CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11829	**Date: February 2, 2023**
	Change Request 13082

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule 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: April 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 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: 11829	Date: February 2 , 2023	Change Request: 13082

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

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

DELAYED- The Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests 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 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 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.
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through 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 Final (PFS) 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/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests

New Codes Effective April 1, 2023

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled **"CY2023 CLFS Quarter 2 Updates"**, Tab "**New Codes Effective 04-01-2023**". The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of April 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 April 1, 2023

Please see table attached to the Transmittal entitled "**CY2023 CLFS Quarter 2 Updates**", Tab "**Delete Codes Eff. 04-01-2023**". The listed codes are being deleted with a delete date of April 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	
13082.1	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
13082.1.1	CMS shall notify contractors by email approximately six weeks prior to the beginning of the quarter when the Clinical Laboratory Fee Schedule (CLFS) data file is ready for download. CMS shall provide the file name.									CMS
13082.2	Contractors shall retrieve and load for testing and claims processing purposes the April 2023 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
13082.2.1	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.FULLREPL 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	X	X							VDC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	July release) with January = 1, April = 2, July = 3, and October = 4 For example, for the April release or the 2nd quarter release of 2023, the data file names are listed below: Data File #1: MU00.@BF12394.CLAB.V2023Q2.UPDTONLY Data File #2: MU00.@BF12394.CLAB.V2023Q2.FULLREPL									
13082.2.2	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
13082.2.3	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
13082.3	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							
13082.4	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								
13082.5	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	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13082.5.1	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							
13082.6	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		
13082.7	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® 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.	X	X			

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 April 1, 2023

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of April 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
clonoSEQ® Assay, Adaptive Biotechnologies	0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate	ONC HL NEO GEN SEQ ALYS ALG	5	04/01/2023
Oncuria® Detect, DiaCarta Clinical Lab, DiaCarta, Inc	0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer	ONC BLDR 10 PRB BLDR CA	5	04/01/2023
Oncuria® Monitor, DiaCarta Clinical Lab, DiaCarta, Inc	0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer	ONC BLDR 10 PRB RECR BLDR CA	5	04/01/2023
Oncuria® Predict, DiaCarta Clinical Lab, DiaCarta, Inc	0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection	ONC BLDR 10 FLWG TRURL RESCJ	5	04/01/2023
GI assay (Gastrointestinal Pathogen with ABR), Lab Genomics LLC, Thermo Fisher Scientific	0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique	IADNA GI PTHGN 31 ORG&21 ARG	5	04/01/2023
Lesion Infection (Wound), Lab Genomics LLC, Thermo Fisher Scientific	0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibioticresistance genes, multiplex amplified probe technique, wound swab	IADNA SURG WND PTHGN 34&21	5	04/01/2023
Qlear UTI, Lifescan Labs of Illinois, Thermo Fisher Scientific	0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine	IADNA GU PTHGN SEMIQ DNA16&1	5	04/01/2023
Qlear UTI - Reflex ABR, Lifescan Labs of Illinois, Thermo Fisher Scientific	0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	NFCT DS GU PTHGN ARG DETCJ	5	04/01/2023
Respiratory Pathogen with ABR (RPX), Lab Genomics LLC, Thermo Fisher Scientific	0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen	IADNA RSP TR NFCT 17 8 13&16	5	04/01/2023
Urogenital Pathogen with Rx Panel (UPX), Lab Genomics LLC, Thermo Fisher Scientific	0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine	IADNA GU PTHGN 21 ORG&21ARG	5	04/01/2023
OvaWatchSM, Aspira Women's HealthSM, Aspira Labs, Inc	0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score	ONC OVRN BCHM ASY 7 PRTN ALG	5	04/01/2023
ArteraAI Prostate Test, Artera Inc©, Artera Inc©	0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate	ONC PRST8 CA IMG ALYS 128	5	04/01/2023
Liposcale®, CIMA Sciences, LLC	0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)	CV DS QUAN ADVSRM/PLSM LPRTN	5	04/01/2023
UCGSL RFC1 Repeat Expansion Test, University of Chicago Genetic Services Laboratories	0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab	RFC1 REPEAT XPNSJ VRNT ALYS	5	04/01/2023
Solid Tumor Expanded Panel, Quest Diagnostics®, Quest Diagnostics®	0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden	TGSAP SL OR NEO DNA523&RNA55	5	04/01/2023
PersonalisedRX, Lab Genomics LLC, Agena Bioscience, Inc	0380U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype	RX METB ADVRS TRGT SQ ALY 20	5	04/01/2023

Branched-Chain Amino Acids, SelfCollect, Blood Spot, Mayo Clinic, Laboratory Developed Test	0381U	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of alloisoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LCMS/MS)	MAPLE SYRUP UR DS MNTR QUAN	5	04/01/2023
Phenylalanine and Tyrosine, SelfCollect, Blood Spot, Mayo Clinic, Laboratory Developed Test	0382U	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)	HYPRPHENYLALNI NMIA MNTR QUAN	5	04/01/2023
Tyrosinemia FollowUp Panel, SelfCollect, Blood Spot, Mayo Clinic, Laboratory Developed Test	0383U	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)	TYROSINEMIA TYP I MNTR QUAN	5	04/01/2023
NaviDKDTM Predictive Diagnostic Screening for Kidney Health, Journey Biosciences, Inc, Journey Biosciences, Inc	0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease	NEPH CKD RSK HI STG KDN DS	5	04/01/2023
PromarkerD, Sonic Reference Laboratory, Proteomics International Pty Ltd	0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing	NEPH CKD ALG RSK DBTC KDN DS	5	04/01/2023
Envisage, Capsulomics, Inc, Capsulomics, Inc	0386U	Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer	GI BARRETT ESOPH MTHYLTN ALY	5	04/01/2023

Deleted Codes Effective April 1, 2023		
The following codes are being deleted with a deletion date of April 1, 2023.		
CPT Code	**Long Descriptor**	**Delete Date**
0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug	04/01/2023
0325U	Oncology (ovarian), spheroid cell culture, poly (ADPribose) polymerase (PARP) inhibitors (niraparib, olaparib,rucaparib, velparib), tumor response prediction for each drug	04/01/2023