smokers), this service must be billed by a physician. The physician and IDTF must have a business arrangement for cooperatively providing this portion of the benefit and the IDTF shall look to the physician for payment.**"*

In response to CMS and MAC's assertion above, LCA and key stakeholders concluded that MACs are not adhering to Medicare's lung cancer screening National Coverage Determination (NCD) and should be considered out of compliance for these IDTF screening denials. The lung cancer screening NCD does not include such restriction to the IDTF setting, and G0297 (low dose CT lung cancer screening) should not be categorized as a therapeutic exam.

LCA has communicated this to CMS in both written and verbal form over the last several years and submitted a formal letter on May 11 with key stakeholders. The American College of Radiology, Radiology Business Managers Association, LCA and others have repeatedly explained that all imaging settings including hospitals are meeting NCD criteria "makes available smoking cessation interventions to current smokers" through smoking cessation patient education materials, etc. They are not providing a *therapeutic or counseling* exam for the low dose CT screen (G0297), and yet MACs believe otherwise and have deemed this low dose CT imaging exam as a "therapeutic" category.

LCA continued to advocate for the lung cancer community and wrote to CMS national on September 14th asking again for MAC oversight and correction for these IDTF lung cancer screening denials. We also

cited their NCD which specifies on **page 65** that CMS is modifying the “imaging facility eligibility criteria” to “require that smoking cessation interventions, **such as educational materials, be made available.**” The following is the NCD discussion section that clarifies how imaging facilities should meet the required criteria to make smoking cessation interventions available.

*Since “[s]moking is widely recognized as the leading cause of lung cancer” (NCI - <http://seer.cancer.gov/statfacts/html/lungb.html>), smoking cessation interventions were integral interventions in published trials. According to the 2011 Medicare Current Beneficiary Survey (MCBS), 14 percent of beneficiaries reported to be current smokers, and 44 percent reported as former smokers, although pack-year information is not collected. Additionally, we received public comments that also addressed tobacco cessation interventions. Therefore, based on the evidence reviewed and public comments received, we are modifying the imaging facility eligibility criteria to **require that smoking cessation interventions, such as educational materials, be made available.***

This NCD language is clearly stating that provision of “educational materials” is the exact type of intervention CMS had intended all along. This NCD discussion section is unambiguous and provides instruction and rationale regarding the wording used in the NCD for the *imaging facility eligibility criteria* that also includes IDTFs. The purpose of NCD discussion is to provide the context and meaning of CMS’s criteria for “makes available smoking cessation interventions for current smokers” which is being met by all imaging facilities including IDTFs that perform lung cancer screening.

LCA will continue to urge CMS national to 1) apply their NCD language as CMS intended and clearly outlined in the NCD discussion section page 65 and 2) instruct local Medicare contractors accordingly. Formal instructions to MACs occur through a Change Request (CR) Transmittal notice from the national office. We have asked for the following MAC CR Transmittal instruction:

- LDCT lung cancer screening code G0297 is not an intervention/therapeutic service in the lung cancer screening NCD;
- LDCTs are a nationally covered preventive screening service available to Medicare beneficiaries in ALL settings, including IDTFs; and
- Payment for all previously performed LDCTs should be retroactive to February 5, 2015, for all imaging facilities, including IDTFs, in accordance with the NCD criteria.

LCA will advocate for patient rights, as low dose CT is a given screening benefit in place since 2015 by Medicare in ALL settings meeting the NCD criteria. We have also reached out to our friends in Congress to encourage CMS to do the right thing. Please contact Anita McGlothlin, Associate Director of Science and Regulatory Policy (amcglathlin@lungcanceralliance.org) with any questions.