DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Medicare Clinical Laboratory Fee Schedule
Application for Level II Healthcare Common Procedure Coding System Code for Advanced Diagnostic Laboratory Tests and Laboratory Tests Cleared or Approved by the U.S. Food and Drug Administration

Background Information

The Healthcare Common Procedure Coding System (HCPCS) Level II is a standardized coding system used primarily to identify products, supplies, and services that are not included in the HCPCS Level I --American Medical Association's (AMA) CPT code set. Because Medicare and other insurers cover a variety of services, supplies and equipment that are not identified by CPT codes, the HCPCS level II codes were established for submitting claims for these services.

This application for a level II HCPCS code is to be used by the single laboratory requesting advanced diagnostic laboratory test (ADLT) status for a clinical diagnostic laboratory test (CDLT) under the Medicare clinical laboratory fee schedule (CLFS) or the laboratory or manufacturer notifying the Centers for Medicare & Medicaid Services (CMS) about a CDLT (that is not an ADLT) that has been cleared or approved by the U.S. Food and Drug Administration (FDA).

Additionally, this application must only be used to request a unique level II HCPCS code when an ADLT or an FDA cleared or approved CDLT (that is not an ADLT) is not currently assigned a unique HCPCS code and a request for a unique level I HCPCS code is not pending with the AMA, and if the applicant is not in the process of submitting an application for a unique level I HCPCS code to the AMA. A "unique" HCPCS code is one that describes only a single test.

As a preliminary step in the process for requesting the addition of a new code, it may be helpful for you to contact 3rd party payors for Medicare, Medicaid and private insurers to determine if, in their determination, an existing unique HCPCS code (that is, a HCPCS code describing only a single test) identifies the potential ADLT or FDA cleared or approved CDLT (that is not an ADLT).

Please note that this application for a unique level II HCPCS code must be accompanied by either (1) an application requesting ADLT status for a laboratory test or (2) a notification to CMS of an FDA cleared or approved CDLT. Those forms are available on the CMS website via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html

Schedule for Assignment of Level II HCPCS Code

Level II HCPCS code assignments for ADLTs and FDA cleared or approved CDLTs (that are not ADLTs) will be conducted on a quarterly basis. CMS will review all applications for a unique level II HCPCS code to determine whether to establish a code after CMS has either granted ADLT status for the test or verified FDA clearance/approval, as applicable. The assigned HCPCS codes for ADLTs and FDA cleared or approved CDLTs will be given the letter "U" designation (i.e. Uxxxx). Newly established and revised level II HCPCS codes for these tests will be posted on CMS' HCPCS website at https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html under the *U-Codes* section.

Generally, there will be a "lag-time" of one calendar quarter between the assignment of a unique level II HCPCS code and the effective date of the new code. For instance, if CMS assigns a unique level II HCPCS code to an ADLT or FDA cleared or approved CDLT (that is not an ADLT) during the first calendar quarter of a given calendar year (January 1 through March 31), the unique level II HCPCS code will be effective and available for use on the first day of the third calendar quarter, that is, by July 1 of that year. The contact person (as identified at the end of this level II HCPCS coding request form) will be notified via email of the status of CMS's review and decision to establish a unique level II HCPCS code for the laboratory test.

This table shows the schedule for assigning a unique level II HCPCS code for ADLTs and FDA cleared/approved tests for each calendar quarter scenario.

Level II HCPCS Coding Assignment and Effective Date Schedule

Calendar Quarter ADLT or FDA Cleared/Approved CDLT is Assigned Unique Level II HCPCS Code	**Change Request Announcing Unique Level II HCPCS Code is Published**	**Effective Date of Unique Level II HCPCS Code**
Q1. January 1 - March 31	4/1 - 4/30	7/1
Q2. April 1 - June 30	7/1 - 7/31	10/1
Q3. July 1 - September 30	10/1 - 10/31	1/1
Q4. October 1 - December 31	1/1 - 1/31	4/1

Send Completed Applications to:

Applications for requesting a unique level II HCPCS code for an ADLT or FDA cleared or approved CDLT (that is not an ADLT) may be submitted in hard copy and or electronic format to the addresses below. If submitting electronically, send the physically signed application form 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
7500 Security Boulevard
Baltimore, Maryland 21244
Mail Stop: C4-01-26
Attention: CLFS HCPCS Application -- Division of Ambulatory Services

Electronic: CLFSFormSubmission@cms.hhs.gov

Questions regarding the application for a level II HCPCS code for ADLTs and FDA cleared or approved tests under the Medicare CLFS may be sent to:
CLFS_Inquiries@cms.hhs.gov

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Request for a Unique Level II HCPCS Code for an ADLT or FDA Cleared/Approved CDLT Under the Medicare CLFS

1. Applicant Information

(The applicant is the single laboratory that submitted an application for ADLT status for a laboratory test or the laboratory or manufacturer that notified CMS of an FDA cleared or approved CDLT, which is requesting a unique level II HCPCS code for the test.)

Name of Applicant: _____

Address: _____
Number and Street

_____ _____ _____
City/ Town State Zip code

2. Provide the trade/brand name of the laboratory test, a description of this laboratory test and its intended use below. Add additional page(s) if necessary.

Name, Description, and Intended Use of the Laboratory Test.

3. **Item 3 requests information on the existing code(s) and descriptor(s) currently used to bill for the laboratory test that are not a unique HCPCS code, that is, a HCPCS code describing only a single test. Provide the existing code(s) and descriptor(s) currently used to bill for the laboratory test in the table below.**

Existing HCPCS Code or Other Existing Unique Identifier Used to Bill for the Test*	Descriptor*

** In the event that multiple payors are currently paying for the test, item 3 must include all existing HCPCS codes or other unique identifier(s) used for billing the test and corresponding code descriptors.*

4. **Please check the box below if the statement is true:**

☐ • An application requesting advanced diagnostic laboratory test (ADLT) status was submitted to CMS.

If the statement is true, please provide the date (month, day, year) a completed application requesting ADLT status for the laboratory test was submitted to CMS.

Date that an application requesting ADLT status was submitted to CMS:
_____/_____/_____
MM/ DD/ YYYY

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

☐ • A notification of FDA clearance or approval for the laboratory test was submitted to CMS.

If the statement is true, please provide the date (month, day, year) a completed notification of FDA clearance or approval for the CDLT (that is not an ADLT) was submitted to CMS.

Date that notification of FDA cleared/approved test was submitted to CMS:

_____/_____/_____
MM/ DD/ YYYY

6. 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.

7. Certification Statement

The authorized official, as described in paragraph 8, MUST sign and date the section below.

I, the undersigned, certify to the following:

- 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.

- 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.

8. Authorized Official Information and Signature

(An authorized official is an appointed official of the single laboratory requesting ADLT status for a test or an appointed official of the laboratory or manufacturer notifying CMS of an FDA cleared or approved laboratory test, who holds a position of authority (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 and communicate information to CMS regarding Medicare program requirements.)

My signature legally binds the applicant 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: _____

9. Contact Person

(The contact person is an individual who can be reached to answer questions regarding the information furnished in this level II HCPCS coding request.)

Name: _____

Title/Position: _____

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

Email Address: _____