



May 11, 2018

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Department of Health and Human Services
Center for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

RE: Coverage of low-dose Computed Tomography (LDCT) lung cancer screening in Independent Diagnostic Testing Facilities (IDTFs)

Dear Ms. Syrek Jensen:

The American College of Radiology (ACR) represents more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists. The ACR, in collaboration with the Radiology Business Management Association (RBMA), the Healthcare Business Management Association (HBMA) the Association for Quality Imaging (AQI), Medical Imaging and Technology Alliance (MITA), and Lung Cancer Alliance (LCA) continue to advocate for lung cancer screening coverage performed in all facilities, including Independent Diagnostic Testing Facilities (IDTFs).

We are in receipt of your February 8, 2018 letter that attempts to better clarify certain prohibitions on lung cancer screening performed in the IDTF setting. After reviewing this response, we believe that Medicare Administrative Contractors (MACs) are not correctly adhering to the lung cancer screening NCD 210.14. In accordance with the June 12, 2017 Medicare Learning Network Matters article (MM9246), CMS clarified that IDTFs are, in fact, eligible facilities capable of performing LDCT lung cancer screening. Nevertheless, MACs regularly exclude LDCT lung cancer screening coverage when performed in the IDTF setting, **including at sites that meet the NCD criteria.** We hope CMS can clarify these outstanding issues contributing to the MACs' decision to deny coverage of LDCT lung screening at IDTFs.

Outlined below are the areas of concern including specific questions that will help better elucidate CMS's position on this issue. In addition, we have included our understanding and rationale for IDTFs to perform LDCTs. Please confirm if you agree with this rationale and, if not, we respectfully request you more fully explain any subsequent disagreements.

1. Is it appropriate for MACs to broadly deny LDCT lung cancer screening G0297 performed in the IDTF setting?

MACs continue to misinterpret the IDTF regulations regarding diagnostic radiology exams by erroneously excluding screening exams. The term “diagnostic radiology” is intended to exclude “interventional radiology,” yet it encompasses both diagnostic and screening exams.

MACs continue to approve payment to IDTFs for 71250 (non-contrast chest CT), while denying LDCT lung cancer screen (G0297), despite being the same type of service (e.g., chest CT). The MACs state that IDTFs are for diagnostic testing, rather than screening, however, the undersigned coalition members continue to view this very narrow definition and erroneous view of diagnostic radiology as incorrect. Most curiously, MACs permit IDTFs to perform other screening services, such as mammography, by correctly defining them under the broader definition of diagnostic radiology.

Although it appears they have walked back this narrow view of diagnostic radiology, the MACs are now denying G0297 based on the erroneous premise that it is a “therapeutic intervention”. We strongly disagree with this premise and provide further rationale in the sections below. Because lung cancer screening is diagnostic radiology, we believe MACs should approve payment for G0297 claims from IDTFs that meet the NCD criteria.

2. Is it accurate for MACs to broadly deny eligible Medicare beneficiaries lung cancer screening based on the interpretation that G0297 is as an “intervention/therapeutic” service? Is it erroneous to base this denial on the premise that the imaging facility criteria bulleted in the lung cancer screening NCD (i.e., *makes available smoking cessation interventions for current smokers*) defines G0297 as an “intervention/therapeutic” service? What are the consequences to patient access, uptake in screening, IDTFs, hospitals, free-standing imaging centers, and beneficiaries associated with this flawed rationale for Medicare denials?

Diagnostic radiologists perform G0297 as an imaging *screening* exam. As a result, MACs should not consider, nor define G0297 as an intervention/therapeutic service. The lung cancer screening [NCD](#) states, “makes available smoking cessation interventions for current smokers,” and does not apply to those smokers that have quit within the last 15 years. In addition, the NCD does not define G0297 as an intervention/therapeutic service and only requires that smoking cessation interventions, such as educational materials, are available to the patient.

However, G0296 (shared decision-making visit) includes very specific counseling language (i.e., *Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment*) and is appropriately deemed an intervention. If the G0297 code truly requires the provision of smoking cessation

services in conjunction with the LDCT lung cancer screening study, the treating physician would logically need to be on site at the IDTF. That, of course, raises the issue of the IDTF's compliance with the program integrity rule against space sharing contained at 42 CFR 410.33(g)(15). Under this flawed definition of G0297, MACs are essentially encouraging non-compliance with this space sharing prohibition by requiring a treating physician be onsite to deliver an intervention/therapeutic service. In addition, G0297 was not valued to include counseling and therapy and would need additional reimbursement to reflect the cost of having an onsite treating physician.

By classifying G0297 as an intervention, hospitals and free-standing imaging centers would also arguably be unable to offer this screening service. Hospitals, free-standing imaging centers, radiology practices, and IDTFs make available smoking cessation interventions to those Medicare beneficiaries that are current smokers through education brochures and/or referrals to counseling/therapy. Our organizations follow this issue closely. We have seen no evidence that non-IDTFs perform smoking cessation counseling and therapy onsite at their imaging facilities in the manner MACs contend is required in IDTF settings. As a result, the shared decision-making counseling visit (G0296) performed by the treating physicians is the appropriate setting to provide smoking cessation materials.

The ramifications of defining G0297 as an intervention is eligible Medicare beneficiaries being required to pay out-of-pocket or going elsewhere for their screening service. This includes patients that do not need smoking cessation interventions, as they have stopped smoking within the past 15 years and remain eligible for screening. Characterizing the services described by G0297 as an intervention creates a major barrier to screening utilization rates. Correcting this error and requiring reimbursement of G0297 claims retroactive to February 2015 is essential.

3. Is it appropriate that MACs are requiring IDTFs to obtain reimbursement from a treating physician group for the technical service of lung cancer screening?

There remains a clear misunderstanding by MACs regarding IDTFs and lung cancer screening coverage. More specifically, MACs are requiring, effective Nov. 30, 2017 (Palmetto) and Jan. 1, 2018 (Noridian), IDTFs to sell the technical component of the LDCT lung cancer screening study to the treating physician and have the treating physician bill for the technical component. As discussed in the prior section above, our organizations believe the provision of the so-called therapeutic service at the IDTF site by this physician whose group is enrolled in the Medicare program is in conflict with the IDTF space sharing prohibition at 42 CFR 410.33(g) (15).

Further, physicians who order these tests and enter into such financial arrangements with IDTFs to bill for the service as required by the MACS also appear to be subject to the anti-markup rule payment limitations (AMPL) described at 42 CFR 414.50. Since the ordering/billing physician would not "share the practice" with the supplier of either of the technical component or professional component of the CT service, a significant financial disincentive exists for participation by the physician in such a financial arrangement with an IDTF caused by application of the AMPL.

We request that CMS work with the MACs to quickly remove this conflicting language and IDTF financial requirement and allow otherwise qualified IDTFs to perform and bill for the LDCT lung cancer screening service.

4. Unintended consequences to eligible Medicare beneficiaries with the continued denial of LDCT Lung Screening:

Hindering Beneficiaries' Access to Screening Services

Erroneous MAC denials that first began in February 2015 lead to Medicare patient access issues and decreased screening rates. MACs continued refusal to provide LDCT lung cancer screening within IDTFs limits eligible beneficiary access to necessary screening, including patients that have ceased tobacco use 15 years ago but still meet the NCD criteria for screening. If CMS seeks to improve access to screening services, beneficiaries should have access to these services at all qualified imaging centers, including IDTFs.

Increased Out-of-Pocket Costs to Beneficiaries

Beneficiaries who receive regular diagnostic chest CT exam services through IDTFs, even though they should otherwise be eligible for the LDCT lung cancer screening exam, will likely face higher out-of-pocket costs solely due to the site-of-service. Services traditionally provided at no cost to beneficiaries are subsequently now subject to out-of-pocket expenses.

Increased Financial Burden Placed on IDTFs

IDTFs serve a critical role in providing imaging services to Medicare beneficiaries. By denying payment, IDTFs that provide LDCT lung cancer screening to patients will now have to absorb these associated costs. This financial burden limits the ability of IDTFs to provide diagnostic services to beneficiaries, which, in turn, reduces access to life-saving screenings.

In conclusion, our organizations strongly urge CMS to publish a Change Request Transmittal notice instructing all MACs that:

- 1) LDCT lung cancer screening code G0297 is *not* an intervention/therapeutic service in the lung cancer screening NCD;
- 2) LDCTs are a nationally covered preventive screening service available to Medicare beneficiaries in ALL settings, including IDTFs; AND
- 3) 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.

Please make this screening benefit more readably available to the millions of Americans who would benefit from early detection of lung cancer. Thank you for the opportunity to comment on the LDCT lung cancer screening in the IDTF setting.

If you have any questions about our comments, please feel free to contact Katie Keysor at kkeysor@acr.org.

Respectfully Submitted,

The American College of Radiology (ACR)
Radiology Business Management Association (RBMA)
Association for Quality Imaging (AQI)
Medical Imaging and Technology Alliance (MITA)
Lung Cancer Alliance (LCA)

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