CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11551	**Date: August 11, 2022**
	Change Request 12870

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 change request is to provide instructions for the quarterly update to the clinical laboratory fee schedule. This recurring update notification applies to chapter 16, section 20.

EFFECTIVE DATE: October 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2022

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: 11551	Date: August 11, 2022	Change Request: 12870

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

EFFECTIVE DATE: October 1, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2022

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

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following Centers for Medicare & Medicaid Services (CMS) website for additional information regarding these tests: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests--DELAYED

On December 10, 2021, the "Protecting Medicare and American Farmers from Sequester Cuts Act" (S. 610) delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in reduction.

- 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 next data reporting period of January 1, 2023 through March 31, 2023, 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 2026, 2029, etc.).

- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through Calendar Year (CY) 2025. There is a 0.0 percent reduction for CY 2021 and CY 2022, and payment may not be reduced by more than 15 percent for CYs 2023 through 2025.

Clinical Laboratory Fee Schedule Beginning January 1, 2018

- Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by the PAMA of 2014.

- The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

- For more details, visit PAMA Regulations, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

- **Access to Data File:** The quarterly clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Under normal circumstances, CMS will make the updated CLFS data file available to the A/B MACs Parts A and B approximately six (6) weeks prior to the beginning of each quarter. For example, the updated file will typically be made available for download and testing on or before approximately February 15th for the April 1st release. Internet access to the quarterly clinical laboratory fee schedule data file shall be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, shall use the Internet to retrieve the quarterly clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

- **Pricing Information:** The clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees are established in accordance with section 1833(h)(4)(B) of the Act. Also note additional specimen collection codes may be listed below during the PHE.

New Codes Effective October 1, 2022

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled **"New Codes Effective October 1, 2022*"**, Tab "**New Codes**". The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of October 1, 2022 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 also includes code 87593, which will also be contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process.

The table includes the laboratory, long descriptor, short descriptor, and Type of Service (TOS) of each new code.

In addition, the following HCPCS codes were discontinued on September 30, 2022, and are to be removed from the CLFS: 0012U (short descriptor, Germln do gene reargmt detcj); 0013U (short descriptor, Onc sld org neo gene reargmt); 0014U (short descriptor, Hem hmtlmf neo gene reargmt); and 0056U (short descriptor, Hem aml dna gene reargmt).

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	
12870.1	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
12870.1.1	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
12870.2	Contractors shall retrieve and load for testing and claims processing purposes the October 2022 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
12870.2.1	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 July release) with January = 1, April = 2, July = 3, and October = 4	X	X							VDC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	For example, for the October release or the 4th quarter release of 2022, the data file names are listed below: Data File #1: MU00.@BF12394.CLAB.V2022Q4.UPDTONLY Data File #2: MU00.@BF12394.CLAB.V2022Q4.FULLREPL									
12870.2.2	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
12870.2.3	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
12870.3	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 Change Request (CR) only).	X	X							
12870.4	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								
12870.5	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	X	X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	applicable listed in this CR and shall update their systems as necessary to accept/delete/terminate them.									
12870.5.1	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							
12870.6	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		
12870.7	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 , Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@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 October 1, 2022

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 1, 2022 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
EpiSwitch® CiRT (Checkpointinhibitor Response Test), Next Bio-Research Services, LLC, Oxford BioDynamics, PLC	0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy	ONC PAN TUM GEN PRFLG 8 DNA	5	10/01/22
HelioLiver™ Test, Fulgent Genetics, LLC, Helio Health, Inc	0333U	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in highrisk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gammacarboxy-prothrombin (DCP), algorithm reported as normal or abnormal result	ONC LVR SURVEILANC HCC CFDNA	5	10/01/22
Guardant360 TissueNext™, Guardant Health, Inc, Guardant Health, Inc	0334U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffinembedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	ONC SLD ORGN TGSA DNA 84/+	5	10/01/22
IriSight™ Prenatal Analysis – Proband, Variantyx, Inc, Variantyx, Inc	0335U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants □(Do not report 0335U in conjunction with 81425, 0212U)□	RARE DS WHL GEN SEQ FETAL	5	10/01/22
IriSight™ Prenatal Analysis – Comparator, Variantyx, Inc, Variantyx, Inc	0336U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent) □(Do not report 0336U in conjunction with 81426, 0213U)□	RARE DS WHL GEN SEQ BLD/SLV	5	10/01/22
CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC) Test, Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	0337U	Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization, and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood	ONC PLSM CELL DO&MYELOMA ID	5	10/01/22
CELLSEARCH® HER2 Circulating Tumor Cell (CTCHER2) Test, Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	0338U	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker–expressing cells, peripheral blood	ONC SLD TUM CRCG TUM CL SLCT	5	10/01/22
SelectMDx® for Prostate Cancer, MDxHealth®, Inc, MDxHealth®, Inc	0339U	Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer	ONC PRST8 MRNA HOXC6 & DLX1	5	10/01/22
Signatera™, Natera, Inc, Natera, Inc	0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate	ONC PAN CA ALYS MRD PLASMA	5	10/01/22
Single Cell Prenatal Diagnosis (SCPD) Test, Luna Genetics, Inc, Luna Genetics, Inc	0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid	FTL ANEUP DNA SEQ CMPR ALYS	5	10/01/22
IMMray® PanCan-d, Immunovia, Inc, Immunovia, Inc	0342U	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline	ONC PNCRTC CA MULT IA ECLIA	5	10/01/22
miR Sentinel™ Prostate Cancer Test, miR Scientific, LLC, miR Scientific, LLC	0343U	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer	ONC PRST8 XOM ALY 442 SNCRNA	5	10/01/22
OWLiver®, CIMA Sciences, LLC	0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH	HEP NAFLD SEMIQ EVL 28 LIPID	5	10/01/22
GeneSight® Psychotropic, Assurex Health, Inc, Myriad Genetics, Inc	0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	PSYC GENOM ALYS PNL 15 GEN	5	10/01/22
QUEST AD-Detect™, BetaAmyloid 42/40 Ratio, Plasma, Quest Diagnostics	0346U	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma	BETA AMYL Aβ40&Aβ42 LC-MS/MS	5	10/01/22
RightMed® PGx16 Test, OneOme®, OneOme®, LLC	0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes	RX METAB/PCX DNA 16 GEN ALYS	5	10/01/22
RightMed® Comprehensive Test Exclude F2 and F5, OneOme®, OneOme®, LLC	0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes	RX METAB/PCX DNA 25 GEN ALYS	5	10/01/22
RightMed® Comprehensive Test, OneOme®, OneOme®, LLC	0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions	RX METAB/PCX DNA 27GEN RX IA	5	10/01/22
RightMed® Gene Report, OneOme®, OneOme®, LLC	0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes	RX METAB/PCX DNA 27 GEN ALYS	5	10/01/22

MeMed BV®, MeMed Diagnostics, Ltd, MeMed Diagnostics, Ltd	0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factorrelated apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection	NFCT DS BCT/VIRAL TRAIL IP10	5	10/01/22
Xpert® Xpress MVP, Cepheid®	0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis–associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected	NFCT DS BV&VAGINITIS AMP PRB	5	10/01/22
Xpert® CT/NG, Cepheid®	0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected	IADNA CHLMYD&GONORR AMP PRB	5	10/01/22
PreTect HPV-Proofer' 7, GenePace Laboratories, LLC, PreTech	0354U	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)	HPV HI RSK QUAL MRNA E6/E7	5	10/01/22
The following new code is contractor-priced (where applicable) until it is 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).					
	87593	Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each	ORTHOPOXVIRUS AMP PRB EACH	5	07/26/22