

**The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests Advanced
Diagnostic Laboratory Tests Subcommittee (ADLTSC) Meeting
July 19, 2016**

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests ADLTSC Mission Statement:

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests formed the Advanced Diagnostic Laboratory (ADLT) subcommittee (ADLTSC) to solicit input from panel members on the application process for an ADLT under the Clinical Laboratory Fee Schedule.

Frequency of Meetings: The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests ADLTSC will meet up to four times per year.

July 19, 2016 Meeting Notes and Recommendations:

- Subcommittee meeting minutes and recommendations are presented below:

ADLT Sub-committee objective: To provide suggestions in defining content and process for ADLT application

Based on the final rule, certain attestations are necessary:

1. The test is covered under Part B

- How is this determined? Some tests are not covered under Part B such as:
- Don't have benefit category
- Not found "reasonable and necessary"
- Don't apply to Medicare population

Recommendation: This is out of the subcommittee's area of expertise. Specific consideration needs to be given to the reality that coverage under Medicare Part B may not be in place at the time application for ADLT is made.

2. Offered and furnished only by a single lab

Recommendation: TIN is required in application. CLIA number is required for all sites performing the test. Attestation that to the lab's knowledge, the test is offered and furnished only by a single lab other than the original developing laboratory (or a successor owner).

3. Not sold for use

Recommendation:

1. Require attestation that lab has not sold the test to other labs.
2. Require attestation that lab has not licensed the test to other labs.

3. **Require attestation that lab will report if they sell the test to other labs.**
4. **Require attestation that lab will report if they license the test to other labs.**
5. **Require attestation that lab will report if the lab is sold/successor.**

4. Recommendation: Provide existing HCPCS Code and descriptor. Are you in process of applying for a HCPCS code?

If there is not code, nor application for code, CMS will initiate assignment of G code. CMS may provide recommendations for draft code descriptor (such as CPT MAAA code descriptor parameters).

Other Criteria:

- A. **Test is cleared or approved by the FDA**

Recommendation: If applicable, attest that test is cleared or approved by the FDA and provide documentation. If so, then the test meets criteria for ADLT.

- B. **Analysis of multiple biomarkers of DNA, RNA or proteins.**

- **Recommendation: Name the component biomarkers of the algorithm. Define that changes in the list of component biomarkers must be reported and may require new ADLT application.**
- The subcommittee discussed considering requesting documentation of aspects or components of the test or testing process that supports its definition as an ADLT. Supporting documentation may include components of SOP or relevant literature (consider limiting literature references to 3-5).

- C. **Combined with a unique algorithm**

Recommendation: Attestation that the test algorithm is unique.

- D. **To yield a single patient-specific result**

Recommendation: Provide summary, intended use and patient-specific result of test. A sample report is recommended.

- E. **Provides new information not available from other tests**

Recommendation: Attest that the ADLT provides new information not available from other tests. Provide information regarding other tests that may overlap with the intended use or attributes of this test. Provide information that is essential (similarities/differences) to determine that the proposed ADLT provides new information not available from other tests.

Other Discussion:

- Test meets other similar criteria established by the Secretaries

- The AMA PLAs have not yet applied, which may impact this process. Is the submitted request for ADLT also a request for G code at the same time? Answer: it was assumption that request for ADLT meant CMS would ensure that they have G Code at same time.

Parking Lot Issues:

- When does an ADLT no longer qualify as an ADLT and then what is the process for the designation to be changed?
- Examine statute to assess whether it should be interpreted that the statute requires that the test provide new information not available from any other “Medicare covered” test

Considerations Regarding Future Reporting Requirements:

- If the application is approved, what is the list price? Should this be required at the time of request for ADLT designation? If the list price changes, does this need to be reported?
- If the lab adds locations where the test is performed, should they be required to report it?
- Are we interested in knowing if there are any components of the test or algorithm that are performed in a non-CLIA facility or non-FDA approved SOP, or do we accept that the lab has accountability for the entire process?
- If there is a change in the component biomarkers or algorithm, this must be reported (within what period of time?) and ADLT designation may be reconsidered. Or, is there a requirement for re-attestation at the time of required reporting?
- Should CMS make public final determinations? Is there an appeal process? How frequently will CMS approve ADLTs?
- Has this test been paid for previously under the CLFS? If so, what was the date of first such payment?

Housekeeping Recommendations:

- Subcommittee members agree that the subcommittee should continue to exist.