



FOLEY
HOAG LLP

To Be or Not To Be: Advanced Diagnostic Laboratory Tests

Next Generation Dx Summit

Brian Carey

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- Key Requirements For ADLT Status
- Application and Designation Process
- Existing vs. New ADLTs
- Launch and Payment Considerations
- Potential Advantages and Disadvantages

Single laboratory	<ul style="list-style-type: none">• Includes all entities that own or are owned by the lab• Entity that owns multiple labs can perform test at all sites
Offered and furnished	<ul style="list-style-type: none">• Only one single lab can sell the test• Third party can provide marketing support such as developing and implementing a promotional strategy• In lab referral situation the lab that performs the test is the one that offers and furnishes

Developing laboratory	<ul style="list-style-type: none">• ADLT can only be sold for use by the lab that “expends its own resources on all aspects of the test’s development”• <u>Licensing IP</u> for a test may prevent ADLT status
Successor owner allowed	<ul style="list-style-type: none">• Developing lab can be sold to new owner• Entire lab organization must merge or be consolidated• Leasing not allowed

Multiple biomarkers with algorithm	<ul style="list-style-type: none">• DNA, RNA, and proteins included, <u>but</u> only “complex” protein-only tests expected to qualify• Algorithm must be “empirically derived”
New clinical diagnostic information	<ul style="list-style-type: none">• Subjective standard new in regulation• CMS indicates a test may lose ADLT status if new test provides same information

- Application process to be discussed at September meeting of CDLT Advisory Panel
 - Unclear what role the Advisory Panel will play
 - ADLT application release expected later in 2016
- Submission and review cycles for ADLT applications yet to be determined
 - Quarterly cycle recommended by stakeholders
 - Not clear whether labs can respond to an initial decision before CMS denies ADLT status
- Confidentiality concerns may discourage applications if labs must submit non-publicly available information

Existing ADLT	New ADLT
<ul style="list-style-type: none">• Statute defines as tests paid as of PAMA enactment in April, 2014• No ADLTs designated yet because lack of application process• Limited benefit because<ul style="list-style-type: none">– Subject to crosswalk/gapfill– Publication of rate and of unique code delayed	<ul style="list-style-type: none">• Only applies to tests first paid by Medicare after January 1, 2018• Do not go through annual crosswalk/gapfill• Paid at Actual List Charge for first three quarters• Payment starts first day of the quarter after latter of ADLT designation and coverage determination

- “Actual List Charge” locked in when test first marketed to the public
 - Even if not the test has not yet been performed
- Tight private payor data collection and reporting timeline
 - Lab must report private payor data by the end of six months
- Important to contract with commercial payors in parallel with ADLT designation
 - Otherwise, test could go through crosswalk/gapfill
- Recoupment risk
 - If ALC is more than 130% of weighted median of private payor rates, CMS will recoup the difference

To Be or Not to Be an ADLT?

Advantages	Disadvantages
<ul style="list-style-type: none">• New ADLTs avoid crosswalk/gapfill	<ul style="list-style-type: none">• Existing ADLT goes through crosswalk/gapfill
<ul style="list-style-type: none">• Payment at Actual List Charge for first three quarters	<ul style="list-style-type: none">• Evolving application requirements
<ul style="list-style-type: none">• Potential for unique code	<ul style="list-style-type: none">• Annual data collection and reporting
<ul style="list-style-type: none">• Private payor data not released to public	<ul style="list-style-type: none">• Payment rate fluctuates annually
<ul style="list-style-type: none">• Crosswalk/gapfill rate for Existing ADLTs only in place for a year	<ul style="list-style-type: none">• Potential loss of ADLT status

- Initially there may be only a few ADLTs designated
 - Stringent application requirements
 - Lack of incentive to be an Existing ADLT
- CMS should develop the ADLT category to encourage innovation and competition
 - Competition between similar but different tests will create savings for CMS
 - ADLTs more responsive to market pricing because payment rates set annually
- ADLT category will expand as more tests receive FDA clearance or approval

Brian Carey, Partner
Foley Hoag LLP
bcarey@foleyhoag.com
202.261.7398

