

## **Medicare Part B Clinical Laboratory Fee Schedule Guidance for Laboratories on Advanced Diagnostic Laboratory Tests**

### **Providers Affected**

This article provides guidance for Medicare Part B clinical laboratories that submit a request for Advanced Diagnostic Laboratory Test (ADLT) status for a test.

### **Provider Action Needed**

This guidance is intended to assist the laboratory community in meeting the new requirements under Section 1834A of the Social Security Act (the “Act”) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) regarding ADLTs.

Additional information about the new private payor rate-based CLFS is available through separate guidance in MLN Matters Article SE1619.

### **Background**

Under the CLFS in effect until December 31, 2017, each Medicare Administrative Contractor (MAC) paid for clinical diagnostic laboratory tests (CDLTs) based on the local geographic area, and fees were based on charges from laboratories in that geographic area. Payment was the lesser of: (1) the amount billed; (2) the local fee for a geographic area; or (3) a national limitation amount (NLA) for the Healthcare Common Procedure Coding System (HCPCS) code. CLFS amounts could be updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers and a multi-factor productivity adjustment, but were not otherwise updated or changed.

Each year, new laboratory test codes are added to the CLFS, and payment for those tests is based on one of two methodologies—crosswalking or gapfilling. Under crosswalking, an existing test or combination of tests with similar methodology and resources is used as a basis for the payment amount. Gapfilling is used when there is no other test with similar methodology and resources. In this case, MACs develop a payment amount for the test.

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule “[Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule](#)” (CMS-1621-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implements section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payor rate information (applicable information) for their component applicable laboratories. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to CMS during a data reporting period. Crosswalking or gapfilling methodologies will be used to establish payment amounts for new CDLTs and CLDTs for which CMS receives no applicable information.

Section 216(a) of PAMA also establishes a new subcategory of CDLTs known as ADLTs with separate reporting and payment requirements. New ADLTs will be paid at a rate equal to their actual list charge during a new ADLT initial period of three calendar quarters. To be an ADLT under CMS regulations, the test must be covered under Medicare Part B, offered and furnished only by a “single laboratory,” and not sold for use by any other laboratory except that “single laboratory” or a “successor owner.” In addition, the test must meet either *Criterion (A)* (analysis of multiple biomarkers of DNA, RNA, or proteins) or *Criterion (B)* (cleared or approved by the U.S. Food and Drug Administration (FDA)).

## **Summary of Information Contained in this Article**

This article on ADLTs provides information regarding the application laboratories must use to request ADLT status for a laboratory test, the definitions of key terms used in the application for requesting ADLT status, the process for requesting ADLT status for a laboratory test, and where to send completed applications and notifications. This article also provides guidance on the definition of an applicable laboratory, the definition of applicable information, and the reporting entity responsible for reporting applicable information regarding ADLTs to CMS. Additionally, this article explains the payment methodologies for new and existing ADLTs, the schedule for data collection and data reporting during the new ADLT initial period, and the schedule for data collection and data reporting for annual ADLT payment updates.

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## **Section I. ADLT Application and Related Guidance**

In order for a CDLT on the CLFS to be approved as an ADLT, an application to request ADLT status for the test must be submitted to CMS. As discussed later in this publication, each ADLT must be assigned a unique HCPCS code, meaning one that describes only a single test. If the test is not currently assigned a unique HCPCS code, applicants are required to inform CMS if a completed application for a unique level I HCPCS code for the test has been submitted to the American Medical Association (AMA) or if the applicant is in the process of submitting an application to the AMA. If the applicant has not submitted a level I HCPCS code application for the test to the AMA, or is not in the process of preparing an application, the applicant must submit a request for CMS to assign a unique level II HCPCS code for the test.

The CMS application for requesting ADLT status for a laboratory test is available on the CMS website at: <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/adlt-information>.

Applications for a unique level II HCPCS code must be submitted in the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™). Go to <https://mearis.cms.gov> to register/log in, and submit your application.

### **1. Key Terms Used in the Application for ADLT Status Under the CLFS**

**Actual list charge:** The publicly available rate on the first day a new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

**ADLT:** An ADLT is a CLDT covered under Medicare Part B that is offered and furnished only by a single laboratory. Additionally, an ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. And, it must meet one of the following criteria:

*Criterion (A):* The test:

- (i) Is an analysis of multiple biomarkers of DNA, RNA, or proteins;
- (ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies;
- (iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- (iv) May include other assays.

OR:

*Criterion (B):* The test is cleared or approved by the FDA.

Laboratories requesting ADLT status under *Criterion (B)* are required to submit documentation of premarket approval or premarket notification from the FDA.

***Applicant:*** The single laboratory requesting ADLT status for a laboratory test under the CLFS.

***Authorized official:*** An authorized official is an appointed official of the single laboratory (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to make changes or updates to the organization's status in the Medicare program, and commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

***Contact person:*** The contact person is an individual who can be reached to answer questions regarding the information furnished in the ADLT application.

***Publicly available rate:*** The lowest amount charged for the ADLT that is readily accessible in such forums as a company website, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

***Single laboratory:*** For purposes of an ADLT, a single laboratory means a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (that is, 42 C.F.R. § 493.2) that furnishes the test, and that may also design, offer, or sell the test.

A single laboratory also includes an entity that owns the laboratory, which may design, offer or sell the test, and an entity that is owned by the laboratory, which may design, offer or sell the test. Therefore, a single laboratory can be an organization. For example, under the definition of single laboratory, a corporate entity that owns multiple laboratories could furnish an ADLT at each laboratory site. Moreover, other parts of the single laboratory can be involved with aspects of the ADLT, such as research and development. However, only the laboratory components of the single laboratory may perform the test.

Additionally, the single laboratory that designed the test or successor owner (as described below) that meets the definition of a single laboratory can continue to be a single laboratory even if it purchases additional laboratories. For example, a single laboratory may choose to expand its organization by acquiring new laboratory sites to meet increased demand for laboratory testing. As long as the new laboratory sites are under common ownership by the single laboratory that designed the test (or a successor owner), the organization would continue to be a single laboratory for purposes of the ADLT requirements.

***Successor owner:*** A successor owner for purposes of an ADLT means a single laboratory, which has assumed ownership of the laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

- *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.
- *Unincorporated sole proprietorship.* Transfer of title and property to another party.

*Corporation.* The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. However, transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

**Note:** Successor ownership is not limited to just the successor of the single laboratory that developed the test. That is, there can be successor owners to successor owners.

## **2. Summary of Application for ADLT Status Under the Medicare CLFS**

Applicants requesting ADLT status for a laboratory test will need to provide general information about the single laboratory, such as the name and address of all laboratory components of the single laboratory that will furnish the test. If applicable, applicants must provide the name and address of any entity that owns the laboratory or is owned by the laboratory, which may design, offer, or sell the test and a description of the role(s) these entities have within the single laboratory with respect to the potential ADLT. Applicants must also note whether the single laboratory applying for ADLT status is a successor owner to the single laboratory that designed the test. Additionally, applicants must provide all Tax Identification Numbers (TINs) of the single laboratory, and all National Provider Numbers (NPIs) and CMS Certification Numbers (CCNs) included in the single laboratory.

### ***Evidence of Medicare Part B Coverage***

In order for a test to be an ADLT, the test must be covered under Medicare Part B. Applicants requesting ADLT status for a laboratory test must provide evidence of Medicare Part B coverage for the test. Evidence of Medicare Part B coverage must include the date the test was first covered and at least one of the following items:

- Payment for the test by a MAC based on a reasonable and necessary determination for the test (for example, a copy of the remittance notice from the MAC);
- Coverage determination under the Molecular Diagnostic Services (MolDX) program;
- A local coverage determination (LCD) for the test;
- A national coverage determination (NCD) for the test;
- Other documentation that demonstrates Medicare Part B coverage.

NOTE: Although evidence of Medicare Part B coverage is required for a test to receive ADLT status, approval of new ADLT status is not an indication of future coverage status. A Medicare coverage determination for a given Clinical Diagnostic Laboratory Test is a separate, independent process from the determination of ADLT status.

### ***Existing Coding and Payment Information for the Test***

Applicants requesting ADLT status for a laboratory test must provide current coding and payment information for the test. If applicable, applicants must provide the existing HCPCS code or any other identifier used to bill for the test, such as a Not Otherwise Classified (NOC) code, an unlisted CPT code or a MolDX Z-Code Identifier and the descriptors used to describe the test. In the event that multiple payors are currently paying for the test, applicants must include all

existing codes used for billing the test and corresponding code descriptors. Additionally, if there is no payment amount for the test code on the current CLFS, but the test has been paid by Medicare, for example, under the MoIDX program, applicants must provide the MAC's local payment amount for the test and date of that payment determination.

Each ADLT must have a "unique" HCPCS code, meaning a code that describes only that test. Some HCPCS codes are used to describe more than one laboratory test. If the laboratory test that is the subject of the ADLT application is not currently assigned a unique HCPCS code (that is, describing only a single test), the applicant must indicate whether it has submitted an application for a unique level I HCPCS code to the AMA or the applicant is in the process of submitting an application to the AMA. If not, the applicant must submit a request for CMS to assign a unique level II HCPCS code for the test along with the application for requesting ADLT status. In such case, CMS will assign a unique level II HCPCS code if the test is approved for ADLT status.

If the applicant requesting ADLT status for a test is in the process of submitting an application for a level I HCPCS code to the AMA, the applicant must notify CMS after a completed application has been submitted to the AMA. In notifying CMS, the applicant must provide the date a completed application for a unique level I HCPCS code for the test was submitted to the AMA. Once CMS is informed that a completed level I HCPCS code application has been submitted to the AMA, CMS will contact the AMA to ensure that a unique laboratory test code, which describes only a single test, is assigned to the test approved for ADLT status by CMS.

### ***Actual List Charge***

Applicants will need to indicate whether the laboratory test is a new ADLT, meaning an ADLT for which payment has not been made under the CLFS prior to January 1, 2018. As noted previously, new ADLTs will be paid at a rate equal to their actual list charge during a new ADLT initial period of three calendar quarters. If payment for the test has not been made under the CLFS prior to January 1, 2018, applicants must specify:

- The first date on which the test is obtainable by a patient, or marketed to the public.
- All amounts charged on the first date on which the test is obtainable by a patient covered by private insurance, or marketed to the public as a test a patient can receive.
- The actual list charge for the test based on the publicly available rate, as those terms are defined in 42 C.F.R. § 414.502.
- If available, the publicly available source(s) that report the actual list charge and all other amounts charged (if applicable) on the first date on which the test is obtainable by a patient, or marketed to the public.

### ***Information Required for ADLT Status under Criterion A***

Applicants requesting ADLT status for a test under *Criterion (A)* are required to submit a description of the test and the purpose of the proposed ADLT including a summary of the intended clinical use and patient specific result of the test. Applicants are also required to explain how the proposed ADLT provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

The specific information required from applicants requesting ADLT status under *Criterion (A)* is discussed below.

- Description of the proposed ADLT. Applicants are required to provide a general description of the test and identify the deoxyribonucleic acid (DNA), ribonucleic acid (RNA) or protein biomarkers analyzed by the test. Applicants must also provide a specific description of the test's unique (meaning, empirically derived) algorithm.
- Purpose of the proposed ADLT. A summary of the intended clinical use and patient-specific result of the test must be included. The summary must show that the analysis of the biomarkers is combined with a unique (empirically derived) algorithm to yield a result that predicts the probability of an individual developing a certain condition or the probability of an individual's response to a particular therapy. Furthermore, the summary must explain how the test provides new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests (for example, through a synthesis of the component molecular pathology assays included in the laboratory test in question).
- List of potential comparative tests. Applicants must include information regarding other tests that may overlap with the intended clinical use or attributes of this test. That is, a listing of any other laboratory tests (if known) that may analyze similar (or identical) DNA, RNA, or protein biomarkers and/or have a similar intended use.
- Comparisons between proposed ADLT and other similar tests. Applicants must provide information on similarities and differences between the proposed ADLT and the list of comparative tests, which establishes that the proposed ADLT provides new clinical diagnostic information not available from any other test or combination of tests. For instance, information that shows specific comparisons between the clinical diagnostic information provided by the proposed ADLT versus the clinical diagnostic information provided by all other similar tests that are currently available for purchase. The comparison must show that the proposed ADLT provides new clinical diagnostic information not available from any other test or combination of tests on the market.

### ***Information Required for ADLT Status under Criterion B***

Applicants requesting ADLT status under *Criterion (B)* are required to submit documentation that the laboratory test has been cleared or approved by the FDA. This documentation must include the FDA premarket approval or notification number, the date of FDA clearance or approval, and the name and branch of the FDA reviewer.

### ***Notification of Any Changes to the Application for ADLT Status***

The authorized official for the single laboratory must agree to notify CMS of any changes to the submitted application within 30 days of the change. For example, the authorized official must report to CMS if the test is sold or licensed to another laboratory, if the applicant single laboratory is sold to a successor owner (as defined in 42 C.F.R. § 414.502), or if there are changes to the applicant single laboratory information. If requesting ADLT status under *Criterion (A)*, the authorized official must agree to notify CMS if there are any changes to the

biomarkers or algorithms of the test within 30 days of the change.

### ***Note Regarding Proprietary or Confidential Information***

Applicants are not required to submit proprietary or confidential information as part of the ADLT application. However, an applicant may choose to include such information to support its request for ADLT status. Applicants should note that information they include in an ADLT application is not explicitly protected from disclosure under the confidentiality provisions in section 1834A(a)(10) of the Act, nor is it explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request. However, FOIA does include an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. Although applicants may mark information in the application as confidential and proprietary, the information may be subject to disclosure under FOIA unless, consistent with FOIA exemption (b)(4), the information relates to trade secrets and commercial or financial information that is exempt from disclosure. Applicants that mark information as confidential and proprietary must substantiate the confidentiality of this information by expressly claiming substantial competitive harm if the information is disclosed, and demonstrate in a separate statement how the release would cause substantial competitive harm pursuant to the process in Executive Order 12600 for evaluation by CMS. CMS cannot guarantee this information will not be subject to release under FOIA.

### **3. Process for Requesting ADLT Status for a Laboratory Test**

ADLT status determinations and HCPCS code assignments (if necessary) for laboratory tests will be conducted on a quarterly basis. CMS will accept applications for ADLT status under the Medicare CLFS at any time during the year. However, applications must be received during the first month of a calendar quarter for consideration during that quarter as indicated below.

For consideration during:

- Calendar Quarter 1 (January 1 through March 31): Application for requesting ADLT status for a laboratory test must be received by CMS January 1 through January 31;
- Calendar Quarter 2 (April 1 through June 30): Application for requesting ADLT status for a laboratory test must be received by CMS April 1 through April 30;
- Calendar Quarter 3 (July 1 through September 30): Application for requesting ADLT status for a laboratory test must be received by CMS July 1 through July 31;
- Calendar Quarter 4 (October 1 through December 31): Application for requesting ADLT status for a laboratory test must be received by CMS October 1 through October 31.

Applications for ADLT status received during the first month of a calendar quarter will be reviewed by CMS and the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the advisory panel) during the second month of that calendar quarter. The advisory panel will



review each application and make recommendations to CMS. CMS will review the application and the advisory panel's recommendations and make a determination on each application, as described below under "Possible Outcomes of CMS' Review of ADLT Status Request" by the end of the second month of that calendar quarter. During the third month of that calendar quarter, CMS will notify the applicant via email of the outcome of its review. If the test is approved for ADLT status and is not currently assigned a unique HCPCS code, and is not the subject of a planned or pending AMA application for a level I HCPCS code, CMS will assign a unique level II HCPCS code to the test.

As noted above, applications must be received by CMS during the first month of a calendar quarter to be considered during that quarter. Applications received during the second month or third month of a calendar quarter will be reviewed during the next calendar quarter. For example, if an application requesting ADLT status for a laboratory test is received by CMS on February 20 (second month of the first calendar quarter), the application would be reviewed by the advisory panel and CMS in May (second month of the second calendar quarter) and CMS would notify the contact person for the single laboratory via email of the outcome of its review in June (that is, the third month of the second calendar quarter).

### ***Possible Outcomes of CMS' Review of an ADLT Status Request***

CMS' review of an application for ADLT status for a laboratory test may result in the following outcomes:

- Approving the laboratory test for ADLT status.
- Creating a new HCPCS code to describe the ADLT (if no unique HCPCS code exists or is being requested through the AMA).
- Requesting additional information from the applicant. If any required information is missing or incomplete or if CMS has questions regarding a response to a specific item in the application, CMS will notify the contact person for the single laboratory via email. Examples of why additional information may be requested from the applicant include (but are not limited to): (1) The applicant did not include documentation of a Medicare Part B coverage determination for the test; (2) CMS has questions regarding the specific information required from an applicant requesting ADLT status under *Criterion (A)*; (3) The applicant did not include the name and branch of the FDA reviewer, which is a requirement for requesting ADLT status under *Criterion (B)*; and/or (4) The actual list charge for the test was not provided, which is required information for a potential new ADLT.
- Denying the request for ADLT status. If the request for ADLT status is denied, CMS will inform the contact person for the single laboratory via email of the reason(s) for the denial.

**Note:** Section 1834A(d)(5) of the Act requires a CDLT to be covered under Medicare Part B in order for the test to meet the definition of an ADLT. Therefore, evidence of Medicare Part B

coverage is necessary before a determination of ADLT status can be made for the test, and the applicant is responsible for submitting documentation of a coverage determination and the date the test was first covered when requesting ADLT status for a laboratory test. CMS will not approve ADLT status for a test without evidence of Medicare Part B coverage.

This table shows the quarterly ADLT application submission, review and approval schedule.

#### **ADLT Request and Review Schedule**

| <b>Calendar Quarter</b>    | <b>Request Period for ADLT Status</b> | <b>Review by the Advisory Panel and CMS</b> | <b>Notify Contact Person of Outcome of CMS Review</b> | <b>New ADLT Initial Period (If Approved for ADLT Status by end of Quarter)</b> |
|----------------------------|---------------------------------------|---|---|--|
| 1. January 1 - March 31    | 1/1 - 1/31                            | 2/1 - 2/28                                  | 3/1 - 3/31  | 4/1 - 12/31  |
| 2. April 1 - June 30       | 4/1 - 4/30                            | 5/1 - 5/30                                  | 6/1 - 6/30  | 7/1 - 3/31   |
| 3. July 1 - September 30   | 7/1 - 7/31                            | 8/1 - 8/31                                  | 9/1 - 9/30  | 10/1 - 6/30  |
| 4. October 1 - December 31 | 10/1 - 10/31                          | 11/1 - 11/30                                | 12/1 - 12/31  | 1/1 - 9/30   |

If an ADLT status determination has not been made by the end of the requesting quarter, for example because of the need to review additional information from the applicant, the new ADLT initial period would begin on the first day of the first full calendar quarter following approval of ADLT status for the test. For instance, if an applicant requested ADLT status for a test in January and CMS requested additional information from the applicant in March, and because of the need to review additional information the test was not approved for ADLT status until mid-April, the new ADLT initial period would begin July 1. The contact person for the applicant would be notified via email of the tests ADLT status designation at the completion of CMS' review.

#### ***Schedule for Assigning a Unique Level II HCPCS Code***

As noted previously in this section, once the test is approved for ADLT status, CMS will assign a unique level II HCPCS code to the test if the test is not currently assigned a unique HCPCS code, and an application has not been submitted for a unique level I HCPCS code to the AMA or the applicant is not in the process of submitting an application to the AMA. Generally, there will be a "lag-time" of one calendar quarter between the calendar quarter in which CMS approves ADLT status for a test and the effective date of the unique level II HCPCS code. For example, if CMS grants ADLT status for a laboratory test during the first calendar quarter of a given calendar year, CMS will assign a unique level II HCPCS code for the test by the end of the first calendar quarter, that is, by March 31. The unique level II HCPCS code will be effective and

available for use by the single laboratory on the first day of the third calendar quarter, that is, by July 1 of that year.

This table shows the schedule for the assignment and effective date of a unique level II HCPCS code for a test approved as an ADLT for each calendar quarter scenario.

**Level II HCPCS Coding Assignment/Effective Date Schedule for ADLTs**

| <b>Calendar Quarter Test is Approved As ADLT</b> | <b>ADLT is Assigned Unique Level II HCPCS Code</b> | <b>Change Request Announcing Unique Level II HCPCS Code is Published</b> | <b>Effective Date of Unique Level II HCPCS Code</b> |
|--|--|--|---|
| Q1. January 1 - March 31                         | 3/1 - 3/31   | 4/1 - 4/30   | 7/1   |
| Q2. April 1 - June 30                            | 6/1 - 6/30   | 7/1 - 7/31   | 10/1  |
| Q3. July 1 - September 30                        | 9/1 - 9/30   | 10/1 - 10/31   | 1/1   |
| Q4. October 1 - December 31                      | 12/1 - 12/31                                       | 1/1 - 1/31   | 4/1   |

**4. Where to Send ADLT Applications and Notifications**

Completed applications for requesting ADLT status for a laboratory test and notifications of any changes to the completed application for requesting ADLT status may be sent to the following addresses:

Electronic: [CLFSFormSubmission@cms.hhs.gov](mailto:CLFSFormSubmission@cms.hhs.gov)

## **Section II. Requirements for Reporting Applicable Information for ADLTs**

### **5. Applicable Laboratory for Purposes of Reporting Applicable Information for an ADLT**

CMS regulations require a reporting entity to report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period. For ADLTs that are not new ADLTs, this must happen every year beginning January 1, 2017; for new ADLTs, this must happen initially no later than the last day of the second quarter of the new ADLT initial period, and thereafter, every year.

Under the final policies for the new Medicare CLFS, an applicable laboratory is a laboratory (as defined under the CLIA regulatory definition of a laboratory in 42 C.F.R. § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, the laboratory must meet a “majority of Medicare revenues” threshold, that is, in a data collection period it receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or the Physician Fee Schedule (PFS). It also must meet a low expenditure threshold, that is, it receives at least \$12,500 of its Medicare revenues from the CLFS.

**However, a single laboratory that offers and furnishes an ADLT is not subject to the low expenditure threshold with respect to the ADLTs it offers and furnishes.** A single laboratory, as noted previously, is a laboratory (as defined under 42 C.F.R. § 493.2) that furnishes an ADLT and that may also design, offer, or sell the ADLT. A single laboratory includes an entity that owns the laboratory, which may design, offer or sell the test, and an entity that is owned by the laboratory, which may design, offer or sell the test. Therefore, a single laboratory can be an organization. A single laboratory that offers and furnishes an ADLT is subject to the low expenditure threshold with respect to all other CDLTs it furnishes that are not ADLTs.

Thus, for purposes of the applicable laboratory definition, a single laboratory must meet the majority of Medicare revenues threshold, but not the low expenditure threshold, in order to be an applicable laboratory for purposes of reporting applicable information for the ADLTs it offers and furnishes.

To determine whether a single laboratory is an applicable laboratory for purposes of reporting applicable information for an ADLT, the majority of Medicare revenues threshold must be assessed for each laboratory as defined in 42 C.F.R. § 493.2, under its own billing NPI within a single laboratory organization. (Note: More information regarding applicable information for ADLTs is provided in Section II. of this publication.)

The following are examples of how the majority of Medicare revenues threshold is applied to a laboratory’s own billing NPI for purposes of determining whether the laboratory is an applicable laboratory with respect to its ADLT(s):

**Example 1:** A single laboratory offering and furnishing an ADLT includes five laboratories as defined under 42 C.F.R. § 493.2. Each laboratory component has been assigned the same NPI and bills under the same NPI for each of its laboratory services. In this example, the majority of

Medicare revenues threshold is applied based on the combined Medicare revenues of all five laboratory components in the single laboratory that use the same billing NPI.

**Example 2:** A single laboratory offering and furnishing an ADLT includes three laboratories as defined under 42 C.F.R. § 493.2. Each laboratory component has its own unique NPI and bills the Medicare program (and other payors) for laboratory tests separately under each NPI. In this example, the majority of Medicare revenues threshold is applied to each NPI in the single laboratory organization. That is, for purposes of the ADLTs it furnishes, the single laboratory must determine whether each laboratory component within the single laboratory organization meets the majority of revenues threshold. Even though all three laboratories may be under the same Tax Identification Number (TIN), each laboratory is considered a separate laboratory for purposes of the applicable laboratory definition because each bills Medicare Part B for laboratory tests using its own unique NPI.

**Example 3:** A single laboratory that offers and furnishes an ADLT includes five laboratories as defined under 42 C.F.R. § 493.2. Each laboratory component has its own unique NPI. However, only one laboratory's NPI is used for billing by all five laboratories in the single laboratory organization. In this example, the majority of Medicare revenues threshold is applied to the one NPI used for billing by all five laboratories included in the single laboratory organization. In other words, the majority of Medicare revenues threshold must be applied to the combined Medicare revenues of all five laboratory components in the single laboratory that use the same billing NPI.

**Example 4:** A single laboratory that offers and furnishes an ADLT includes five laboratories as defined under 42 C.F.R. § 493.2. One laboratory has been assigned a billing NPI and the other four laboratories have not been assigned an NPI. In other words, only one out of the five laboratories has its own NPI and its NPI is used for billing by all five laboratories in the single laboratory organization. In this example, the majority of Medicare revenues threshold is applied to the one NPI used for billing by all five laboratories included in the single laboratory organization. As in the previous example, the majority of Medicare revenues threshold must be applied to the combined Medicare revenues of all five laboratory components in the single laboratory that use the same billing NPI.

**Example 5:** A single laboratory that offers and furnishes an ADLT has five physician offices and one laboratory as defined under 42 C.F.R. § 493.2. All five physician offices and the laboratory are assigned the same NPI and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold is applied based on the combined revenues of the five physician offices and one laboratory that bill for services under the same NPI.

**Example 6:** A single laboratory that offers and furnishes an ADLT consists of five physician offices and one laboratory as defined under 42 C.F.R. § 493.2. All five physician offices and the laboratory have their own unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, the majority of Medicare revenues threshold is applied to the laboratory's own billing NPI.

**Example 7:** A single laboratory that offers and furnishes an ADLT consists of a hospital and one laboratory as defined under 42 C.F.R. § 493.2. The hospital and the laboratory have their own

unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, the majority of Medicare revenues threshold is applied to the laboratory's own billing NPI.

**Example 8:** A single laboratory that offers and furnishes an ADLT consists of a hospital and one laboratory as defined under 42 C.F.R. § 493.2. The hospital and the laboratory bill for services under the same NPI. The laboratory bills for laboratory tests under the hospital's NPI. In this example, the majority of Medicare revenues threshold is applied to the NPI of the entire hospital. In this example, it is unlikely that the single laboratory will meet the majority of Medicare revenues threshold because the majority of Medicare revenues billed under the hospital's NPI are likely to be from the Hospital Inpatient Prospective Payment System and/or the Hospital Outpatient Prospective Payment System, not from the CLFS and/or the PFS.

As noted previously, the low expenditure threshold still applies when determining whether a single laboratory is an applicable laboratory for all other CDLTs (that are not ADLTs) the laboratory may furnish. In other words, in order for the single laboratory to be an applicable laboratory with respect to all other CDLTs it furnishes (that are not ADLTs), it must meet both the majority of Medicare revenues threshold and the low expenditure threshold when billing under its own NPI.

Below you will find examples of a single laboratory that would be an applicable laboratory for purposes of the ADLT that it offers and furnishes, but would not be an applicable laboratory for purposes of all other CDLTs (that are not an ADLT) it furnishes:

**Example 1:** A single laboratory offering and furnishing one ADLT and several other CDLTs includes three laboratories as defined under 42 C.F.R. § 493.2. Each laboratory has its own unique NPI and bills the Medicare program for laboratory tests separately under its own NPI. Two of the laboratories meet both the majority of Medicare revenues threshold and low expenditure threshold under their own NPIs, while one laboratory only meets the majority of Medicare revenues threshold under its NPI and not the low expenditure threshold. In this example, all three laboratories in the single laboratory would be an applicable laboratory for purposes of reporting applicable information for the ADLT furnished by the single laboratory. However, only two of the laboratories would be an applicable laboratory for purposes of the CDLTs (that are not ADLTs), and the third laboratory is not because it fails to meet the low expenditure threshold.

**Example 2:** A single laboratory offering and furnishing one ADLT and several other CDLTs includes three laboratories as defined under 42 C.F.R. § 493.2. Each laboratory has the same NPI and bills under that same NPI. The combined revenues of all three laboratories in the single laboratory meet the majority of Medicare revenues threshold but do not meet the low expenditure threshold. In this example, the three laboratories would be an applicable laboratory for purposes of reporting applicable information for the ADLT furnished by the single laboratory, but not for all other CDLTs (that are not ADLTs) because the low expenditure threshold was not met.

## 6. Applicable Information for ADLTs

As noted previously, reporting entities (described below) are responsible for reporting certain applicable information for each CDLT, including ADLTs, furnished by their component applicable laboratories during the corresponding data collection period. Applicable information

is the same for ADLTs as it is for all other CDLTs that are not ADLTs.

Applicable information includes three major components for each test:

- (1) The specific HCPCS code associated with the test. That is, a HCPCS code that does not include an unlisted CPT code, as established by the AMA, or a NOC code, as established by the CMS HCPCS Workgroup.
- (2) Each private payor rate for which **final** payment has been made during the data collection period.
- (3) The associated volume of tests performed corresponding to each private payor rate.

#### *Private Payor Defined*

The term “private payor” is defined as:

- (1) A health insurance issuer (as defined in Section 2791(b)(2) of the Public Health Service Act)
- (2) A group health plan (as defined in Section 2791(a)(1) of the Public Health Service Act)
- (3) A Medicare Advantage Plan under Medicare Part C (as defined in Section 1859(b)(1) of the Act)
- (4) A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m)(1)(A) of the Act)

**Note:** Applicable information does **not** include information on tests for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts (see below for additional information on capitated payments). Therefore, private payor rates from Medicaid MCO plans are considered applicable information only to the extent that the specific HCPCS code for the test, private payor rates specific to the test, and the volume of tests paid at each specific rate for the test can be identified.

The following information is **included** as applicable information for ADLTs:

- **The ADLT(s) offered and furnished by a single laboratory.** Applicable information includes the specific HCPCS code for the ADLT, each private payor rate for which payment has been made during the data collection period, and the volume of tests performed corresponding with each private payor rate.
- **Final amount paid by a private payor for the ADLT after all private payor price concessions are applied.** Applicable laboratories should look to their paid claims data from the billing NPI for which final payment was made during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection change that initial payment amount, the final payment amount is the private payor rate for purposes of determining applicable information. For example,

if an initial claim was paid in error 3 months before a data collection period and then corrected, with final payment made by the private payor during the data collection period, the final corrected payment amount for the test is considered the private payor rate for purposes of determining the applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final payment made after the data collection period, the payment amount is not a private payor rate for purposes of determining the applicable information and, therefore, is not reported to CMS.

- **Payments from secondary insurance payors.** Final payments from secondary insurance payors are considered in determining the private payor rates if the final payment was made during the data collection period. The private payor rate is 100 percent of the primary private payors' fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities required by the primary private payor (such as patient deductible and coinsurance amounts) and any payments received from a secondary insurer (if applicable). The important concept here is the reporting entity reports 100 percent of the primary private payors' fee schedule amount for the laboratory test. Reporting entities should not report payments received from secondary insurers separately.
- **Any patient cost sharing amounts, if applicable.** For purposes of applicable information, the private payor rate for an ADLT must include any patient cost sharing amounts required by the private payor (for example, patient deductible and/or coinsurance amounts). In other words, as noted above the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- **Multiple private payor rates for the same ADLT.** If an applicable laboratory is paid more than one private payor rate by the same private payor for the same test or more than one private payor rate from different private payors for the same test, each private payor rate along with the associated volume for the test code at each such rate must be included as applicable information. In this case, the reporting entity must report each private payor rate and the associated volume for the ADLT at each such rate.
- **Appeals resolved during the data collection period.** Private payor rates (and the associated volume of tests) for laboratory test claims under appeal are included as applicable information if the final payment amount is determined and paid by the private payor during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period and the appeal was resolved so that final payment for the test was made during the data collection period, the final rate paid is used to determine the private payor rate that is included in the applicable information.
- **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories as long as the final payment for the laboratory test was made by the private payor during the data collection period. Non-contracted amounts paid to laboratories include any patient cost sharing amounts (for example, deductible and coinsurance responsibilities, if applicable).



The following information is **excluded** from applicable information for ADLTs:

- **Price concessions applied by a laboratory.** A laboratory’s decision to waive a patient’s deductible, copay, and/or coinsurance responsibility for an ADLT must not be factored into the determination of the private payor rate for a test. Such concessions do not reflect the rates paid by private payors. As noted above, the private payor rate is 100 percent of the private payor’s fee schedule amount for the test.
- **Information about denied payments.** When a private payor denies payment for an ADLT, making the payment amount \$0.00 or “zero dollars,” this is not considered a private payor rate for purposes of determining applicable information under the new CLFS. Laboratories should **not** report “zero dollars” for a laboratory test code where a private payor has denied payment within a data collection period.
- **Unresolved appeals.** Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid is not considered a private payor rate for which final payment has been made, and therefore is not considered applicable information. Additionally, if the appeal was settled during the data collection period but final payment was not made by the private payor until after the data collection period, the payment amount cannot be used for a private payor rate and therefore is excluded from applicable information.
- **Payments made on a capitated basis.** Generally, a capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period of time, regardless of whether the particular beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, applicable information does not include information about a test for which payment is made on a capitated basis.
- **Payments where the associated test volume cannot be determined.** As discussed above, applicable information includes the associated volume of tests performed corresponding to each private payor rate. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor’s remittance, those payment amounts are not considered applicable information and should not be reported to CMS.
- **Remittances where the payor has grouped individual HCPCS code-level payments into an encounter or claim-level payment.** When a private payor groups payments for individual HCPCS codes into a single encounter or claim-level payment, those payments are not considered applicable information. In other words, if individual HCPCS codes are billed by the laboratory and the payor bundles the individual HCPCS codes into groups not represented by the billed HCPCS codes, the payor’s bundled payment amount is not considered applicable information. In general, if an applicable laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a

specific HCPCS code, that amount is not a private payor rate for purposes of applicable information. Estimated private payor rates and volumes are also not considered applicable information.

## 7. Reporting Entity for Purposes of Reporting Applicable Information Regarding ADLTs

The entity that reports applicable information to CMS is not necessarily an applicable laboratory. Reporting entities—which are TIN-level entities—must report applicable information for each CDLT furnished by their component applicable laboratories during the corresponding data collection period, according to the data reporting schedules. As with all other CDLTs (that are not ADLTs), the TIN-level reporting entity of the single laboratory must report applicable information regarding the ADLT(s) that it furnishes during the data collection period. However, given that a single laboratory includes all of the laboratories under common ownership that furnish the ADLT, the single laboratory’s reporting entity must report collectively for all NPI-level components that are applicable laboratories. The reporting entity should **not** report applicable information for an ADLT by each individual NPI-level entity that meets the definition of an applicable laboratory (as is the case for all other CDLTs that are not ADLTs). The reporting entity must report applicable information for an ADLT collectively, for the entire single laboratory, as discussed below.

### *Collective Reporting*

For purposes of reporting applicable information for its ADLTs, the reporting entity must report **collectively** for all its NPI-level components that are applicable laboratories within the single laboratory. In other words, for each ADLT furnished by the single laboratory during the data collection period, the reporting entity must report the specific HCPCS code associated with the test, each private payor rate for which final payment has been made during the data collection period, and the associated volume of tests performed corresponding to each private payor rate across all NPI-level entities that are applicable laboratories. The following is an example of collective reporting for “single laboratory XYZ,” which consists of three applicable laboratories furnishing one ADLT paid at three different private payor rates:

#### **Applicable Laboratory A**

| <b>Private Payor Rates</b> | <b>Associated Volume</b> |
|----------------------------|--------------------------|
| Private Payor Rate 1       | 150                      |
| Private Payor Rate 2       | 100                      |
| Private Payor Rate 3       | 75                       |

#### **Applicable Laboratory B**

| <b>Private Payor Rates</b> | <b>Associated Volume</b> |
|----------------------------|--------------------------|
| Private Payor Rate 1       | 60                       |
| Private Payor Rate 2       | 50                       |
| Private Payor Rate 3       | 100                      |

**Applicable Laboratory C**

| <b>Private Payor Rates</b> | <b>Associated Volume</b> |
|----------------------------|--------------------------|
| Private Payor Rate 1       | 200                      |
| Private Payor Rate 2       | 125                      |
| Private Payor Rate 3       | 75                       |

**Collective Reporting for “Single Laboratory XYZ”**

| <b>HCPCS Code</b> | <b>Private Payor Rate</b> | <b>Associated Volume</b> |
|-------------------|---------------------------|--------------------------|
| HCPCS for Test    | Private Payor Rate 1      | 410                      |
| HCPCS for Test    | Private Payor Rate 2      | 275                      |
| HCPCS for Test    | Private Payor Rate 3      | 250                      |

In this example, the reporting entity reports the specific HCPCS code assigned to the ADLT, each private payor rate and the **sum** of the associated volume paid at each private payor rate across all applicable laboratories of the single laboratory: applicable laboratory A, applicable laboratory B and applicable laboratory C.

***Single Laboratory with One TIN***

As discussed previously in this publication, a single laboratory can be an organization and, therefore, could have more than one TIN-level entity.

These are examples of a single laboratory that has only one TIN-level entity that is the reporting entity and must report applicable information for ADLTs **collectively** for all of the single laboratory’s NPI-level applicable laboratories:

**Example 1:** A single laboratory with one TIN-level entity consists of five laboratories as defined under 42 C.F.R. § 493.2 that furnish an ADLT. Each laboratory bills Medicare Part B using its own NPI and all five laboratories individually meet the majority of Medicare revenues threshold. This single laboratory consists of five applicable laboratories for purposes of the ADLT it offers and furnishes. In this case, the reporting entity reports applicable information for the ADLT collectively for all five of its applicable laboratories under its TIN. As discussed above, the reporting entity combines the applicable information of all NPIs that are applicable laboratories and reports applicable information for the ADLT during the data reporting period. In this example, where the single laboratory includes five separate applicable laboratories (by unique billing NPIs), the single laboratory’s reporting entity must select a single NPI as the reporting NPI. In other words, the reporting entity will designate one applicable laboratory’s NPI as the reporting NPI for the entire single laboratory. The reporting entity can select any NPI included in the single laboratory that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI.

**Example 2:** A single laboratory with one TIN-level entity consists of five laboratories as defined under 42 C.F.R. § 493.2, with each laboratory billing Medicare Part B for services under its own NPI. However, only three of the laboratories individually meet the majority of Medicare revenues threshold while the remaining two laboratories do not individually meet the majority of Medicare revenues threshold. In other words, two of the five laboratories receive less than 50 percent of their total Medicare revenue from the CLFS and/or PFS during the data collection period. This single laboratory consists of three applicable laboratories. In such case, the reporting entity will combine the applicable information of all three applicable laboratories and collectively report applicable information for the ADLT during the data reporting period. The reporting entity will not include information regarding the ADLT for the two laboratories that are not applicable laboratories. As with the previous example, the reporting entity will designate one applicable laboratory's NPI as the reporting NPI.

**Example 3:** A single laboratory with one TIN-level entity consists of five laboratories as defined under 42 C.F.R. § 493.2. Each laboratory has been assigned the same NPI and bills Medicare Part B under this same NPI. Collectively, by its own billing NPI, the five laboratories meet the majority of Medicare revenues threshold. This single laboratory consists of one applicable laboratory for purposes of the ADLT(s) it furnishes. In such case, the reporting entity reports applicable information collectively for all laboratories associated with the same NPI during the data reporting period.

### ***Single Laboratory with Multiple TINs***

In the case of a single laboratory with multiple TINs, the single laboratory shall designate one of its TIN-level entities as the reporting entity for all applicable laboratories across all TINs included in the single laboratory. The single laboratory can select any one of the TINs included in the single laboratory and designate that TIN as the reporting entity. An example of data reporting for a single laboratory with more than one TIN is provided below.

**Example:** A single laboratory has three TIN-level entities. TIN-level Entity A consists of three applicable laboratories, while both TIN-level Entity B and TIN-level Entity C each have one applicable laboratory. This single laboratory consists of five applicable laboratories for purposes of the ADLT it offers and furnishes. In this case, the single laboratory designates one of its TIN-level entities as the reporting entity for the entire single laboratory. The reporting entity combines applicable information for the ADLT collectively for all five applicable laboratories across all three TIN-level entities included in the single laboratory and collectively submits applicable information for the ADLT during the data reporting period. As discussed in previous examples, where the single laboratory includes five separate applicable laboratories (by unique billing NPIs) the reporting entity shall designate one applicable laboratory's NPI as the reporting NPI.

## **Section III. Payment Methodology and Data Collection and Reporting Periods for ADLTs**

### **8. Payment Methodology for ADLTs**

Generally, ADLTs are paid on the CLFS using the same methodology based on the weighted median of private payor rates as other CDLTs. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment. Additionally, section 1834A(b)(3) of the Act and 42 C.F.R. § 414.507(d) provide limits on the amounts that the CLFS rates for each CDLT that is not a new ADLT or new CDLT can be reduced as compared to the payment rates for the preceding year. For the first three years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next three years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Updates to ADLT payment rates occur annually. As discussed below, there are special payment requirements for new ADLTs during the new ADLT initial period.

#### ***Payment for Existing ADLTs***

An existing ADLT is a laboratory test for which ADLT status has been granted by CMS and payment for the test has been made under the Medicare CLFS prior to January 1, 2018. Prior to January 1, 2018, existing ADLTs were paid based on either crosswalking or gapfilling methodologies. Beginning January 1, 2018, the payment amount for existing ADLTs is based on the weighted median of private payor rates methodology that applies to all other CDLTs, which are not ADLTs. In other words, existing ADLTs are paid at the weighted median of private payor rates for the test (as described previously in this section).

#### ***Payment for New ADLTs***

A new ADLT is a laboratory test for which ADLT status has been granted by CMS and for which payment has not been made under the Medicare CLFS prior to January 1, 2018. The payment methodology is different before, during, and after the new ADLT initial period. The new ADLT initial period and the various payment methodologies for new ADLTs are discussed below.

##### **➤ *New ADLT Initial Period***

A new ADLT initial period consists of three full calendar quarters. The new ADLT initial period begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made for the test or the date ADLT status is granted by CMS. As previously discussed, an ADLT must be a Medicare Part B covered service and applicants must submit documentation showing the test is covered under Medicare Part B as part of the application for requesting ADLT status. Therefore, the date ADLT status is granted by CMS will follow the date a Medicare Part B coverage determination is made for the test. For example, if the test is covered under Medicare Part B on March 25, 2018 and CMS grants ADLT status for

the test on May 31, 2018 the new ADLT initial period would begin on July 1, 2018 and end on March 31, 2019. See table below.

**Example of Duration of New ADLT Initial Period\***

| <b>Date of Medicare Part B Coverage Determination</b> | <b>Date of ADLT Status Determination</b> | <b>Start of New ADLT Initial Period</b> | <b>End of New ADLT Initial Period</b> |
|---|--|---|---------------------------------------|
| 03/25/2018  | 05/31/2018                               | 07/01/2018                              | 03/31/2019                            |

\* For illustrative purposes only. The start and end dates of a particular ADLT's new ADLT initial period will depend on the actual date ADLT status is granted for the test by CMS.

➤ ***Payment Before New ADLT Initial Period***

After a laboratory test is granted ADLT status by CMS and **before** the new ADLT initial period begins, the local MAC determines the payment amount for the test based on information provided by the laboratory seeking new ADLT status for its laboratory test, such as charges for the test and routine discounts to charges, resources required to perform the test and other criteria the local MAC deems appropriate. For example, if a test is approved as an ADLT on June 10, the local Part B MAC will determine the payment rate for the new ADLT from June 10 through June 30, and the new ADLT initial period will begin on July 1.

➤ ***Payment During New ADLT Initial Period***

Once a new ADLT initial period begins, payment for the new ADLT is made based on its actual list charge amount for the entire duration of the new ADLT initial period. In the example above, this would be July 1, 2018 through March 31, 2019.

➤ ***Payment After New ADLT Initial Period***

After the new ADLT initial period is over, payment for a new ADLT is based on the applicable information reported to CMS. In other words, once the new ADLT initial period is finished, payment amounts for new ADLTs will be determined using the same weighted median of private payor rates methodology that is used for all other CDLTs, as described previously in this section.

➤ ***Actual List Charge***

The actual list charge for a new ADLT is the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date. As noted above, the actual list charge will be used as the payment amount for the new ADLT during its

new ADLT initial period. Therefore, applicants must submit the actual list charge for the test as part of the application for ADLT status.

➤ ***Publicly Available Rate***

The publicly available rate is the lowest amount charged for the new test that is readily accessible in such forums as a company website, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

➤ ***Recoupment Threshold***

After the new ADLT initial period, if CMS determines the actual list charge of a new ADLT is greater than 130 percent of the weighted median calculated under the payment methodology in 42 C.F.R. § 414.507, CMS will recoup the difference between the actual list charge and 130 percent of the weighted median. If the actual list charge amount is less than the recoupment threshold (that is, not greater than 130 percent of the weighted median private payor rate amount), the recoupment provision will not apply. CMS will notify the contact person of the single laboratory if the ADLT’s actual list charge exceeded the recoupment threshold prior to recouping the difference between the ADLT actual list charge and 130 percent of the ADLT’s weighted median of private payor rates.

➤ ***Chronology of New ADLT Payment Methodologies***

This table provides an example of the chronology of payment methodologies before, during, and after the new ADLT initial period, and the corresponding date ranges for a test approved by CMS as a new ADLT on May 15, 2018.

**Example of Chronology of New ADLT Payment Methodologies**

| <b>MAC Determines Payment Amount (Before New ADLT Initial Period)</b> | <b>Actual List Charge (During New ADLT Initial Period)</b> | <b>Weighted Median Payment Amount (Based on applicable information collected during New ADLT Initial Period)</b> | <b>Weighted Median Payment Amount (Based on applicable information collected for annual update)</b> |
|---|--|--|---|
| 5/15/2018 – 6/30/2018   | 7/1/2018 - 3/31/2019                                       | 4/1/2019 – 12/31/2020  | 1/1/2021 – 12/31/2021   |
|   |  |  | New CLFS Rate Every Year  |

***Payment for ADLTs If No Applicable Information Is Received (Existing and New ADLTs)***

For both **existing** ADLTs and **new** ADLTs, in cases where no applicable information is received for the test during a data reporting period, the ADLT would be priced by either crosswalking or gapfilling methodologies until private payor rate data is received for the next annual update. For new ADLTs, in cases where no applicable information is received for the

test by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by gapfilling or crosswalking methodologies.

## 9. Schedule for Data Collection and Data Reporting During New ADLT Initial Period

As noted previously, there are special data reporting requirements for ADLTs during the new ADLT initial period. With respect to a new ADLT, applicable information must be reported initially by the last day of the **second quarter** of the new ADLT initial period, and thereafter, every year.

The **data collection period** for a new ADLT is the period during which applicable information for the single laboratory furnishing the ADLT is obtained from claims for which the laboratory received final payment during the period. The data collection period is the **first five months** of the new ADLT initial period. The **data reporting period** is the **sixth month** of the new ADLT initial period. Once the new ADLT initial period is over, payment for the test will be made at the weighted median of the private payor rates based on applicable information collected and reported during the new ADLT initial period.

For example, if the new ADLT initial period is July 1, 2018 through March 31, 2019, the data collection period would be July 1, 2018 through November 30, 2018. The data reporting period would be from December 1, 2018 through December 31, 2018. CMS would calculate the weighted median private payor rate for the test from applicable information reported during the data reporting period and this rate would be effective once the new ADLT initial period is over until the next annual update for the ADLT. In this example, the weighted median private payor rate calculated from applicable information **reported during** the new ADLT initial period would be in effect from April 1, 2019 through December 31, 2020.

This table shows the new ADLT data collection and data reporting schedule during the initial period.

**Data Collection and Reporting Schedule (New ADLT Initial Period)**

| <b>New ADLT Initial Period<br/>(Payment at Actual List Charge)</b> | <b>Data Collection Period</b> | <b>Data Reporting Period</b> | <b>Data Used For CLFS<br/>(weighted median payment amount)</b> |
|--|-------------------------------|------------------------------|--|
| 1/1/2018 - 9/30/2018   | 1/1/2018 - 5/31/2018          | 6/1/2018 - 6/30/2018         | 10/1/2018 - 12/31/2020   |
| 4/1/2018 - 12/31/2018  | 4/1/2018 - 8/31/2018          | 9/1/2018 - 9/30/2018         | 1/1/2019 - 12/31/2020  |
| 7/1/2018 - 3/31/2019   | 7/1/2018 - 11/30/2018         | 12/1/2018 - 12/31/2018       | 4/1/2019 - 12/31/2020  |
| 10/1/2018 - 6/30/2019  | 10/1/2018 - 2/28/2019         | 3/1/2019 - 3/31/2019         | 7/1/2019 - 12/31/2020  |
| Continues Every Year   | Continues Every Year          | Continues Every Year         | Continues Every Year   |



### ***Data Reporting During New ADLT Initial Period***

As explained previously in this publication, each ADLT must be assigned a unique HCPCS code, meaning one that describes only a single test. When submitting an application for ADLT status for a test, applicants are required to inform CMS whether the test already has been assigned a unique HCPCS code. If the test is not currently assigned a unique HCPCS code, applicants are required to inform CMS if a completed application for a unique level I HCPCS code for the test was submitted to the AMA or whether the applicant is in the process of submitting an application to the AMA. If the potential ADLT does not already have a unique HCPCS code and the applicant has not submitted a level I HCPCS code application for the test to the AMA, or is not in the process of preparing an application, the applicant must submit a request for CMS to assign a unique level II HCPCS code for the test.

If a unique HCPCS code is assigned to the new ADLT before the start of the data reporting period within the new ADLT initial period, applicable information must be reported using the unique HCPCS code assigned to the test.

**Example:** On, July 10, 2018 an applicant submits an application for new ADLT status for a test, for which the single laboratory had been billing using a MoIDX Z-Code Identifier. CMS approves the test as a new ADLT effective September 1, 2018. Therefore, the new ADLT initial period is October 1, 2018 through June 30, 2018. The data collection period during the new ADLT initial period is October 1, 2018 through February 28, 2019 and the data reporting period during the new ADLT initial period is March 1, 2019 through March 31, 2019. The test did not already have a unique HCPCS code and a request for a unique level I HCPCS code was not pending with the AMA. Therefore, CMS assigned a unique level II HCPCS code to the new ADLT on September 10, 2018 and the new code became effective January 1, 2019.

Since the unique level II HCPCS code was assigned to the new ADLT before the data reporting period of the new ADLT initial period, the reporting entity must report applicable information for the new ADLT using the unique level II HCPCS code. The MoIDX Z-Code Identifier that was originally used by the single laboratory to bill for the test should not be reported. In other words, even though the unique level II HCPCS code for the new ADLT was not effective and available for use until July 1, 2018, and the single laboratory billed for the new ADLT using a MoIDX Z-Code Identifier for a portion of the data collection period of the new ADLT initial period, the reporting entity should report applicable information for the test using the unique HCPCS code assigned to the new ADLT.

Using the example above, if a unique HCPCS code is assigned to the ADLT on March 10, 2018, but does not become effective and available for use until after the start of the data reporting period of the new ADLT initial period, the reporting entity would still report the unique HCPCS code assigned to the test. In other words, as long as the unique HCPCS code is assigned to the new ADLT before the reporting period begins, the reporting entity must report applicable information by the unique HCPCS code assigned to the new ADLT, regardless of the actual effective date of the unique HCPCS code.

However, when the assignment of a new ADLT's unique HCPCS code is pending for the entire data collection period of the new ADLT initial period, the reporting entity must report applicable information for the new ADLT by the original HCPCS code or other existing identifier that was used by the single laboratory to bill for the test during the data collection period.

**Example:** On July 10, 2018, an applicant submits an application for new ADLT status for a test, for which the single laboratory had been billing using a MoIDX Z-Code Identifier. CMS approves the test as a new ADLT effective September 1, 2018. Therefore, the new ADLT initial period is October 1, 2018 through June 30, 2019. The data collection period during the new ADLT initial period is October 1, 2018 through February 28, 2019 and the data reporting period during the new ADLT initial period is March 1, 2019 through March 31, 2019. The test did not already have a unique HCPCS code at the time an application for ADLT status was submitted to CMS, however, the single laboratory requesting ADLT status was in the process of preparing an application for a unique level I HCPCS code. The single laboratory submitted a request for a unique level I HCPCS code to the AMA on January 6, 2019. The AMA assigned a unique level I HCPCS code to the ADLT on April 1, 2019.

Since in the example, the unique level I HCPCS code was not assigned to the new ADLT before the data reporting period of the new ADLT initial period, the reporting entity must report applicable information for the new ADLT using the MoIDX Z-Code Identifier that was originally used by the single laboratory to bill for the test during the data collection period of the new ADLT initial period.

## 10. Schedule for Data Collection and Data Reporting for Annual ADLT Payment Updates

The Medicare payment rates for ADLTs are updated annually, as opposed to every 3 years (as is the case for all other CDLTs that are not ADLTs). Applicable information for ADLTs must be collected and reported to CMS annually, except for new ADLTs during the new ADLT initial period (in which case, as discussed previously in Section III, a reporting entity must report applicable information during the sixth month of the new ADLT initial period). The data collection period refers to the period during which applicable information is collected for ADLTs; the data reporting period is the period during which a reporting entity reports the applicable information for ADLTs to CMS.

The data collection period and data reporting period for ADLTs is the same as all other CDLTs that are not ADLTs. That is, the data collection period is the 6-month period from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, and the data reporting period is the three-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. In other words, applicable information is collected for the ADLT every year from January 1 through June 30 and subsequently reported the following year from January 1 through March 31.

A 6-month window follows the data collection period and precedes the data reporting period (the period in which applicable information must be reported to CMS). The 6-month window should be used to determine whether the single laboratory is an applicable laboratory for purposes of reporting applicable information for an ADLT. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information before it is reported to CMS.

### *Annual Payment Updates for New ADLTs*

With regard to **new ADLTs** (that is, an ADLT for which payment has **not** been made under the Medicare CLFS prior to January 1, 2018) the first annual data collection period is January 1 through June 30 **following** the calendar year in which the new ADLT initial period began. In other words, for all new ADLT initial periods beginning in a given calendar year, the first **annual** data collection period would start on January 1 of the next calendar year. For example, if a new ADLT initial period is April 1, 2018 through December 31, 2018, the first annual data collection period would be January 1, 2019 through June 30, 2019. For a new ADLT initial period of July 1, 2018 through March 31, 2019, the first annual data collection period would also be January 1, 2019 through June 30, 2019 because the new ADLT initial period began in calendar year 2018.

**Note:** For any new ADLT initial period of October 1 through June 30, there would be a 2-month overlap for the data collection period applicable during the new ADLT initial period and the data collection period for the first annual update. For example, if a new ADLT initial period is October 1, 2018 through June 30, 2019, the data collection during the new ADLT initial period would occur from October 1, 2018 through February 28, 2019 (month 1 through month 5 of the new ADLT initial period). For the first annual update, the data collection period is January 1, 2019 through June 30, 2019 because the new ADLT initial period began in calendar year 2018. Therefore, in this example, applicable information collected January 1, 2019 through February 28, 2019 would be

used to calculate the weighted median rate effective April 1, 2019 through December 31, 2020 (that is, once the new ADLT initial period is over until the first annual update) and for the first annual update period, that is, January 1, 2021 through December 31, 2021.

This table illustrates the new ADLT data collection and data reporting schedule for purposes of the first annual payment update for new ADLT initial periods starting in calendar year 2018.

#### **Annual Data Collection and Reporting Periods for New ADLTs**

| <b>New ADLT Initial Period</b> | <b>First Annual Data Collection Period</b> | <b>First Annual Six-Month Window</b> | <b>First Annual Data Reporting Period</b> | <b>Used for CLFS Rate Year</b> |
|--------------------------------|--|--------------------------------------|---|--------------------------------|
| 1/1/2018 - 09/30/2018          | 1/1/2019 - 6/30/2019                       | 7/1/2019 - 12/31/2019                | 1/1/2020 - 3/31/2020                      | 2021                           |
| 4/1/2018 - 12/31/2018          | 1/1/2019 - 6/30/2019                       | 7/1/2019 - 12/31/2019                | 1/1/2020 - 3/31/2020                      | 2021                           |
| 7/1/2018 - 03/31/2019          | 1/1/2019 - 6/30/2019                       | 7/1/2019 - 12/31/2019                | 1/1/2020 - 3/31/2020                      | 2021                           |
| 10/1/2018 - 06/30/2019         | 1/1/2019 - 6/30/2019*                      | 7/1/2019 - 12/31/2019                | 1/1/2020 - 3/31/2020                      | 2021                           |
|                                | Continues Every Year                       | Continues Every Year                 | Continues Every Year                      | New CLFS Rate Every Year       |

\* Includes a 2-month overlap with data collected from the new ADLT initial period data collection period. For instance, data from 1/1/2019 through 2/28/2019 will be included in the data collection during the new ADLT initial period and for the first annual update.

#### ***Annual Payment Updates for Existing ADLTs***

As explained previously in this article, an existing ADLT is a laboratory test for which ADLT status has been granted by CMS and payment for the test has been made under the Medicare CLFS prior to January 1, 2018.

Through the application process, CMS will approve a test as either an existing ADLT or a new ADLT. If the test meets the requirements for ADLT status and was paid under the Medicare CLFS prior to January 1, 2018, it will be approved as an existing ADLT. If the test meets the requirements for ADLT status and was paid under the Medicare CLFS on or after January 1, 2018, it will be approved as a new ADLT.

As noted previously, there is no “new ADLT initial period” for existing ADLTs. Existing ADLTs will immediately be subject to the general data collection and data reporting requirements for ADLTs and payment rates will be updated annually. Therefore, the first annual data collection period for an existing ADLT is January 1 through June 30 of the same calendar year in which the test was approved as an existing ADLT. The 6-month window, during which applicable laboratories and their reporting entity review and validate applicable information, is July 1 through December 31 of the same calendar year in which the test was approved as an existing ADLT. The

first annual data reporting period for an existing ADLT is January 1 through March 31 following the calendar year in which the test was approved as an existing ADLT. The following is an example of the first annual data collection period and first annual data reporting period for an existing ADLT.

**Example:** A laboratory submits an application for ADLT status for a laboratory test on April 23, 2018, and the laboratory test was **first paid** under the Medicare CLFS as a CDLT on February 10, 2014. CMS approves the test as an existing ADLT on May 28, 2018. The test is approved as an existing ADLT because payments were made for the test under the CLFS prior to January 1, 2018. In this example, the first annual data collection period would be January 1, 2018 through June 30, 2018 and the first annual data reporting period would be January 1, 2019 through March 31, 2019. The new rate would be effective beginning January 1, 2020.

This table illustrates the annual data collection and data reporting periods for a test approved as an existing ADLT in calendar year 2018.

#### **Annual Data Collection and Reporting Periods for an Existing ADLT**

| <b>Data Collection Period</b> | <b>Six-Month Window</b> | <b>Data Reporting Period</b> | <b>Used for CLFS Rate Year</b> |
|-------------------------------|-------------------------|------------------------------|--------------------------------|
| 1/1/2018 - 6/30/2018          | 7/1/2018 - 12/31/2018   | 1/1/2019 - 3/31/2019         | 2020                           |
| 1/1/2019 - 6/30/2019          | 7/1/2019 - 12/31/2019   | 1/1/2020 - 3/31/2020         | 2021                           |
| Continues Every Year          | Continues Every Year    | Continues Every Year         | New CLFS Rate Every Year       |

#### ***Data Reporting for Existing ADLTs for the First Annual Payment Update***

As explained previously, if an ADLT does not already have a unique HCPCS code, that is, a code that describes only a single test, the AMA or CMS will assign a unique HCPCS codes to the test.

If a unique HCPCS code is assigned to the existing ADLT before the first annual data reporting period begins, applicable information must be reported using the unique HCPCS code assigned to the test. However, in the event that a unique HCPCS code is not assigned to an existing ADLT before the first annual data reporting period, the reporting entity must report applicable information for the existing ADLT by the original HCPCS code or other existing identifier that was used by the single laboratory to bill for the test. Note that in most cases, existing ADLTs would already have been assigned a unique level I HCPCS code by the AMA before the first annual data reporting period. Therefore, the need to report applicable information by the original HCPCS code (or other existing identifier) used to bill for an existing ADLT would be unlikely.

## **Additional Information**

The CMS application for requesting ADLT status for a laboratory test is available on the CMS website at: <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/adlt-information>.

Applications for a unique level II HCPCS code must be submitted in the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™). Go to <https://mearis.cms.gov> to register/log in and submit your application.

For more information about data collection and reporting visit [CLFS PAMA Educational Resources | CMS](#) and [CLFS Reporting | CMS](#)

If you have questions about the CLFS, please email the CLFS Inquiries mailbox at [CLFS\\_Inquiries@cms.hhs.gov](mailto:CLFS_Inquiries@cms.hhs.gov).

If you have any additional questions, please contact your MAC. [Who are the MACs | CMS](#)