CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12021	**Date: May 4, 2023**
	Change Request 13195

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 clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: July 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 3, 2023

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: 12021	Date: May 4, 2023	Change Request: 13195

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

EFFECTIVE DATE: July 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 3, 2023

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

B. Policy: Clinical Laboratory Fee Schedule

Expiration of the federal Public Health Emergency for COVID-19 (PHE)

- Under Section 319 of the Public Health Service Act, the Department of Health and Human Services federal PHE expires effective May 11, 2023. Because of the termination of the PHE, Healthcare Common Procedure Coding System (HCPCS) codes G2023, G2024, U0003, U0004, and U0005 will no longer be payable for dates of service on or after May 12, 2023, and the HCPCS codes will be terminated.

DELAYED- The Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests (CDLTs) is DELAYED until January 1, 2024 - March 31, 2024

- On December 29, 2022, Section 4114 of Consolidated Appropriations Act, 2023 revised the next data reporting period for CDLTs that are not Advanced Diagnostic Laboratory (ADLTs) and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. The next data reporting period of **January 1, 2024 through March 31, 2024**, will be based on the original data collection period of January 1, 2019 through June 30, 2019. After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs (that is 2027, 2030, etc.).

- 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 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.

- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through Calendar Year (CY) 2026. There is a 0.0 percent reduction for CYs 2021, 2022, and 2023 and payment may not be reduced by more than 15 percent for CYs 2024 through 2026.

Calendar Year (CY) 2023 Medicare Physician Fee Schedule (PFS) Final Rule:

On November 1, 2022, the CMS issued a final rule that includes updates and policy changes for Medicare payments under the PFS, and other Medicare Part B issues, effective on or after January 1, 2023.

CLFS updates and policy changes are as follows:

- Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests
    - Specimen Collection Policy: We finalized an increase to the nominal fee for specimen collection based on the Consumer Price Index for all Urban Consumers (CPI-U). Therefore, for CY 2023, the general specimen collection fee will increase from $3 to $8.57 and as required by Protecting Access to Medicare Act of 2014 (PAMA), we will increase this amount by $2 for those specimens collected from a Medicare beneficiary in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA), which will result in a $10.57 specimen collection fee for those beneficiaries. In addition, we finalized a policy to update this fee amount annually by the percent change in the CPI-U. We also finalized our proposals to codify and clarify various laboratory specimen collection fee policies in § 414.523(a)(1). This is because the policies implementing the statutory
    - requirements under section 1833(h)(3)(A) of the Act for the laboratory specimen collection fee, which are currently described in the Medicare Claims Processing Manual publication 100-04, chapter 16, § 60.1, did not have corresponding regulations text and some of the manual guidance is no longer applicable.
    -
    - Travel Allowance Policy: We finalized as proposed to codify in our regulations, and make certain modifications and clarifications to, the Medicare CLFS travel allowance policies. We finalized the addition of § 414.523(a)(2) "Payment for travel allowance" to reflect the requirements for the travel allowance for specimen collection. Specifically, in accordance with section 1833(h)(3)(B) of the Act, we finalized to include in our regulations the following requirements for the travel allowance methodology: (1) a general requirement, (2) travel allowance basis requirements, and (3) travel allowance amount requirements.

- Please refer to the following CMS websites for additional information regarding these policies:

    - https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched
    - https://www.cms.gov/files/document/mm13071-travel-allowance-fees-specimen-collection-2023-updates.pdf

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, 2023

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled **"CY2023 CLFS Quarter 3 Updates"**, Tab "**New Codes Effective 07-01-2023**". The listed new codes were added to the national HCPCS file with an effective date of July 1, 2023 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. The table includes the laboratory, long descriptor, short descriptor, and type of service (TOS) of each new code.

Deleted Codes Effective July 1, 2023

Please see table attached to the Transmittal entitled "**CY2023 CLFS Quarter 3 Updates**", Tab "**Delete Codes Eff. 07-01-2023**". The listed codes are being deleted with a delete date of July 1, 2023.

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

II. 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	CWF	
13195.1	Contractors shall be aware that the CLFS will be released quarterly, as needed, and establish hours to accommodate retrieval and implementation of the quarterly CLFS data file.	X	X							VDC
13195.1.1	CMS shall notify contractors by email approximately six weeks prior to the beginning of the quarter when the CLFS data file is ready for download. CMS shall provide the file name.									CMS
13195.2	Contractors shall retrieve and load for testing and claims processing purposes the July 2023 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
13195.2.1	Contractors shall note that two CLFS data files will be available. Contractors shall use the file that they prefer. The CLFS data file name will be in the following format: Date File #1: MU00.@BF12394.CLAB.VyyyyQr.UPDTONLY Data File #2: MU00.@BF12394.CLAB.VyyyyQr.FU	X	X							VDC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	LLREPL Note: Data File #1 includes the changes only file (i.e., the changes from the previous quarter). Data File #2 includes the full replacement file. The naming convention of the file is such that "yyyy" equals the calendar year (for example, V2020) and "r" equals the release number (for example, Q3 reflects Quarter 3 or July release) with January = 1, April = 2, July = 3, and October = 4 For example, for the July release or the 3rd quarter release of 2023, the data file names are listed below: Data File #1: MU00.@BF12394.CLAB.V2023Q3.UPDTONLY Data File #2: MU00.@BF12394.CLAB.V2023Q3.FULLREPL									
13195.2.2	Contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., SSM or A/B MAC Part B name and number).	X	X							VDC
13195.2.3	Contractors shall address any questions/concerns regarding the content of the files and/or specific HCPCS codes contained within by emailing CLFS_Inquiries@cms.hhs.gov.	X	X							VDC
13195.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This requirement is applicable to the January quarterly release CR only).		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13195.4	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients (**NOTE** - This requirement is applicable to the January quarterly release CR only).	X								
13195.5	Contractors shall be aware of any new Advanced Diagnostic Laboratory Test (ADLT) codes, and/or 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	
13195.5.1	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 on the CLFS file and/or, for Part A claims, the IOCE.	X	X							
13195.6	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							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13195.7	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects®	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.					

IV. 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

V. CONTACTS

Pre-Implementation Contact(s): Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov , Rasheeda Arthur, 410-786-3434 or rasheeda.johnson1@cms.hhs.gov

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

VI. 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, 2023

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of July 1, 2023 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
AMBLor® melanoma prognostic test, Avero® Diagnostics	0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression (Do not report 0387U in conjunction with 88341, 88342)	ONC MLNMA AMBRA1&AMLO	5	07/01/2023
InVisionFirst®-Lung Liquid Biopsy, Inivata, Inc, Inivata, Inc	0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection	ONC NONSM CLL LNG CA 37 GEN	5	07/01/2023
KawasakiDx, OncoOmicsDx Laboratory, mProbe	0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alphainducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD	PED FBRL KD IFI27&MCEMP1 RNA	5	07/01/2023
PEPredictDx, OncoOmicsDx Laboratory, mProbe	0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score	OB PE KDR ENG&RBP4 IA ALG	5	07/01/2023
Strata SelectTM, Strata Oncology, Inc, Strata Oncology, Inc	0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score	ONC SLD TUM DNA&RNA 437 GEN	5	07/01/2023
Medication Management Neuropsychiatric Panel, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug	RX METAB GENRX IA 16 GENES	5	07/01/2023
SYNTap® Biomarker Test, Amprion Clinical Laboratory, Amprion Clinical Laboratory	0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative	NEU PRKSN MSFL α-SYNCLN PRTN	5	07/01/2023
PFAS Testing & PFASureTM, National Medical Services, NMS Labs, Inc	0394U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative	PFAS 16 PFAS COMPND LC MS/MS	5	07/01/2023
OncobiotaLUNG, MicronomaTM, MicronomaTM	0395U	Oncology (lung), multi-omics (microbial DNA by shotgun nextgeneration sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease	ONC LNG MULTIOMICS PLSM ALG	5	07/01/2023
Spectrum PGT-M, Natera, Inc, Natera, Inc	0396U	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions	OB PREIMPLTJ TST 300000 DNA	5	07/01/2023
Agilent Resolution ctDx FIRST, Resolution Bioscience, Inc, Resolution Bioscience, Inc	0397U	Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations	ONC NONSM CLL LNG CA 109	5	07/01/2023
ESOPREDICT® Barrett's Esophagus Risk Classifier Assay, Capsulomics, Inc d/b/a Previse	0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer	GI BARET ESPH DNA MTHYLN ALY	5	07/01/2023
FRAT® (Folate Receptor Antibody Test), Religen Inc, Religen Inc	0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected	NEURO CERE FOLATE DEFNCY SRM	5	07/01/2023
Genesys Carrier Panel, Genesys Diagnostics, Inc	0400U	Obstetrics (expanded carrier screening), 145 genes by nextgeneration sequencing, fragment analysis and multiplex ligationdependent probe amplification, DNA, reported as carrier positive or negative	OB XPND CAR SCR 145 GENES	5	07/01/2023
CARDIO inCodeScore (CICSCORE), GENinCode U.S. Inc, GENinCode U.S. Inc	0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event	CRD C HRT DS 9 GEN 12 VRNTS	5	07/01/2023

Deleted Codes Effective July 1, 2023		
The following codes are being deleted with a deletion date of July 1, 2023.		
CPT Code	**Long Descriptor**	**Delete Date**
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade	07/01/2023
0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	07/01/2023