September 30, 2016

VIA ELECTRONIC MAIL: valerie.miller@cms.hhs.gov

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Dr. Steve Phurrough
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7500 Security Boulevard
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Re: September 12, 2016 Advisory Panel on Clinical Diagnostic Laboratory Tests - ADLT Application and Designation Recommendations

Dear Ms. Miller and Dr. Phurrough:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciated the opportunity to present our recommendations regarding the application and designation process for Advanced Diagnostic Laboratory Tests (ADLTs) to the Advisory Panel on Clinical Diagnostic Laboratory Tests at its September 12, 2016 meeting. As a follow up to the Advisory Panel meeting, we would like to provide supplemental responses to several of the questions raised by the Panel. As CMS prepares the sub-regulatory guidance for the ADLT application and designation process, we believe it is important to implement the ADLT payment category in a way that promotes continued competition and innovation in precision medicine.

1. Medicare Coverage Information in ADLT Application

The Panel recommended "**that the application [f]or ADLT status include an LCD or NCD as demonstration of part B coverage**." We are concerned that the Panel's recommendation would require a Medicare coverage determination be completed prior to the submission of an ADLT application. This appears contrary to the statute and Final Rule, and would significantly delay the application and designation process.

Section 1834A(d)(5) of the Act defines an ADLT as a "clinical diagnostic laboratory test covered under this part . . .." We believe that this language is best read to require that an ADLT be of ***a type of test*** eligible for coverage under Part B. It should not be read to require than the test has a specific Part B coverage policy at the time of ADLT application or designation. Congress meant to exclude from ADLT status certain categories of tests that are ineligible for payment under Part B, not otherwise eligible tests that are pursuing ADLT status and Medicare coverage simultaneously.

The Final Rule supports this reading. CMS states in the Final Rule that payment for a new ADLT at Actual List Charge (ALC) will only begin "when the test has been both covered under Medicare Part B and approved for ADLT status, ***regardless of the order in which the events take place***."[1] If the ADLT application requires the inclusion of an LCD or NCD, ADLT approval could ***never*** take place prior to a Part B coverage determination. Therefore, it is clear that an LCD or NCD is not a prerequisite to a test being designated an ADLT. This reading also makes practical sense as the LCD process can take 12 to 18 months to complete and requiring an LCD in the ADLT application would delay the application process.

Moreover, as we have discussed, payment as an ADLT at ALC requires the merger of three events: (1) coverage, (2) designation as an ADLT, and (3) assignment of a test-specific code. To require each step to be completed before the other can begin is burdensome for all parties—and unnecessary under the Final Rule.

We agree that an ADLT would not be eligible for payment at ALC until such time as coverage has been determined at the local or national level. Existence of Medicare coverage could be documented by any of the following sources: NCD, LCD, article or history of contractor paid claims.

2. Code Information in ADLT Application

C21 agrees with the Panel's recommendation that the application for ADLT status only need to "**include a unique HCPCS code or the application for a unique CPT code or the request for a unique G code**." The ADLT application and designation process will need to be sequenced with the application for a unique code. We have prepared the attached timeline that details the steps that will be involved with a new ADLT. Laboratories will need the unique code for collecting and reporting private payer data. Therefore, laboratories may need to apply for a HCPCS code and ADLT status simultaneously. We understand that the application process for the new Proprietary Laboratory Analyses Section of CPT will be on a quarterly schedule similar to the quarterly assignment of G codes by the agency. If CMS finalizes a quarterly ADLT application and designation process, it would align with the coding process to ensure that each new ADLT has time to receive a unique code.

Accordingly, we agree with the Panel recommendation that a laboratory need only disclose on the application whether it has a unique HCPCS code or is applying for one.

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[1] 81 Fed. Reg. 41067 (Jun. 23, 2016) (emphasis added).

3. Changes to ADLTs

There was extensive discussion at the Panel meeting regarding the impact of any changes to the biomarkers or algorithm in a test that has already been designated as an ADLT. The Panel recommended that the ADLT application include an attestation that the proponent laboratory "**agree[s] to report to us any changes in biomarkers or algorithms**."

We agree with the Panel that it should not be necessary for a laboratory to submit a new ADLT application whenever a change is made to a biomarker component or the algorithm of an ADLT. Because precision medicine is rapidly evolving, ADLTs are constantly going through validation and enhancements. We are concerned that laboratories will be discouraged from innovating and improving their ADLTs if small modifications trigger a requirement to submit the test for ADLT status again.

In general, we believe that once a test has received ADLT status, it should remain an ADLT as long as it continues to be offered and furnished by a single laboratory, or a laboratory requests that the ADLT status be withdrawn. Neither the statute nor the Final Rule indicates that there are any other circumstances in which ADLT status must be revoked. Nor is it CMS's interest that the status be withdrawn. Annual reporting, which is required for ADLTs, provides CMS with more robust private payer data than triennial reporting.

4. Test Performed Outside United States

The Panel also discussed recommending that the new clinical diagnostic information requirement only apply to "clinical diagnostic information . . . produced by any test or combination of tests **offered in the United States**." C21 believes that tests offered in the United States but performed outside the United States should not be considered when determining whether a test provides new clinical diagnostic information.

It is difficult to assess the reliability and accuracy of tests performed outside of the United States. Tests performed outside the United States are not lawfully offered in the United States unless the foreign laboratory is certified under CLIA. It is doubtful that many foreign laboratories have received CLIA certification.

Additionally, the ADLT application process should not compare applicants to information from tests that are prohibited from being paid by Medicare. Medicare cannot pay for tests performed outside the United States. Section 1862 of the Act prohibits payment by "**for any expenses incurred for items or services . . . which are not provided within the United States**."[2] The Medicare Benefit Policy Manual states that this rule applies "even though the beneficiary may

[2] Social Security Act § 1862(a)(4) codified at 42 U.S.C. §1395y(a)(4) (emphasis added).

have contracted to purchase the item while they were within the United States or purchased the item from an American firm."[3]

For these reasons, C21 respectfully requests that CMS clarify that only tests performed in the United States are considered when determining whether a prospective ADLT "provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests."

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Thank you for considering these comments. We look forward to working with the agency and the Advisory Panel to continue to provide input on the ADLT payment category in advance of implementation of these requirements.

Sincerely,

Coalition for 21st Century Medicine

[3] CMS Change Request 5427, Transmittal 66, "Services Not Provided Within the United States." (Feb. 23, 2007), codified at 16 Medicare Benefit Policy Manual § 60.