

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 12519</b>	<b>Date: February 22, 2024</b>
	<b>Change Request 13541</b>

**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: April 1, 2024**

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

**IMPLEMENTATION DATE: April 1, 2024**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 12519	Date: February 22, 2024	Change Request: 13541
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**EFFECTIVE DATE: April 1, 2024**

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**IMPLEMENTATION DATE: April 1, 2024**

## **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**

### **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--DELAYED**

On November 16, 2023, Section 502 of the Further Continuing Appropriations and Other Extensions Act of 2024 was passed and delayed data reporting requirements for clinical diagnostic laboratory tests (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.

- The next data reporting period will be from January 1, 2025 – March 31, 2025 and based on the original data collection period of January 1, 2019 through June 30, 2019.
- A 0% payment reduction will be applied for CY 2024 so that a CDLT that is not an ADLT may not be reduced compared to the payment amount for that test in CY 2023, and for CYs 2025-2027 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 2028, 2031, 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>



Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
13541.1.2	A/B MAC Part A 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., A/B MAC Part A name and number).	X								VD C
13541.2	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	
13541.2.1	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							
13541.3	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		
13541.4	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	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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.					

**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**

**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, 2024**

**Proprietary Laboratory Analysis (PLAs)**

The following new codes have been added to the national HCPCS file with an effective date of April 1, 2024 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
Epi+Gen CHDTM, Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	0439U	Cardiology (coronary heart disease [chd]), dna, analysis of 5 single-nucleotide polymorphisms (snps) (rs11716050 [loc105376934], rs6560711 [wdr37], rs3735222 [scinloc107986769], rs6820447 [intergenic], and rs9638144 [esyt2]) and 3 dna methylation markers (cg00300879 [transcription start site (tss200) of cnksr1], cg09552548 [intergenic], and cg14789911 [body of spatic1]), qpcr and digital pcr, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic chd	Crđ chđ dna aly5 5 snp 3 dna	5	04/01/24
PrecisionCHDTM, Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	0440U	Cardiology (coronary heart disease [chd]), dna, analysis of 10 single-nucleotide polymorphisms (snps) (rs710987 [linc010019], rs1333048 [cdkn2b-as1], rs12129789 [kcnk3], rs942317 [ktn1-as1], rs1441433 [ppp3ca], rs2869675 [prex1], rs4639796 [zbtb41], rs4376434 [linc00972], rs12714414 [tmem18], and rs7585056 [tmem18]) and 6 dna methylation markers (cg03725309 [sars1], cg12586707 [cxd1, cg04988978 [mpo], cg17901584 [dhcr24-dt], cg21161138 [ahr], and cg12655112 [ehd4]), qpcr and digital pcr, whole blood, algorithm reported as detected or not detected for chd	Crđ chđ dna aly5 10 snp 6dna	5	04/01/24
IntelliSep® test, Cytovale®	0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index	Nfct ds bct fngl/viral semiq	5	04/01/24
FebriDx® Bacterial/Non-Bacterial Point-of-Care Assay, Lumos Diagnostics, LLC, Lumos Diagnostics, LLC	0442U	Infectious disease (respiratory infection), myxovirus resistance protein a (mxa) and c-reactive protein (crp), fingerstick whole blood specimen, each biomarker reported as present or absent	Nfct ds respir nfctj mxa&crp	5	04/01/24
Neurofilament Light Chain (NFL), Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine, Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine	0443U	Neurofilament light chain (nfl), ultra-sensitive immunoassay, serum or cerebrospinal fluid	Neurflmrt lt chn ultrsens ia	5	04/01/24
Aventa FusionPlusTM, Aventa Genomics, LLC	0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using dna from formalin-fixed paraffin-embedded (ffpe) tumor tissue, report of clinically significant variant(s)	Onc sld orgn neo tgsap 361	5	04/01/24
Elecsys® Phospho-Tau (181P) CSF (pTau181) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc (US owner/operator)	0445U	B-amyloid (abeta42) and phospho tau (181p) (ptau181), electrochemiluminescent immunoassay (eclia), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	Abeta42 & ptau181 eclia csf	5	04/01/24
aisle® DX Disease Activity Index, Progentec Diagnostics, Inc, Progentec Diagnostics, Inc	0446U	Autoimmune diseases (systemic lupus erythematosus [sle]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity	Ai ds sle aly5 10 cytokine	5	04/01/24
aisle® DX Flare Risk Index, Progentec Diagnostics, Inc, Progentec Diagnostics, Inc	0447U	Autoimmune diseases (systemic lupus erythematosus [sle]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare	Ai ds sle aly5 11 cytokine	5	04/01/24
oncoRevealTM DX Lung and Colon Cancer Assay, Pillar® Biosciences, Pillar® Biosciences	0448U	Oncology (lung and colon cancer), dna, qualitative, nextgeneration sequencing detection of single-nucleotide variants and deletions in egfr and kras genes, formalin-fixed paraffinembedded (ffpe) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options	Onc lng&cln ca dna qual ngs	5	04/01/24
UNITY Carrier ScreenTM, BillionToOne Laboratory, BillionToOne, Inc	0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (cfr, smn1, hbb, hba1, hba2)	Car scr sev inh cond 5 genes	5	04/01/24

**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

**Deleted Codes Effective April 1, 2024**

The following codes are being deleted with a deletion date of April 1, 2024.

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>Delete Date</b>
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)	04/01/2024
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	04/01/2024