Application for Advanced Diagnostic Laboratory Test (ADLT) Status under the Medicare Clinical Laboratory Fee Schedule (CLFS)

Instructions

This application is to be used for a single laboratory to request ADLT status for a clinical diagnostic laboratory test (CDLT) under the CLFS.

This form must not be used to notify CMS about CDLTs that are cleared or approved by the FDA, that are not ADLTs. Laboratories must use the CLFS Form-Notification of FDA Cleared or Approved CDLT for that purpose, which is available from the CMS website via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

Background Information

On June 23, 2016, the Centers for Medicare & Medicaid Services (CMS) published the CLFS final rule, "**Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule**" (CMS-1621-F; 81 *Fed. Reg.* 41036 through 41101). The final rule implements Section 1834A of the Social Security Act (the Act), which requires extensive revisions to the Medicare payment, coding, and coverage for CDLTs.

Section 1834A of the Act also establishes a new subcategory of CDLTs known as ADLTs with separate reporting and payment requirements. 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 FDA). See 42 C.F.R. § 414.502.

Important terms are described in the "Key Terms Used in the Application for ADLT Status Under the CLFS" section below. For additional guidance on ADLTs and the process for submitting an application for ADLT status for a CDLT, see "Guidance for Laboratories on Advanced Diagnostic Laboratory Tests" available from the CMS website via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.

Send Completed Applications to:

Applications for ADLT status may be submitted in hard copy or electronic format to the addresses below. If submitting electronically, scan and send the signed application form, all addenda items, and any additional relevant attachments as a single file in PDF format. The application must include a physical signature. Digital signatures and digital initials will not be accepted.

Hard Copy:
Centers for Medicare & Medicaid Services
CM/HAPG/Division of Ambulatory Services 7500 Security Boulevard
Baltimore, Maryland 21244
Mail Stop: C4-01-26
Attention: CLFS Team

Electronic: CLFSFormSubmission@cms.hhs.gov

Questions regarding the application for ADLT status under the CLFS may be sent to:
CLFS_Inquiries@cms.hhs.gov.

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 Social Security 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 this 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.

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 clinical diagnostic laboratory test 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 this 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 that 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.

Single Laboratory Information

Name of Single Laboratory:_____

Address: _____
Number and Street

_____ _____ _____
City/ Town State Zip code

Items 1 through 3 pertain to general information about the single laboratory and evidence of Medicare Part B coverage for the laboratory test.

1. **Provide the following information in *Addendum A* - Information Regarding the Single Laboratory:**
    a. Description of the entire single laboratory. Specifically, provide the name and address of all laboratory components of the single laboratory that will furnish the test. If applicable, provide the name and address of any entity that owns the laboratory, or is owned by the laboratory, that may design, offer, or sell the test. Additionally, provide a description of the role(s) these entities have within the single laboratory with respect to the potential ADLT. Also, note whether the single laboratory applying for ADLT status is a successor owner to the single laboratory that designed the test.
    b. All Tax Identification Numbers (TINs) of the single laboratory.
    c. All National Provider Identifiers (NPIs) included in the single laboratory.
    d. All CMS Certification Numbers (CCNs) included in the single laboratory.

2. **Provide the following information in *Addendum B* - Evidence of Medicare Part B Coverage.** Provide evidence of Medicare Part B coverage for the test. Evidence must include the date the test was first covered and at least one of the following items:

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

3. In the boxes below, please check the box if the statement is true. Note: Each statement must be true in order for the test to qualify for ADLT status:

☐ a. The test is furnished only by the laboratory (as defined in 42 C.F.R. § 493.2) component(s) of the single laboratory.

☐ b. The test has not been sold to other laboratories.

☐ c. The test has not been licensed to other laboratories.

Items 4 through 6 pertain to current coding and payment information for the test.

4. Please provide information about the existing code(s) and descriptors(s) currently used by the single laboratory to bill for the test. If the test is currently described by an existing level I Healthcare Common Procedure Coding System (HCPCS) code (CPT code) or level II HCPCS code, or some other code or identifier that is being used by the single laboratory to bill for the test, include the following information, as applicable, in ***Addendum C* – Existing Coding and Payment Information**:

    a. The specific HCPCS code (as defined in 42 C.F.R. § 414.502), the Not Otherwise Classified (NOC) code, or the unlisted CPT code;
    b. The MolDX Z-Code Identifier;
    c. The code or other descriptors used to describe the test; and
    d. If there is no payment amount for the code on the current CLFS, but the test has been paid by Medicare, for example, under the MolDX program, provide the MAC's local payment amount for the test and date of that payment determination.

5. Item 5 asks for information that is required for a test that does not currently have a unique HCPCS code, that is, a HCPCS code describing only a single test. If the test has already been assigned a unique HCPCS code, item 5 should be omitted. Note that a MolDX Z-Code Identifier, even if it is currently used by the single laboratory to bill for the test, is not classified as a "HCPCS" code.

    If the test is **not currently assigned** a unique HCPCS code (that is, a HCPCS code describing only a single test):

    a. Provide the date (month, day, year) a completed application for a unique level I HCPCS code (i.e. CPT code) for the test was submitted to the American Medical Association (AMA):

    _____/_____/_____
    MM/ DD/ YYYY

    or,

b. If you have not submitted a level I HCPCS code application for the test to the AMA but you are in the process of preparing an application, provide an estimated submission date (month, day, year):

_____/_____/_____
MM/ DD/ YYYY

or,

c. If you have not submitted a level I HCPCS code application for the test to the AMA and are not in the process of preparing an application, submit to CMS, along with this application, a request for CMS to assign a unique level II HCPCS code for the test. The level II HCPCS laboratory test code request form can be downloaded from the *CLFS PAMA Regulations* web page at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

A request for CMS to assign a unique level II HCPCS code for this test should **not** be sent to the CMS National Level II HCPCS coding program (HCPCS workgroup).

6. If payment for the test has not been made under the CLFS prior to January 1, 2018, include in ***Addendum D* – Actual List Charge**:

a. The first date on which the test is obtainable by a patient, or marketed to the public.
b. 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.
c. 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.
d. 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. If none are available, specify in ***Addendum D***, "None Available."

Items 7 through 11 ask for information that we require for ADLT status under Criterion (A). Note: If this application is a request for ADLT status under Criterion (B), items 7 through 11 may be omitted.

Include responses to items 7 through 10 in ***Addendum E* - ADLT Status Under Criterion (A):**

7. Description of the proposed ADLT. Provide a general description of the test and identify the deoxyribonucleic acid (DNA), ribonucleic acid (RNA) or protein biomarkers analyzed by the test. Please also provide a specific description of the test's unique (meaning, empirically derived) algorithm.

8. Purpose of the proposed ADLT. A summary of the intended clinical use and patient-specific result of the test. 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).

9. List of potential comparative tests. Information regarding other tests that may overlap with the intended clinical use or attributes of this test**.** That is, provide 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.

10. Comparisons between proposed ADLT and other similar tests. Information on similarities and differences between the proposed ADLT and the tests listed in item 9, 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.

11. In the boxes below, please check the box if the statement is true. Note: Each statement must be true for a test to qualify for ADLT status under Criterion (A):

☐ a. The test algorithm is unique (as described in item 8).

☐ b. The proposed test provides new clinical diagnostic information not available from other tests or combinations of tests (as described in item 10).

Items 12 and 13 ask for information that we require for ADLT status under Criterion (B). Note: If this application is a request for ADLT status under Criterion (A), items 12 through 13 may be omitted.

12. Please check the box below if the statement is true:

☐ a. The test is cleared or approved by the U.S. Food and Drug Administration (FDA).

13. Provide below, and/or attach to this application, information that shows the test is cleared or approved by the FDA. This information must include the FDA premarket approval or premarket notification (i.e., 510[k]) number for the test):

a. FDA premarket approval or notification number: _____

b. Date of FDA clearance or approval: _____/_____/_____
MM/ DD/ YYYY

c. Name and branch of the FDA reviewer:_____
name and branch

14. Penalties For Falsifying Information on this Application

18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. Individual offenders are subject to fines of up to $250,000 and imprisonment for up to five years. Offenders that are organizations are subject to fines of up to $500,000 (18 U.S.C. § 3571). Section 3571(d) also authorizes fines of up to twice the gross gain derived by the offender if it is greater than the amount specifically authorized by the sentencing statute.

15. Certification Statement

The Certification Statement contains additional requirements for initial and continuous qualification for ADLT status. Review these requirements carefully. By signing this application, the authorized official, on behalf of the single laboratory, is attesting to having read the requirements and understanding them. In addition, by signing this application, the authorized official binds the single laboratory to all of the requirements listed herein and acknowledges that ADLT status for a test may be denied if any requirements are not met.
The authorized official MUST sign and date the section below in order to request ADLT status for a test.

I, the undersigned, certify to the following:

- This application is being completed on behalf of a single laboratory, as that term is defined in 42 C.F.R. § 414.502.
- The information provided on this application is true, correct and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS of this fact immediately.
- I authorize CMS to verify the information contained herein. I agree to notify CMS of any changes in this application within 30 days of the change. For example, I will 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 required under item 1. If requesting ADLT status under Criterion (A), I agree to notify CMS if there are any changes to the biomarkers or algorithms of this test within 30 days of the change.
- The single laboratory's Medicare enrollment is in good standing and not subject to any actions under 42 C.F.R. § 424.535.
- I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.

16. Authorized Official Information and Signature

My signature legally binds the single laboratory to the Certification Statement. By my signature, I certify under penalty of perjury that the information contained herein is true, accurate and complete.

Name: _____

Title/Position: _____

Signature: _____ Date: _____

17. Contact Person
(The contact person is an individual who can be reached to answer questions regarding the information furnished in this application.)

Name: _____

Title/Position: _____

Telephone Number: _____
Include Area Code and Extension (if Applicable)

Email Address: _____

Addendum A: Information Regarding Single Laboratory

For use in providing information required for item 1. Attach additional pages if necessary.

1a. Description of the Entire Single Laboratory:

1b. Tax Identification Number(s) (TINs):

1c. National Provider Identifiers (NPIs):

1d. CMS Certification Numbers (CCNs):

Addendum B: Evidence of Medicare Part B Coverage

For use in submitting required information for item 2. Attach additional pages if necessary.

Addendum C: Existing Coding and Payment Information

For use in submitting required information for item 4. Add rows if necessary.

(Template for Addendum C)

Existing HCPCS or Other Existing Unique Identifier Used to Bill for the Test*	Descriptor*	Medicare Payment Amount**	Date of Payment Determination***

** In the event that multiple payors are currently paying for the test, the applicant must include all existing HCPCS codes (or other unique identifier(s) used for billing the test and corresponding code descriptors).*

*** If the test is covered under Medicare Part B but is not currently on the Medicare CLFS, for example, if it is paid under the MolDX program, applicants must provide the Medicare Administrative Contractor's (MAC's) local payment amount for the test.*

**** If the test is currently paid at the MAC's local payment amount, applicants must provide the date of that payment determination.*

Addendum D: Actual List Charge

For use in submitting required information for item 6.

6a. First Date Test is Obtainable

(Provide 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.)

6b. Amounts Charged

(List 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.)

6c. Actual List Charge Amount:

(Provide the lowest amount charged on the date entered in 6a that is readily accessible in forums such as a website, test registry or price listing.)

6d. Publicly Available Source(s)

(Provide the publicly available source(s) of the actual list charge and all other amounts charged (if applicable) 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.)

Addendum E: ADLT Status Under Criterion (A)

For use in submitting required information for items 7 through 10. Attach additional pages if necessary.

7. Description of the Proposed ADLT.

8. Purpose of the Proposed ADLT.

9. List of Potential Comparative Tests.

10. Comparisons Between Proposed ADLT and Other Similar Tests.