

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13763	Date: May 7, 2026
	Change Request 14476

SUBJECT: July 2026 Quarterly Update to the Clinical Laboratory Fee Schedule (CLFS) and Clinical Laboratory Improvement Amendments (CLIA): Healthcare Common Procedure Coding System (HCPCS) Codes, Waived Tests, and Reasonable Charge Payments

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of quarterly updates to the CLFS.

EFFECTIVE DATE: July 1, 2026

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

IMPLEMENTATION DATE: July 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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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

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I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of quarterly updates to the CLFS.

II. GENERAL INFORMATION

A. Background: This CR combines three formerly individual recurring CRs into one recurring quarterly CR:

- Quarterly CLFS updates
- Annual CLIA edits and new waived test updates
- Quarterly CLIA edits and new waived test updates

Clinical Laboratory Fee Schedule (CLFS):

- The CLFS, codified under Section 1833(h) of the Social Security Act, establishes Medicare Part B payment rates for clinical diagnostic laboratory tests (CDLTs) based on statutory methodologies and regulatory requirements at 42 CFR Part 414, Subpart G. Under the Protecting Access to Medicare Act (PAMA) of 2014, applicable laboratories must report private payer rates and associated volumes for each HCPCS code, which CMS uses to calculate a weighted median payment rate for each CDLT.
- This applies to Chapter 16, Section 20.

Clinical Laboratory Improvement Amendments (CLIA):

- The CLIA regulations require facilities to be appropriately certified for each test they perform. To ensure that Medicare and Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that qualifies as a CLIA laboratory test is currently edited at the CLIA certificate level. Each year, the HCPCS codes considered as laboratory tests under CLIA may change. Contractors need to be updated on the new HCPCS codes subject to and excluded from CLIA edits, as well as discontinued HCPCS codes.

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

- Protecting Access to Medicare Act of 2014 (PAMA)
 - 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% (15 percent) compared to the payment amount established for a test the preceding year.
 - Information on data collection and reporting can be found at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-pama-reporting-resources>
- 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 July 1, 2026
 - *Proprietary Laboratory Analysis (PLAs) and Additional New Codes*
 - Please see the table attached to the Transmittal entitled "**Quarter 3 of 2026 Update CLFS CLIA,**" Tab "**Q3 New Codes**".
 - The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of July 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, effective date, Type of Service (TOS) of each new code and CLIA status (Waived 'Y' or non-Waived 'N').
- Deleted Codes Effective July 1, 2026
 - Please see the table attached to the Transmittal entitled "**Quarter 3 of 2026 Update CLFS CLIA,**" Tab "**Q3 Deleted Codes.**" The listed codes are being deleted with a delete date of July 1, 2026.
 - The table includes the code, short descriptor and the delete date of the code.
- **Clinical Laboratory Improvement Amendments**
 - All HCPCS codes listed in "**Quarter 3 of 2026 Update CLFS CLIA,**" Tab "**Q3 New Codes**" with an indicator of 'N' in Column G are subject to CLIA edits . These HCPCS codes require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). Facilities without a valid, current CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2), or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4), must not be paid for these tests unless they bill the appropriate HCPCS service code with a QW modifier.
 - *****NOTE***** This instruction is NOT intended to replace any previous instructions indicating that laboratories with a valid CLIA certificate of waiver or CLIA certificate for provider-performed microscopy procedures can bill the above codes with a QW modifier. This applies to Chapter 16, Section 70.9.
 - Tests marked with an indicator of 'Y' in column G listed on "**Quarter 3 of 2026 Update CLFS CLIA,**" indicate the test(s) are approved by the Food and Drug

Administration (FDA) as waived tests under CLIA. The HCPCS codes for these new tests must include the QW modifier to be recognized as waived tests.

- This applies to Chapter 16, Section 70.8 of the IOM. Note: FDA approval information about these tests and their uses can be found by using the search feature at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm> and referring to the FDA Review Decision Summary documentation about the tests.

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
14476.1	<p>Contractors shall review the CY2026 CLFS Quarter 3 Updates; and</p> <ul style="list-style-type: none"> • Add new ADLT, CPT, and HCPCS codes (with TOS designations and effective dates) on the "Q3 New Codes" tab; and/or • Terminate HCPCS codes on the "Q3 Deleted Codes" tab 	X	X						X	CVM
14476.2	Contractors shall, as needed, update their systems/files with HCPCS codes subject to and excluded from CLIA editing, as identified in table "Quarter 3 of 2026_Update_CLFS_CLIA."		X						X	
14476.2.1	Contractors shall include new waived tests in CLIA covered code files. HCPCS codes must have the modifier QW to be recognized as a waived test(s).		X							
14476.3	Contractors shall apply CLIA edits to the HCPCS codes identified in table		X							

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	“Quarter 3 of 2026_Update_CLFS_CLIA” as subject to CLIA edits.									
14476.4	<p>Contractors shall deny claims submitted with the following criteria:</p> <ul style="list-style-type: none"> • CLIA certificate of waiver (certificate type code 2), when billed <i>without</i> the ‘QW’ modifier, OR • CLIA certificate for provider-performed microscopy procedures certificate type code 4) (when billed <i>without</i> the ‘QW’ modifier). 		X							
14476.5	Contractors shall not reject claims utilizing the FDA website Review Decision Summary (RDS) documentation for HCPCS codes identified in table “Quarter 3 of 2026_Update_CLFS_CLIA.”		X							
14476.6	Contractors shall update any new ADLT codes, and/or CPT/HCPCS codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as applicable.	X	X					X		
14476.7	Contractors shall locally price covered CLFS codes not on the quarterly CLFS	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	file or the quarterly Integrated Outpatient Code Editor (IOCE) until they appear on the CLFS file and/or IOCE.									
14476.8	Contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
14476.9	Contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X								
14476.10	Contractors shall retrieve the CY 2026 Clinical Laboratory Fee Schedule from the CMS cloud.	X								Hybrid Cloud Data Center (HCDC) , PCS
14476.11	Contractors shall process claims utilizing the cloud fee schedule for the payment limit of separately payable Medicare Part B laboratory tests.	X	X							PCS
14476.12	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors shall adjust claims if they are brought to their attention.	X	X							

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:
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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 July 1, 2026

The following new codes have been added to the national HCPCS file with an effective date of July 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.

Laboratory	HCPCS Code	Effective Date	Short Descriptor	Long Descriptor	TO S	CLIA waived ? "Y" or "N"	CLIA Waived Effective Date
Northstar Select CH™, BillionToOne Laboratory, BillionToOne, Inc	0631U	7/1/2026	ONC SOL TUM DNA SEQ ALYS 15	Oncology (solid tumor), DNA, sequence analysis of 15 genes including BRCA1 and BRCA2 for identification of clonal hematopoiesis, blood, reported as tumor-derived or nontumor-derived	5	N	7/1/2026
UNITY Fetal RhD NIPT, BillionToOne Laboratory, BillionToOne, Inc	0632U	7/1/2026	RBC AG FTL RHD GEN ALYS MPCR	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected (Do not report X219U in conjunction with 0488U)	5	N	7/1/2026
Fetal Focus, Natera™, Inc, Natera™, Inc	0633U	7/1/2026	OB 1-GENE N-INVAS PRNTL TST	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), next-generation sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm	5	N	7/1/2026

				reported as a fetal risk score			
GeneStrat® ESR1, Biodesix, Inc	0634U	7/1/2026	ONC BRST CA CFDNA EVL 11ESR1	Oncology (breast cancer), cell-free DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative	5	N	7/1/2026
AdvanceAD-Tx™, Castle Biosciences, Inc, Castle Biosciences, Inc	0635U	7/1/2026	AI AD MRNA GENE XPRSN 487GEN	Autoimmune (atopic dermatitis), mRNA, next-generation sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy	5	N	7/1/2026
Babesia ImmunoBlot IgG Test, IGeneX, Inc	0636U	7/1/2026	BABESIA 20 RPRTN GRPS IGG	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG	5	N	7/1/2026
Babesia ImmunoBlot IgM Test, IGeneX, Inc	0637U	7/1/2026	BABESIA 20 RPRTN GRPS IGM	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM	5	N	7/1/2026
Bartonella ImmunoBlot IgG Test, IGeneX, Inc	0638U	7/1/2026	BARTONELLA ANTB DETCJ 32 IGM	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG	5	N	7/1/2026

Bartonella ImmunoBlot IgM Test, IGeneX, Inc	0639U	7/1/2026	BARTONELLA ANTB DETCJ 32 IGG	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM	5	N	7/1/2026
CNSide CSF Tumor Cell Enumeration (TCE), CNSide® Diagnostics LLC, CNSide® Diagnostics LLC	0640U	7/1/2026	ONC LM TUMOR CELL SLCTN ID	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells	5	N	7/1/2026
PredicineBEACON Baseline, Predicine Inc, Predicine Inc	0641U	7/1/2026	ONC MRD TUM DNA NGS FFPE 1ST	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment	5	N	7/1/2026
PredicineBEACON MRD (Longitudinal), Predicine Inc, Predicine Inc	0642U	7/1/2026	ONC MRD TUM DNA NGS WHL BLD	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level	5	N	7/1/2026
PredicineCARE Urine Assay, Predicine Inc, Predicine Inc	0643U	7/1/2026	ONC GU CA CFCTDNA 200GEN NGS	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for single-nucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number	5	N	7/1/2026

				alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability			
FusionMRD™ Baseline, Pairidex®, Pairidex®	0644U	7/1/2026	ONC LEUKEMIA MRD BASELINE	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification	5	N	7/1/2026
FusionMRD™ Monitoring, Pairidex®, Pairidex®	0645U	7/1/2026	ONC LEUKEMIA MRD BASED DPCR	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance	5	N	7/1/2026
Plasma Detect Genome MRD - Baseline, Labcorp, Laboratory Developed Test	0646U	7/1/2026	ONC MR DS CFDNA WHL BLD&FFPE	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffin-embedded (FFPE) tumor tissue DNA, baseline assessment	5	N	7/1/2026
Plasma Detect Genome MRD - Monitoring, Labcorp, Laboratory Developed Test	0647U	7/1/2026	ONC MR DS WGS CFDNA CTDNA	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patient-specific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)	5	N	7/1/2026
Oncomine Dx Express Test, Thermo Fisher Scientific, Inc, Thermo Fisher Scientific, Inc	0648U	7/1/2026	ONC SOL TUM TGSA 42/10/18GEN	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from	5	N	7/1/2026

				formalin-fixed paraffin-embedded (FFPE) tissue			
MAP-AD®, ADmit Therapeutics S.L., ADmit Therapeutics S.L.	0649U	7/1/2026	NEURO ALZ DS DNA NGS AD-1&2	Neurology (Alzheimer disease), DNA, targeted next-generation sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status	5	N	7/1/2026
CKM PGx™ Panel (Hypertension and Cardiovascular-kidney-metabolic pharmacogenetic panel), Personalized Medicine Care Diagnostics	0650U	7/1/2026	RX METAB ADVRS RXNS&RSPSE 9	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function	5	N	7/1/2026
OncoDx™ (Hereditary Germline Cancer Genetics Panel), Personalized Medicine Care Diagnostics	0651U	7/1/2026	ONC HERED CA 55GEN NGS DMLPA	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification	5	N	7/1/2026
RenaPGx™ (Renal Pharmacogenetic Test), Personalized Medicine Care Diagnostics	0652U	7/1/2026	RX METAB ADVERSE DNA ALYS 13	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status	5	N	7/1/2026

RenaXome™ (Renal Disease Whole Exome Sequencing), Personalized Medicine Care Diagnostics	0653U	7/1/2026	NFRO INH KDN DO DNA 700GENS	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants	5	N	7/1/2026
Complex I Assembly Western Blot Assay, Children's Hospital Colorado Laboratory	0654U	7/1/2026	IEM PMD 1NZM COMPLEX WB ALYS	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result	5	N	7/1/2026
Complex V Hydrolysis Enzyme Assay, Children's Hospital Colorado Laboratory	0655U	7/1/2026	IEM PMD 1NZM COMPLEX SK ASY	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result	5	N	7/1/2026
Pyruvate Dehydrogenase (PDH) Enzyme Assay, Children's Hospital Colorado Laboratory	0656U	7/1/2026	IEM PMD 1NZM COMPLEX RADACT	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result	5	N	7/1/2026
GenomeDx Rapid, Comparator, GeneDx	0657U	7/1/2026	RARE DS SEQ ALYS CMPRTR NUC	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results (Use 0657U in conjunction with 0658U)	5	N	7/1/2026

GenomeDx Rapid, Proband, GeneDx	0658U	7/1/2026	RARE DS NUC&MITOCHDR L DNA	Rare diseases (constitutional/heritabl e disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants (Use 0658U in conjunction with 0657U)	5	N	7/1/2026
GenomeDx ultraRapid, Proband, GeneDx	0659U	7/1/2026	RARE DS ULTRAPID WGSALYS DNA	Rare diseases (constitutional/heritabl e disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next- generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants	5	N	7/1/2026

New Codes Effective July 1, 2026

The following new codes have been added to the national HCPCS file with an effective date of July 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.

Laboratory	HCPCS Code	Effective Date	Short Descriptor	Long Descriptor	TOS	CLIA waived? "Y" or "N"	CLIA Waived Effective Date
Northstar Select CH™, BillionToOne Laboratory, BillionToOne, Inc	0631U	7/1/2026	ONC SOL TUM DNA SEQ ALYS 15	Oncology (solid tumor), DNA, sequence analysis of 15 genes including BRCA1 and BRCA2 for identification of clonal hematopoiesis, blood, reported as tumor-derived or nontumor-derived	5	N	7/1/2026
UNITY Fetal RhD NIPT, BillionToOne Laboratory, BillionToOne, Inc	0632U	7/1/2026	RBC AG FTL RHD GEN ALYS MPCR	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected (Do not report X219U in conjunction with 0488U)	5	N	7/1/2026

Fetal Focus, Natera™, Inc, Natera™, Inc	0633U	7/1/2026	OB 1-GENE N-INVAS PRNTL TST	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), next-generation sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score	5	N	7/1/2026
GeneStrat® ESR1, Biodesix, Inc	0634U	7/1/2026	ONC BRST CA CFDNA EVL 11ESR1	Oncology (breast cancer), cell-free DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative	5	N	7/1/2026
AdvanceAD-Tx™, Castle Biosciences, Inc, Castle Biosciences, Inc	0635U	7/1/2026	AI AD MRNA GENE XPRSN 487GEN	Autoimmune (atopic dermatitis), mRNA, next-generation sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy	5	N	7/1/2026
Babesia ImmunoBlot IgG Test, IGeneX, Inc	0636U	7/1/2026	BABESIA 20 RPRTN GRPS IGG	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG	5	N	7/1/2026

Babesia ImmunoBlot IgM Test, IGeneX, Inc	0637U	7/1/2026	BABESIA 20 RPRTN GRPS IGM	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM	5	N	7/1/2026
Bartonella ImmunoBlot IgG Test, IGeneX, Inc	0638U	7/1/2026	BARTONELLA ANTB DETCJ 32 IGM	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG	5	N	7/1/2026
Bartonella ImmunoBlot IgM Test, IGeneX, Inc	0639U	7/1/2026	BARTONELLA ANTB DETCJ 32 IGG	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM	5	N	7/1/2026
CNSide CSF Tumor Cell Enumeration (TCE), CNSide® Diagnostics LLC, CNSide® Diagnostics LLC	0640U	7/1/2026	ONC LM TUMOR CELL SLCTN ID	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells	5	N	7/1/2026

PredicineBEACON Baseline, Predicine Inc, Predicine Inc	0641U	7/1/2026	ONC MRD TUM DNA NGS FFPE 1ST	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment	5	N	7/1/2026
PredicineBEACON MRD (Longitudinal), Predicine Inc, Predicine Inc	0642U	7/1/2026	ONC MRD TUM DNA NGS WHL BLD	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level	5	N	7/1/2026
PredicineCARE Urine Assay, Predicine Inc, Predicine Inc	0643U	7/1/2026	ONC GU CA CFCTDNA 200GEN NGS	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for single-nucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability	5	N	7/1/2026
FusionMRD™ Baseline, Pairidex®, Pairidex®	0644U	7/1/2026	ONC LEUKEMIA MRD BASELINE	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification	5	N	7/1/2026

FusionMRD™ Monitoring, Pairidex®, Pairidex®	0645U	7/1/2026	ONC LEUKEMIA MRD BASED DPCR	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance	5	N	7/1/2026
Plasma Detect Genome MRD - Baseline, Labcorp, Laboratory Developed Test	0646U	7/1/2026	ONC MR DS CFDNA WHL BLD&FFPE	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffin-embedded (FFPE) tumor tissue DNA, baseline assessment	5	N	7/1/2026
Plasma Detect Genome MRD - Monitoring, Labcorp, Laboratory Developed Test	0647U	7/1/2026	ONC MR DS WGSA CFDNA CTDNA	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patient-specific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)	5	N	7/1/2026
Oncomine Dx Express Test, Thermo Fisher Scientific, Inc, Thermo Fisher Scientific, Inc	0648U	7/1/2026	ONC SOL TUM TGSA 42/10/18GEN	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalin-fixed paraffin-embedded (FFPE) tissue	5	N	7/1/2026

MAP-AD [®] , ADmit Therapeutics S.L., ADmit Therapeutics S.L.	0649U	7/1/2026	NEURO ALZ DS DNA NGS AD-1&2	Neurology (Alzheimer disease), DNA, targeted next-generation sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status	5	N	7/1/2026
CKM PGx [™] Panel (Hypertension and Cardiovascular-kidney-metabolic pharmacogenetic panel), Personalized	0650U	7/1/2026	RX METAB ADVRS RXNS&RSPSE 9	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function	5	N	7/1/2026
OncoDx [™] (Hereditary Germline Cancer Genetics Panel), Personalized Medicine Care Diagnostics	0651U	7/1/2026	ONC HERED CA 55GEN NGS DMLPA	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification	5	N	7/1/2026
RenaPGx [™] (Renal Pharmacogenetic Test), Personalized Medicine Care Diagnostics	0652U	7/1/2026	RX METAB ADVERSE DNA ALYS 13	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status	5	N	7/1/2026

RenaXome™ (Renal Disease Whole Exome Sequencing), Personalized Medicine Care Diagnostics	0653U	7/1/2026	NFRO INH KDN DO DNA 700GENS	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants	5	N	7/1/2026
Complex I Assembly Western Blot Assay, Children's Hospital Colorado Laboratory	0654U	7/1/2026	IEM PMD 1NZM COMPLEX WB ALYS	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result	5	N	7/1/2026
Complex V Hydrolysis Enzyme Assay, Children's Hospital Colorado Laboratory	0655U	7/1/2026	IEM PMD 1NZM COMPLEX SK ASY	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result	5	N	7/1/2026
Pyruvate Dehydrogenase (PDH) Enzyme Assay, Children's Hospital Colorado Laboratory	0656U	7/1/2026	IEM PMD 1NZM COMPLEX RADACT	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result	5	N	7/1/2026

GenomeDx Rapid, Comparator, GeneDx	0657U	7/1/2026	RARE DS SEQ ALYS CMPRTR NUC	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results (Use 0657U in conjunction with 0658U)	5	N	7/1/2026
GenomeDx Rapid, Proband, GeneDx	0658U	7/1/2026	RARE DS NUC&MITOCHD RL DNA	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants	5	N	7/1/2026
GenomeDx ultraRapid, Proband, GeneDx	0659U	7/1/2026	RARE DS ULTRAPID WGSALYS DNA	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants	5	N	7/1/2026

Deleted Codes Effective July 1, 2026

The following codes are being deleted with a deletion date of July 1, 2026.

CPT Code	Short Descriptor	Delete Date
0029U	RX METAB ADVRS TRGT SEQ ALYS	7/1/2026
0031U	CYP1A2 GENE	7/1/2026
0423U	PSYC GENOMIC ALYS PNL 26 GEN	7/1/2026
0577U	ONC OVR SERUM ALYS 39 GPS	7/1/2026