CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13362	**Date: September 5, 2025**
	Change Request 14211

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: October 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 6, 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: 13362	Date: September 5, 2025	Change Request: 14211

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

EFFECTIVE DATE: October 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 6, 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 October 1, 2025

Proprietary Laboratory Analysis (PLAs) and Additional New Codes

Please see the table attached to the Transmittal entitled **"CY2025 CLFS Quarter 4 Updates,"** Tab "**New Codes Effective 10-1-25.**" The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of October 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 October 1, 2025

Please see the table attached to the Transmittal entitled "**CY2025 CLFS Quarter 4 Updates,**" Tab "**Deleted Codes Effective 10-1-25.**" The listed codes are being deleted with a delete date of October 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	
14211.1	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
14211.1.1	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	Shared-System Maintainers				Other
		A	B	HHH	MAC	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.									
14211.2	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							
14211.3	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 October 1, 2025.	X	X							PCS
14211.4	The A/B MACs Part A shall retrieve the CY 2025 Clinical Laboratory Fee Schedule from the CMS cloud on or after October 1, 2025.	X								Hybrid Cloud Data Center (HCDC), PCS

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 October 1, 2025

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 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
HepatoTrackTM, LuminoDx Laboratory, LuminoDx Inc	0575U	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes (miR-122, miR-885, miR-23a housekeeping, spike-in control), serum, algorithm reported as risk of liver allograft rejection	TRNSPLJ MED LAR RTPCR 4GENES	5	10/1/2025
OmniGraf® Liver, Eurofins Transplant Genomics, LLC, Eurofins Transplant Genomics, LLC	0576U	Transplantation medicine (liver allograft rejection), quantitative donor-derived cell-free DNA (cfDNA) by whole genome nextgeneration sequencing, plasma and mRNA gene expression profiling by multiplex real-time PCR of 56 genes, whole blood, combined algorithm reported as a rejection risk score	TRNSPLJ MED LAR QUAN DDCFDNA	5	10/1/2025
GlycoKnowTM Ovarian, InterVenn Biosciences	0577U	Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy	ONC OVR SERUM ALYS 39 GPS	5	10/1/2025
MerlinTM Test, SkylineDx USA, Inc, SkylineDx USA, Inc	0578U	Oncology (cutaneous melanoma), RNA, gene expression profiling by realtime qPCR of 10 genes (8 content and 2 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reports a binary result, either low-risk or high-risk for sentinel lymph node metastasis and recurrence	ONC CUTAN MLN RNA QPCR 10GEN	5	10/1/2025
Promarker®D, Proteomics International USA, Proteomics International Pty Ltd	0579U	Nephrology (diabetic chronic kidney disease), enzymelinked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline	NFRO DBTC CKD ELISA APOA4	5	10/1/2025
iDartTM Lyme IgG ImmunoBlot Kit, ID-FISH Technology, Inc	0580U	Borrelia burgdorferi, antibody detection of 24 recombinant protein groups, by immunoassay, IgG	BBRGDRFERI ANTB DETC 24RPRTN	5	10/1/2025
Autoantibody to NonHuman Leukocyte Antigen (non-HLA), Mayo Clinic Jacksonville, Mayo Clinic	0581U	Transplantation medicine, antibody to non-human leukocyte antigens (nonHLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported	Trnspl med antb nohla 39trgt	5	10/1/2025

Rapid Whole Genome Sequencing, Mayo Clinic, Mayo Clinic	0582U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome DNA sequencing for singlenucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported	Rare ds rpd whlgen dna vrnts	5	10/1/2025
Rapid Genome Sequencing Family Member Comparator, Mayo Clinic, Mayo Clinic	0583U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome comparator DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported with proband results (List separately in addition to code for primary procedure)	Rare ds rpd whlgen cmptr dna	5	10/1/2025
RT-QuIC Prion, CSF, Mayo Clinic, Mayo Clinic	0584U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quakinginduced conformational conversion, qualitative	Neuro csf prion prtn qual	5	10/1/2025
Labcorp® Plasma CompleteTM, Labcorp, Laboratory Developed Test	0585U	Targeted genomic sequence analysis panel, solid organ neoplasm, circulating cell-free DNA (cfDNA) analysis from plasma of 521 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability, report shows identified mutations, including variants with clinical actionability	Tgsap so neo cfdna 521 genes	5	10/1/2025
RNA Salah Targeted Expression Panel, Moffitt Cancer Center Advanced Diagnostics Laboratory, Laboratory Developed Test	0586U	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalinfixed paraffin-embedded (FFPE) tissue, quantitative, reported as log2 ratio per gene	Onc mrna gen xprsn 216 genes	5	10/1/2025
SafeDrugs, Astraeus Lab, LLC, Quantlio Technologies	0587U	Therapeutic drug monitoring, 60-150 drugs and metabolites, urine, saliva, quantitative liquid chromatography with tandem mass spectrometry (LCMS/MS), specimen validity, and algorithmic analyses for presence or absence of drug or metabolite, risk score predicted for adverse drug effects	Ther rx mntr 60150rx&metabl	5	10/1/2025
TriVerityTM, InflammatixTM, Inc	0588U	Infectious disease (bacterial or viral), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by splitwell multiplex reverse transcription loop-mediated isothermal amplification (RTLAMP), whole blood, reported as continuous risk scores for likelihood of bacterial and viral infection and likelihood of severe illness within the next 7 days	Nfct ds bct/vir 32genes mrna	5	10/1/2025
PFAS (Forever Chemicals) Panel 2 – 24 PFAS, Quest Diagnostics®, Quest Diagnostics®	0589U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LCMS/MS), plasma or serum, quantitative	Pfas24cmpnd hiperf lc-ms/ms	5	10/1/2025

BIOTIA-IDTM Urine NGS Assay, Biotia Inc, Biotia Inc	0590U	Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism	Nfct ds bct&fngl dna 44 orgs	5	10/1/2025
MiCheck® Prostate, Minomic®, Inc, Minomic®, Inc	0591U	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer	Onc prst8 ca 3prtns plsm srm	5	10/1/2025
Aventa Lymphoma, Aventa Genomics, LLC	0592U	Oncology (hematolymphoid neoplasms), DNA, targeted genomic sequence of 417 genes, interrogation for gene fusions, translocations, rearrangements, utilizing formalin-fixed paraffinembedded (FFPE) tumor tissue, results report clinically significant variant(s)	Onc hl neo dna tgs 417 genes	5	10/1/2025
Taq Array Card Urinary Tract Infection PCR Panel, SoftCell Laboratories LLC, Doc Lab Inc	0593U	Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected	Nfct ds gu pthgn dna 46trgt	5	10/1/2025
IVD CAPSULE PSP – Rapid Sepsis Test, Abionic SA	0594U	Infectious disease (sepsis), semiquantitative measurement of pancreatic stone protein concentration, whole blood, reported as risk of sepsis	Nfct ds sepsis pncrtc spc	5	10/1/2025
BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel, bioMérieux, bioMérieux	0595U	Infectious disease (tropical fever pathogens), vectorborne and zoonotic pathogens, including 2 viruses (Chikungunya virus and Dengue virus serotypes 1, 2, 3, and 4), 1 bacterium (Leptospira species), and 1 parasite with species differentiation (Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale), real-time RTPCR, whole blood, each pathogen reported as detected or not detected	Nfct ds tfp vctrbrn&zoonotic	5	10/1/2025
Precivity-ApoETM, C2N Diagnostics, LLC	0596U	Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LCMS/MS), reported as an APOE prototype	Neuro alzds plsm 3dstnct isp	5	10/1/2025
AidaBreastTM, PreludeDxTM, Prelude Corporation	0597U	Oncology (breast), RNA expression profiling of 329 genes by targeted nextgeneration sequencing and 20 proteins by multiplex immunofluorescence, formalin-fixed paraffinembedded (FFPE) tissue, algorithmic analyses to determine tumor-recurrence risk score	Onc breast rna xprsn 329gens	5	10/1/2025
inFoods® IBS, Ethos Laboratories, Biomerica	0598U	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels	Gi ibs igg antb 18food items	5	10/1/2025

PancreaSureTM, Immunovia, Inc, Immunovia, Inc	0599U	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative	Onc pncrtc ca mult ia serum	5	10/1/2025

Deleted Codes Effective October 1, 2025		
The following codes are being deleted with a deletion date of October 1, 2025.		
CPT Code	**Short Descriptor**	**Delete Date**
0450U	ONC MM LC-MS/MS MONOC P-PRTN	10/1/2025
0451U	ONC MM LC-MS/MS PEP ION QUAN	10/1/2025