

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12721	Date: July 18, 2024
	Change Request 13717

**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, 2024**

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

**IMPLEMENTATION DATE: October 7, 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

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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, 2024**

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## 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 (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 October 1, 2024

*Proprietary Laboratory Analysis (PLAs) and Additional New Codes*

Please see table attached to the Transmittal entitled "CY2024 CLFS Quarter 4 Updates," Tab "New Codes Effective 10-1-24." The listed new codes were added to the national HCPCS file with an effective date of October 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 October 1, 2024**

Please see table attached to the Transmittal entitled "CY2024 CLFS Quarter 4 Updates," Tab "Deleted Codes Effective 10-1-24." The listed codes are being deleted with a delete date of October 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 MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13717.1	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	
13717.1.1	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							
13717.2	Contractors shall not search their files to either retract	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.									
13717.3	The contractor shall use the cloud fee schedule to determine the payment limit for claims for separately payable Medicare Part B laboratory tests processed or reprocessed on or after October 1, 2024.	X	X			X				
13717.4	A/B MAC Parts A and B contractors shall retrieve and download to the mainframe a copy of the CY 2024 Clinical Laboratory Fee Schedule data files from the CMS cloud fee file API on or after June 1, 2024.	X							DRaaS-CACHE Data Center	

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13717.5	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.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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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, 2024

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 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), § 1834(c) and § 1834(A)(I). MACs shall only price PLA codes for laboratories within their jurisdiction.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
RightMed Mental Health Gene Report, OneOme, LLC, OneOme, LLC	0476U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder (ADHD), schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis and reported phenotypes	RX METAB PSYC 14GEN&CYP2D6	5	10/01/2024
RightMed Mental Health Medication Report, OneOme, LLC, OneOme, LLC	0477U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder (ADHD), schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, including impacted gene-drug interactions and reported phenotypes	RX METAB PSY 14&CYP2D6 GN-RX	5	10/01/2024
Lung HDP/RTM, Protein BioDiagnostics, Protein BioDiagnostics	0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection	ONC NSCLC DNA&RNA DPCR IGENS	5	10/01/2024
ALZpath pTau217, Neurocode USA, Inc., QuinientaALZpath	0479U	Tau, phosphorylated, pTau217	TAU PHOSPHORYLATED PTAU217	5	10/01/2024
Bacteria, Virus, Fungus, and Parasite Metagenomic Sequencing, Spiral Fluid (MSCSF), Mayo Clinic, Laboratory Developed Test	0480U	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification	NFCT DS CSF METAG NGS ALYS	5	10/01/2024
IDH1, IDH2, and TERT Mutation Analysis, NextGeneration Sequencing, Tumor (IDT/RT), Mayo Clinic, Laboratory Developed Test	0481U	IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system (CNS) tumors), next-generation sequencing (single-nucleotide variants [SNVs], deletions, and insertions)	IDH1 IDH2&TERT PROMOTER NGS	5	10/01/2024
Preecampsa sFlt1/PlGF Ratio (PERA), Mayo Clinic, Laboratory Developed Test	0482U	Obstetrics (pre-eclampsia), biochemical assay of soluble fmslike tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF), serum, ratio reported as quantitative for progression for pre-eclampsia with severe features within 2 weeks	OB PE BIOCHEM ASY SFLT1&PLGF	5	10/01/2024
Ciprofloxacin Susceptibility of Neisseria gonorrhoeae, MedAhor Diagnostics, SpeedX, Inc.	0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance	NFCT DS NG GYRA S91F PT MUT	5	10/01/2024
Macrolide Resistance of Mycoplasma genitalium, MedAhor Diagnostics, SpeedX, Inc.	0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance	NFCT DS MGEN 23S RRNA PT MUT	5	10/01/2024
Caris AssureTM, Caris MPI, Inc. dba Caris Life Sciences®, Caris MPI, Inc. dba Caris Life Sciences®	0485U	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden	ONC SOL TUM CFDNA&RNA NGS GM	5	10/01/2024
Northstar ResponderTM, BillionToOne Laboratory, BillionToOne, Inc.	0486U	Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor burden	ONC PAN SOL TUM NGS CFCTDNA	5	10/01/2024
Northstar SelectorTM, BillionToOne Laboratory, BillionToOne, Inc.	0487U	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidy/corrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability	ONC SOL TUM CFCDNA TGS&P84	5	10/01/2024
UNITY Fetal AntigenTM NPT, BillionToOne Laboratory, BillionToOne, Inc.	0488U	Obstetrics (fetal antigen noninvasive prenatal test), cell-free DNA sequence analysis for detection of fetal presence or absence of 1 or more of the Rb, C, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigens detected or not detected	OB FETAL AG NPT CFDNA ALYS	5	10/01/2024
UNITY Fetal Risk ScreenTM, BillionToOne Laboratory, BillionToOne, Inc.	0489U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA sequence analysis of 1 or more targets (eg, CTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation dosage analysis based on molecular counts to determine fetal inheritance of maternal mutation, algorithm reported as a fetal risk score for the condition (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)	OB SGNPT CFDNA SEQ ALYS 1+	5	10/01/2024
CELSEARCH® Circulating Melanoma Cell (CMC) Test, Menarini Silicon Biosystems Inc., Menarini Silicon Biosystems Inc.	0490U	Oncology (cutaneous or ocular melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular-weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood	ONC CUTAN/OCUL MELNMA CDT146	5	10/01/2024
CELSEARCH® ER Circulating Tumor Cell (CTC-ER) Test, Menarini Silicon Biosystems Inc., Menarini Silicon Biosystems Inc.	0491U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker-expressing cells, peripheral blood	ONC SOL TUM CTC SLCT ER PRTN	5	10/01/2024
CELSEARCH® PDL1 Circulating Tumor Cell (CTCPD-1) Test, Menarini Silicon Biosystems Inc., Menarini Silicon Biosystems Inc.	0492U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker-expressing cells, peripheral blood	ONC SOL TUM CTC SLCTN PD-L1	5	10/01/2024
ProsperaTM, NateraTM Rb Test, NateraTM	0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA	TRNSPL MED QUAN DD-CFDNA NGS	5	10/01/2024
Stochim3, BioAnalytix Diagnostics	0494U	Red blood cell antigen (fetal RHD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RHD negative, reported as positive or negative	RBC AG FTL RHD GENE ALYS NGS	5	10/01/2024
ColoCap™ PLUS, DiaCarta, Inc., DiaCarta, Inc.	0495U	Oncology (prostate), analysis of circulating plasma proteins (PSA, IPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer	ONC PRST8 ALYS CRCG PLSM PRT	5	10/01/2024
ColoCap™ PLUS, DiaCarta, Inc., DiaCarta, Inc.	0496U	Oncology (colorectal), cell-free DNA, 3 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported as positive or negative for colorectal cancer or advanced adenoma risk	ONC CLRCT CFDNA 8/7 GENES	5	10/01/2024
OncoAssure™ Prostate, DiaCarta, Inc., DiaCarta, Inc.	0497U	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALA51, and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer	ONC PRST8 MRNA RT-PCR 6GENES	5	10/01/2024
OptiSeq™ Colorectal Cancer NGS Panel, DiaCarta, Inc., DiaCarta, Inc.	0498U	Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation	ONC CLRCT NGS MUT DETC 43GEN	5	10/01/2024
OptiSeq™ Dual Cancer Panel Kit, DiaCarta, Inc., DiaCarta, Inc.	0499U	Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (KRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection	ONC CLRCT&LUNG DNA NGS 8GENES	5	10/01/2024
OCamp5 Plex VEXAS UBE1A Mutation Test, DiaCarta, Inc., DiaCarta, Inc.	0500U	Autoinflammatory disease (VEXAS syndrome), DNA, UBE1A gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.1189-118-2del, 556F, 562I)	AUTOINFLAM DS VEXAS SYND DNA	5	10/01/2024
QuantID™ Colorectal Cancer Triage Test, DiaCarta, Inc., DiaCarta, Inc.	0501U	Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA)	ONC CLRC BLD QUAN MEAS	5	10/01/2024
QuantVirus™ HPV E6E7 mRNA Test for Cervical Cancer, DiaCarta, Inc., DiaCarta, Inc.	0502U	Human papillomavirus (HPV), E6E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV	HPV E6E7 MRK HRSK TYP CRV	5	10/01/2024
PrechytA2™TM, C2N Diagnostics, LLC, C2N Diagnostics, LLC	0503U	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/Aβ40 ratio) and tau protein (pTau217, p-Tau217, p-Tau217/217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm reported as likelihood of positive or negative for amyloid plaques	NEURO ALZ DS BAMYLETAU PRTN	5	10/01/2024
Urinary Tract Infection Testing, NuGen MDx, LLC, NuGen MDx, LLC	0504U	Infectious disease (urinary tract infection), identification of 17 pathogenic organisms, urine, real-time PCR, reported as positive or negative for each organism	NFCT DS UTI ID 17 PATH ORGS	5	10/01/2024
Vaginal Infection Testing, NuGen MDx, LLC, NuGen MDx, LLC	0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism	NFCT DS VAG INFCT ID 32ORGS	5	10/01/2024
EndoSign® Barrett's Esophagus Test, Cycled Health Inc., Cycled Health Inc.	0506U	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus	GI BARRETT'S ESOPHGL CELL 89	5	10/01/2024
Avarect Ovarian Cancer Test, ClearNorth Health	0507U	Oncology (ovarian), DNA, whole-genome sequencing with 5Hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected	ONC OVR DNA WHOLE GEN W5HMC	5	10/01/2024
VitaGrat™ Kidney Baseline + 1st Plasma Test, Oncoocyte Corporation, Oncoocyte Corporation	0508U	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection	TRNSPLJ MED DCCFDNA 40 SNPS	5	10/01/2024
VitaGrat™ Kidney Subsequent, Oncoocyte Corporation, Oncoocyte Corporation	0509U	Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection	TRNSPLJ MED DCCFDNA+12 SNPS	5	10/01/2024
PuriSTM, Tempus AI, Inc., Tempus AI, Inc.	0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole transcriptome data, reported as probability of predicted molecular subtype	ONC PNCRCT CA ALG ALYS 16GEN	5	10/01/2024
PARIS, Tempus AI, Inc., Tempus AI, Inc. (by its wholly owned subsidiary E5ngine Precision Medicine, LLC)	0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug	ONC SOL TUM 3DMICROENVIR 36	5	10/01/2024
Tempus p-MSI, Tempus AI, Inc., Tempus AI, Inc.	0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of MSI-high (MSI-H)	ONC PRST8 ALYS DGTZ IMG MSI	5	10/01/2024
Tempus p-Prostate, Tempus AI, Inc., Tempus AI, Inc.	0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker	ONC PRST8 ALG ALYS MSI&HRD	5	10/01/2024
Proctee ADLTM, ProcteeDx Inc.	0514U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	GI BD IA QUAN DETER ADL LVL	5	10/01/2024
Proctee IFXTM, ProcteeDx Inc.	0515U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of infliximab (FX) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	GI BD IA QUAN DETER IFX LVL	5	10/01/2024
MySen/Ar Pharmacogenomics Test, Geisinger Medical Laboratories, Geisinger Medical Laboratories	0516U	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status	RX METAB RXGENOMIC GNOTYP 40	5	10/01/2024
PreView® CNS, Phenomics Health™ Inc., Phenomics Health™ Inc.	0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications	THER RX MNTR 80+ PSYACTIV RX	5	10/01/2024
SynView® Pain, Phenomics Health™ Inc., Phenomics Health™ Inc.	0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	THER RX MNTR 90+ NMNTL HLTH	5	10/01/2024
SynView® ParPPlus, Phenomics Health™ Inc., Phenomics Health™ Inc.	0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LCMS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation	THER RX MNTR MEDS PDA 110+	5	10/01/2024
SynView® Rx, Phenomics Health™ Inc., Phenomics Health™ Inc.	0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LCMS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	THER RX MNTR 200+ RX/SBSTS	5	10/01/2024

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), § 1834(A) and § 1834(A)(I).

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
Epigenostx CNS Tumor Methylation Classifier, Heidelberg Epigenostx GmbH	0020M	Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass	ONC CNS ALYS 30000 DNA LOCI	5	07/01/2024

**Deleted Codes Effective October 1, 2024**

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

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>Delete Date</b>
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	10/01/2024
0396U	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions	10/01/2024