

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 13639</b>	<b>Date: February 20, 2026</b>
	<b>Change Request 14371</b>

**SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment**

**I. SUMMARY OF CHANGES:** The purpose of this Recurring Update Notification (RUN) is to provide instructions for the quarterly update to the CLFS. This RUN applies to chapter 16, section 20.

**EFFECTIVE DATE: April 1, 2026**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: April 6, 2026**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	N/A

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 13639	Date: February 20, 2026	Change Request: 14371
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## **II. GENERAL INFORMATION**

**A. Background:** The purpose of this RUN is to provide instructions for the quarterly update to the CLFS. This RUN applies to chapter 16, section 20.

### **B. Policy: Clinical Laboratory Fee Schedule (CLFS)**

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (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 implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period is the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the collection period.

#### Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests

On February 3, 2026, Section 6226 of the Consolidated Appropriations Act of 2026 specified an updated data reporting for clinical diagnostic laboratory tests (CDLTs) that aren’t advanced diagnostic laboratory tests (ADLTs). It also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation:

- The next data reporting period will be from May 1, 2026 – July 31, 2026 and based on the data collection period of January 1, 2025 through June 30, 2025.
- There is no phased-in reduction in CY 2026. Beginning January 1, 2027, payment may not be reduced by more than 15%-percent compared to the payment amount established for a test the preceding year.

#### Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests:  
<https://www.cms.gov/medicare/clinical-laboratory-fee-schedule/adlt-information>

#### New Codes Effective April 1, 2026

*Proprietary Laboratory Analysis (PLAs) and Additional New Codes*

Please see the table attached to the Transmittal entitled "**CY2026 CLFS Quarter 2 Updates,**" Tab "**New Codes Effective 04-1-26.**" The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of April 1, 2026, and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act Subsection (§) 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction. The table includes the laboratory, long and short descriptors, and Type of Service (TOS) of each new code.

**Deleted Codes Effective April 1, 2026**

Please see the table attached to the Transmittal entitled "**CY2026 CLFS Quarter 2 Updates,**" Tab "**Deleted Codes Effective 04-1-26.**" The listed codes are being deleted with a delete date of April 1, 2026.

The table includes the code, long descriptor and the delete date of the code.

**III. BUSINESS REQUIREMENTS TABLE**

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CBF	
14371.1	Contractors shall be aware of any new ADLT codes, and/or (Common Procedural Terminology) CPT/HCPCS codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as applicable listed in this change request and shall update their systems as necessary to accept/delete/terminate them.	X	X						X	CVM
14371.1.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) update, contractors shall locally price the codes until they appear with a rate on the CLFS file and/or, for Part A claims, the IOCE.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
14371.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X							
14371.3	Contractors shall use the cloud fee schedule to determine the payment limit for claims for separately payable Medicare Part B laboratory tests processed or reprocessed on or after April 1, 2026.	X	X							
14371.4	The A/B MACs Part A shall retrieve the CY 2026 Clinical Laboratory Fee Schedule from the CMS cloud on or after April 1, 2026.	X								Hybrid Cloud Data Center (HCDC)

**IV. PROVIDER EDUCATION**

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

**Impacted Contractors:** A/B MAC Part A, A/B MAC Part B

**V. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information:** N/A

## **VI. CONTACTS**

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## **VII. FUNDING**

### **Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 1**

**New Codes Effective April 1, 2026**

*Proprietary Laboratory Analysis (PLAs)*

The following new codes have been added to the national HCPCS file with an effective date of April 1, 2026 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

MACs shall only price PLA codes for laboratories within their jurisdiction.

<b>Laboratory</b>	<b>CPT Code</b>	<b>Short Descriptor</b>	<b>Long Descriptor</b>	<b>TOS</b>	<b>Effective Date</b>
Blue Native Polyacrylamide Gel Electrophoresis (PAGE), Children's Hospital Colorado Laboratory	0614U	IEM PMD ALYS 4 NZM CPLX PAGE	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result	5	4/1/2026
iDart™ Lyme IgM ImmunoBlot Kit, ID-FISH Technology, Inc	0615U	BBRGDRFERI LD ANTB DETCJ 26	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM	5	4/1/2026
TruD MDS Alzheimer's & MCI, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0616U	NEUROL DEMENTIA ALYS >30000	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS ASCVD, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0617U	CV ASCVD DNA ALYS >20000	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Bipolar, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0618U	PSYC BD DNA MTHYL ALYS>10000	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS COPD, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0619U	PULM COPD DNA ALYS >18000	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Hepatocellular Carcinoma, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0620U	ONC HCC DNA MTHYLN ALYS>5000	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Lyme Disease, TruDiagnostic™, Inc, TruDiagnostic™, Inc	0621U	NFCT DS LB DNA ALYS>10000	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026

TruD MDS Major Depressive Disorder, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0622U	PSYC MDD DNA ALYS >20000	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Multiple Sclerosis, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0623U	AI MS DNA MTHYL ALYS >5000	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS NASH, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0624U	HEP NASH DNA MTHYL ALYS 5000	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Osteoporosis, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0625U	ENDOCRINOL OP DNA ALYS>5000	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Parkinson's, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0626U	NEUROL PD DNA ALYS >20000	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
TruD MDS Schizophrenia, TruDiagnosticTM, Inc, TruDiagnosticTM, Inc	0627U	PSYC SCZ DNA ALYS >15000	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk	5	4/1/2026
RenaDxTM: Comprehensive Renal Disease Panel Test, Personalized Medicine Care Diagnostics, Personalized Medicine Care Diagnostics	0628U	NFRO KDN DS GENETIC COND 449	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles	5	4/1/2026
CRISPR-TB Blood TestTM, Ruthenium Diagnostics, LLC	0629U	NFCT DS TB DNA ALY 1TRGT PCR	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected	5	4/1/2026
Blueprint® Molecular Subtyping Test, Agendia® Inc	0630U	ONC BRST MRNA GEN PRFLG 80	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)	5	4/1/2026

