CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13192	**Date: April 24, 2025**
	Change Request 14055

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: July 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 7, 2025

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/revised 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

Pub. 100-04	Transmittal: 13192	Date: April 24, 2025	Change Request: 14055

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

EFFECTIVE DATE: July 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 7, 2025

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.

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 (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019, through June 30, 2019.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests

On September 26, 2024, Section 221 of the Continuing Appropriations and Extensions Act, 2025 was passed and delayed data reporting requirements for CDLTs that are not advanced diagnostic laboratory tests, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation. Please see below for the following changes:

- The next data reporting period will be from January 1, 2026 – March 31, 2026, and based on the original data collection period of January 1, 2019, through June 30, 2019.
- A 0% payment reduction will be applied for Calendar Year (CY) 2025 so that a CDLT that is not an ADLT may not be reduced compared to the payment amount for that test in CY 2024, and for CYs 2026-2028 payment may not be reduced by more than 15-percent per year compared to the payment amount established for a test the preceding year.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2029, 2032, etc.).

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, 2025

Proprietary Laboratory Analysis (PLAs) and Additional New Codes

Please see the table attached to the Transmittal entitled **"CY2025 CLFS Quarter 3 Updates,"** Tab "**New Codes Effective 07-1-25.**" The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of July 1, 2025 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 descriptor, short descriptor, and Type of Service (TOS) of each new code.

Deleted Codes Effective July 1, 2025

Please see the table attached to the Transmittal entitled "**CY2025 CLFS Quarter 3 Updates,**" Tab "**Deleted Codes Effective 07-1-25.**" The listed codes are being deleted with a delete date of July 1, 2025.

The table includes the code, short 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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14055.1	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
14055.1.1	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,	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	contractors shall locally price the codes until they appear with a rate on the CLFS file and/or, for Part A claims, the IOCE.									
14055.2	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							
14055.3	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 July 1, 2025.	X	X							
14055.4	The A/B MACs Part A shall retrieve the CY 2025 Clinical Laboratory Fee Schedule from the CMS cloud on or after July 1, 2025.	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 July 1, 2025

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of July 1, 2025 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	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
Igenomix®, Part of Vitrolife Group™	0552U	Reproductive medicine (preimplantation genetic assessment), analysis for known genetic disorders from trophectoderm biopsy, linkage analysis of disease-causing locus, and when possible, targeted mutation analysis for known familial variant, reported as low-risk or high-risk for familial genetic disorder	REPR MED PGA GDO TE BX LOCUS	5	07/01/2025
Igenomix®, Part of Vitrolife Group™	0553U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested	REPR MED PGA EMBRY TE STRUX	5	07/01/2025
Igenomix®, Part of Vitrolife Group™	0554U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from trophectoderm biopsy for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal (euploidy), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested	REPR MED PGA 24CHRM TE BX QC	5	07/01/2025
Igenomix®, Part of Vitrolife Group™	0555U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested	REPR MED PGA EMBRYONIC TE QC	5	07/01/2025
HealthTrackRx	0556U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	NFCT DS P-S DNA&RNA 12 TRGTS	5	07/01/2025
HealthTrackRx	0557U	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism	NFCT DS BV DNA MRK VAG FLUID	5	07/01/2025
Milagen, Inc	0558U	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression	ONC CLRCT ELISA BF7 AG SERUM	5	07/01/2025
Milagen, Inc	0559U	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression	ONC BRS QUAN ELISA BF9AG SRM	5	07/01/2025
Quest Diagnostics®	0560U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments	ONC MRD GSA CFDNA BASELINE	5	07/01/2025
Quest Diagnostics®	0561U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD	ONC MRD GSA CFDNA SUBSEQUENT	5	07/01/2025
Personal Genome Diagnostics Inc	0562U	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants	ONC SOL TUM TGSA 33GENS SNVS	5	07/01/2025
bioMérieux	0563U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative	NFCT DS PTHGN-SNA 11VIR&4BCT	5	07/01/2025
bioMérieux	0564U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative	NFCT DS PTHGN-SNA 10VIR&4BCT	5	07/01/2025
EarlyDiagnostics Laboratory	0565U	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected	ONC HCC NGS DETC 6626EPIGALT	5	07/01/2025
Precision Epigenomics Inc	0566U	Oncology (lung), qPCR-based analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result	ONC LNG QPCR-BSD ALYS 13DMRS	5	07/01/2025

Variantyx Inc	0567U	Rare diseases (constitutional/heritable disorders), whole-genome sequence analysis combination of short and long reads, for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variants	RARE DS WHL GEN SEQ SRS&LRS	5	07/01/2025
Quanterix Corporation	0568U	Neurology (dementia), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology	NEUROL DEMENTIA βAMYL PTAU	5	07/01/2025
Guardant Health, Inc	0569U	Oncology (solid tumor), next-generation sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate	ONC SOL TUM NGS TMM>20000DMR	5	07/01/2025
Abbott Point of Care	0570U	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison	NEUROL TBI ALYS GFAP&UCH-L1	5	07/01/2025
Lucence Health, Inc	0571U	Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants	ONC SOL TUM DNA80&RNA10G NGS	5	07/01/2025
Life Length S.L.	0572U	Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer	ONC PRST8 HTTL QFISH WHL BLD	5	07/01/2025
Amplified Sciences, Inc	0573U	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous	ONC PANCREAS 3BMRK PCLF ALG	5	07/01/2025
NanoPin Technologies, Inc	0574U	Mycobacterium tuberculosis, culture filtrate protein-10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS)	MTB CFP-10 SERUM/PLSM LC-MS	5	07/01/2025

Deleted Codes Effective July 1, 2025		
The following codes are being deleted with a deletion date of July 1, 2025.		
CPT Code	**Short Descriptor**	**Delete Date**
0240U	NFCT DS VIR RESP RNA 3 TRGT	07/01/2025
0241U	NFCT DS VIR RESP RNA 4 TRGT	07/01/2025
0369U	IADNA GI PTHGN 31 ORG&21 ARG	07/01/2025
0370U	IADNA SURG WND PTHGN 34&21	07/01/2025
0373U	IADNA RSP TR NFCT 17 8 13&16	07/01/2025
0374U	IADNA GU PTHGN 21 ORG&21ARG	07/01/2025