CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12606	**Date: May 2, 2024**
	Change Request 13613

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, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 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.*

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: 12606	Date: May 2, 2024	Change Request: 13613

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

EFFECTIVE DATE: July 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 1, 2024

I. GENERAL INFORMATION

A. Background: 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.

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

New Codes Effective July 1, 2024

Proprietary Laboratory Analysis (PLAs) and Additional New Codes

Please see table attached to the Transmittal entitled **"CY2024 CLFS Quarter 3 Updates,"** Tab "**New Codes Effective 7-1-24.**" The listed new codes were added to the national HCPCS file with an effective date of July 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. The table includes the laboratory, long descriptor, short descriptor, and type of service (TOS) of each new code.

Deleted Codes Effective July 1, 2024

Please see table attached to the Transmittal entitled "**CY2024 CLFS Quarter 3 Updates,**" Tab "**Deleted Codes Effective 7-1-24.**" The listed codes are being deleted with a delete date of July 1, 2024.

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	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13613.1	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	
13613.1.1	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							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13613.2	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		
13613.3	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 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.	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

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, 2024

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of July 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
M-inSight® Patient Definition Assay, Corgenix Clinical Laboratory, Sebia	0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides	ONC MM LC-MS/MS MONOC P-PRTN	5	07/01/2024
M-inSight® Patient Follow-Up Assessment, Corgenix Clinical Laboratory, Sebia	0451U	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance	ONC MM LC-MS/MS PEP ION QUAN	5	07/01/2024
EarlyTect® Bladder Cancer Detection (EarlyTect® BCD), Promis Diagnostics, Inc, Promis Diagnostics, Inc	0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer	ONC BLDR MTHYL PENK LTE-QMSP	5	07/01/2024
ColonAiQ®, Breakthrough Genomics, Singlera Genomics, Inc	0453U	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylationbased quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)	ONC CLRCT CA CFDNA QPCR ASY	5	07/01/2024
Chromosome Genome Mapping, UR Medicine Labs, Bionano Genomics, Inc	0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	RARE DS ID OPT GENOME MAPG	5	07/01/2024
Abbott AlinityTM m STI Assay, Abbott Molecular, Inc	0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected	NFCT AGT STI MULT AMP PRB UR	5	07/01/2024
PrismRA®, Scipher Medicine®, Scipher Medicine®	0456U	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy	AI RA NGS 19 GENES ANTI-CCP	5	07/01/2024
PFAS (Forever Chemicals) 9 Panel, Quest Diagnostics®, Quest Diagnostics®	0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative	PFAS 9 CMPND LCMS/MS PLS/SR	5	07/01/2024
Auria®, Namida Lab, Inc, Namida Lab, Inc	0458U	Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score	ONC BRST CA S100 A8&A9 ELISA	5	07/01/2024
Elecsys® Total Tau CSF (tTau) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc (US owner/operator)	0459U	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	ABETA42 & TTAU ECLIA CSF	5	07/01/2024
RightMed® Oncology Gene Report, OneOme® LLC, OneOme® LLC	0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes	ONC WHL BLD/BUCC RTPCR 24GEN	5	07/01/2024
RightMed® Oncology Medication Report, OneOme® LLC, OneOme® LLC	0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes	ONC RXGENOM ALYS RTPCR 24GEN	5	07/01/2024
Salimetrics® Salivary Melatonin Profile (Circadian Phase Assessment), Salimetrics® Clinical Laboratory, Salimetrics®, LLC	0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary	MELATONIN LVL TST SLP STD7/9	5	07/01/2024
Proofer '7 HPV mRNA E6 and E7 Biomarker Test, Global Diagnostics Labs, LLC, PreTect AS, a Mel-Mont Medical, Inc, wholly-owned subsidiary	0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker	ONC CRVX MRNA GENXPRSN 14BMK	5	07/01/2024
Cologuard PlusTM, Exact Sciences Laboratories, LLC, Exact Sciences Corporation	0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result	ONC CLRCT SCR QRTSA DNA MRK	5	07/01/2024
UriFind® Blood Cancer Assay, DiaCarta, Inc, AnchorDx	0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative	ONC URTHL CARC DNA QMSP 2GEN	5	07/01/2024
CardioRisk+, Gene by Gene, Ltd, OpenDNA, Ltd	0466U	Cardiology (coronary artery disease [CAD]), DNA, genomewide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease	CRD CAD DNA GWAS 564856 SNP	5	07/01/2024
UroAmp MRD, Convergent Genomics, Inc, Convergent Genomics, Inc	0467U	Oncology (bladder), DNA, nextgeneration sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden	ONC BLDR DNA NGS 60GEN&ANEUP	5	07/01/2024
NASHnextTM (NIS4TM), Labcorp, Labcorp	0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis	HEP NASH MIR34A5P A2M YKL40	5	07/01/2024
IriSightTM CNV Analysis, Variantyx Inc, Variantyx Inc	0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination	RARE DS WHL GEN SEQ FTL SAMP	5	07/01/2024
HPV-SEQ Test, Sysmex Inostics, Inc, Sysmex Inostics, Inc	0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma	ONC OROP DETCJ MRD 8 DNA HPV	5	07/01/2024
CRCdx® RAS Mutation Detection Kit, EntroGen, Inc, EntroGen, Inc	0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalinfixed paraffin-embedded (FFPE), predictive, identification of detected mutations	ONC CLRC CA 35 VRN KRAS&NRAS	5	07/01/2024
Early Sjögren's Syndrome Profile, Immco Diagnostics, Inc, Immco Diagnostics, Inc	0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjögren syndrome	CA VI PSP&SP1 ANTB SJÖGREN	5	07/01/2024
xT CDx, Tempus AI, Inc, Tempus AI, Inc	0473U	Oncology (solid tumor), nextgeneration sequencing (NGS) of DNA from formalin-fixed paraffinembedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden	ONC SLD TUM BLD/SLV 648 GENE	5	07/01/2024
GeneticsNow® Comprehensive Germline Panel, GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	0474U	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using nextgeneration sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene	HERED PAN CA GSAP 88GENE NGS	5	07/01/2024

ProstateNowTM Prostate Germline Panel, GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	0475U	Hereditary prostate cancerrelated disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer	HERED PRST8 CA GSAP 23 GENES	5	07/01/2024

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 July 1, 2024		
The following codes are being deleted with a deletion date of July 1, 2024.		
CPT Code	**Long Descriptor**	**Delete Date**
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected	07/01/2024
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	07/01/2024