

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12210	Date: August 17, 2023
	Change Request 13321

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: October 1, 2023

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

IMPLEMENTATION DATE: October 2, 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: 12210	Date: August 17, 2023	Change Request: 13321
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SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: October 1, 2023

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

IMPLEMENTATION DATE: October 2, 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 (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 October 1, 2023

Proprietary Laboratory Analysis (PLAs) and Additional New Codes

Please see table attached to the Transmittal entitled "**CY2023 CLFS Quarter 4 Updates,**" Tab "**New Codes Effective 10-1-23.**" The listed new codes were added to the national HCPCS file with an effective date of October 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 October 1, 2023

Please see table attached to the Transmittal entitled "**CY2023 CLFS Quarter 4 Updates,**" Tab "**Deleted Codes Effective 10-1-23.**" The listed codes are being deleted with a delete date of October 1, 2023.

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

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	
	<p>October = 4</p> <p>For example, for the October release or the 4th quarter release of 2023, the data file names are listed below:</p> <p>Data File #1: MU00.@BF12394.CLAB.V2023Q4.UPDTONLY</p> <p>Data File #2: MU00.@BF12394.CLAB.V2023Q4.FULLREPL</p>									
13321.2.2	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							VD C
13321.2.3	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							VD C
13321.3	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							
13321.4	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								
13321.5	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),	X	X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	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.									
13321.5.1	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							
13321.6	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		
13321.7	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:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

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 October 1, 2023

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 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
Abbott AlinityTM m STI Assay, Abbott Molecular, Inc	0402U	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected	NFCT AGT STI MULT AMP PRB TO	5	10/01/23
MyProstateScore 2.0, LynxDX, LynxDX	0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer	ONC PRST8 MRNA 18 GEN DRE UR	5	10/01/23
DiviTum@TKa, Biovica Inc, Biovica International AB	0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression	ONC BRST SEMIQ MEAS THYM KN	5	10/01/23
BTG Early Detection of Pancreatic Cancer, Breakthrough Genomics, Breakthrough Genomics	0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected	ONC PNCRTC 59 MTHLTN BLK MRK	5	10/01/23
CyPath® Lung, Precision Pathology Services, bioAffinity Technologies, Inc	0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer	ONC LUNG FLOW CYTMTRY 5 MRK	5	10/01/23
IntexDKDTM, Renalytix Inc, Renalytix Inc, NYC, NY	0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function	NEPH DBTC CKD MULT ECLIA ALG	5	10/01/23
OmniaTM SARSCoV-2 Antigen Test, Qorvo Biotechnologies, Qorvo Biotechnologies	0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])	IAAD BLK AC WV BSNR SARSCV2	5	10/01/23
LiquidHALLMARK®, Lucence Health, Inc	0409U	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability	ONC SLD TUM DNA 80 & RNA 36	5	10/01/23
AvantectTM Pancreatic Cancer Test, ClearNoteTM Health, ClearNoteTM Health	0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected	ONC PNCRTC DNA WHL GN SEQ 5-	5	10/01/23
IDgenetix®, Castle Biosciences, Inc, Castle Biosciences, Inc	0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6 (For additional PLA code with identical clinical descriptor, see 0345U. See Appendix O to determine appropriate code assignment)	PSYC GENOM ALYS PNL 15 GEN	5	10/01/23
PrecivityAD® blood test, C2N Diagnostics LLC, C2N Diagnostics LLC	0412U	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology	BETA AMYLOID Aβ42/40 IMPRCIP	5	10/01/23
DH Optical Genome Mapping/Digital Karyotyping Assay, The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, Bionano Genomics	0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations	ONC HL NEO OPT GEN MAPG DNA	5	10/01/23
LungOI, Imagene	0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffinembedded (FFPE) tissue, reported as positive or negative for each biomarker	ONC LNG AUG ALG ALY WHL SLD8	5	10/01/23
SmartHealth Vascular DxTM, Morningstar Laboratories, LLC, SmartHealth DX	0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS	CV DS ACS BLD ALG 5 YR SCORE	5	10/01/23
GENETWORx UTI with ABR, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	0416U	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine	IADNA GU PTHGN 20BCT&FNG ORG	5	10/01/23
Genomic Unity® Comprehensive Mitochondrial Disorders Analysis, Variantyx Inc, Variantyx Inc	0417U	Rare diseases (constitutional/hereditary disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder-associated genetic variants	RARE DS ALYS 335 NUC GENES	5	10/01/23
PreciseDx Breast Biopsy Test, PreciseDx, PreciseDx, Inc NYC, NY	0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	ONC BRST AUG ALG ALY WHL SL8	5	10/01/23
Tempus nP, Tempus Labs, Inc, Tempus Labs, Inc	0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	NRPSYC GEN SEQ VRNT ALY 13	5	10/01/23

Additional Codes

The following new code has been added to the national HCPCS file and does not need to be manually added to the HCPCS files by the MACs. However, this new code is 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).

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
SOMAmer® SomaLogic	0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations	CV DS PLASMA ALYS PRTN BMRK	5	10/01/23

Deleted Codes Effective October 1, 2023

The following codes are being deleted with a deletion date of October 1, 2023.

CPT Code	Long Descriptor	Delete Date
0357U	Oncology (melanoma), artificial intelligence (AI)-enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents	10/01/2023
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	10/01/2023
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	10/01/2023