

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12389	Date: November 30, 2023
	Change Request 13467

SUBJECT: Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule 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 CY 2023 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: January 1, 2024

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

IMPLEMENTATION DATE: January 2, 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: 12389	Date: November 30, 2023	Change Request: 13467
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SUBJECT: Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2024

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

IMPLEMENTATION DATE: January 2, 2024

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2024 clinical laboratory fee schedule (CLFS), mapping for new codes for clinical laboratory tests, updates for laboratory costs subject to the reasonable charge payment, and other CLFS related information. 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/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs>

Clinical Laboratory Fee Schedule Update to Fees

For a pap smear test, Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the National Limitation Amount, but not less than a national minimum payment amount. However, for pap smear tests, payment may also not exceed the actual charge. The **CY 2024** national minimum payment amount is **\$17.76** (This value reflects the **CY 2023** national minimum payment with a **2.6 percent** increase or **\$17.31 times 1.026**). The affected codes for the national minimum payment amount are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

The annual update to payments made on a reasonable charge basis for all other laboratory services is the CPI-U, which for **CY 2024 is 3.0 percent** (See 42 CFR 405.509(b)(1)).

The Part B deductible and coinsurance do not apply for services paid under the CLFS.

Access to Data File

The CY 2024 CLFS data file shall be retrieved electronically through CMS' mainframe telecommunications system. A/B MAC contractors shall retrieve the data file on or after December 1, 2023.

The January 1, 2024 CY 2024 CLFS Public Use File (PUF) will be available on the CMS website in the last week of December, at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files>. The CLFS PUF is available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 22, 2023, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2023 and new CY 2024 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the **Federal Register** on April 14, 2023 (CMS-1796-N). Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted proposed payment determinations on the web site at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings>. Additional written comments from the public were accepted until October 27, 2023. CMS also posted a summary of the public comments and the rationale for the final payment determinations at the same CMS web site identified in the previous sentence.

Pricing Information

The CY 2024 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, P9615, and G0471). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual basis. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2024, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2024 clinical laboratory fee schedule may also include codes that have a "QW" modifier to both identify codes and determine payment for tests performed by a laboratory having only a CLIA certificate of waiver. Code will be listed if applicable.

Mapping Information

Please see table attached to the Transmittal entitled "CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment", Tab "**A. Mapping Information,**" which lists the mapping information for codes.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2024

Hospital outpatient claims are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index (CPI) for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The CPI update for CY 2024 is **3.0 percent**.

Manual instructions for determining the reasonable charge payment can be found in publication 100-04, Medicare Claims Processing Manual, chapter 23, section 80 through 80.8. If there is not sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

Services described by Healthcare Common Procedural Coding System (HCPCS) codes in the following list are performed for independent dialysis facility patients. Publication 100-04, Medicare Claims Processing Manual, chapter 8, section 60.3 instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital Outpatient Prospective Payment System (OPPS).

Blood Products

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

Transfusion Medicine

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

Reproductive Medicine Procedures

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

New Codes

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**C. New Codes Eff. 1-1-2024.**"

The listed new codes have been added to the national HCPCS file with an effective date of January 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.

Deleted Codes Effective January 1, 2024

Please see table attached to the Transmittal entitled "CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment," Tab "D. Deleted Codes Eff. 1-1-2024."

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

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	
13467.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2024 Clinical Laboratory Fee Schedule data files (filenames: MU00.@BF12394.CLAB.V2024Q1.FULLREPL MU00.@BF12394.CLAB.V2024Q1.UPDTONLY) from the CMS mainframe on or after December 1, 2023. Please note that the two data files will have the same contents since all records will have an update.	X	X							
13467.1.1	A/B MAC Part B 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 B name and number).		X							VD Cs
13467.1.2	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 Cs
13467.2	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							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
13467.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
13467.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2022 through June 30, 2023, updated by the inflation-index update for year CY 2024 of 3.0 percent.		X							
13467.5	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.	X								
13467.6	CMS shall issue a separate instruction on the clinical laboratory travel fees, if there is a revision to the standard mileage rate for CY 2024.									CM S

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13467.7	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

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2023 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0377U	NEW	Crosswalk to 83704 + 80061
0381U	NEW	Gapfill
0382U	NEW	Gapfill
0383U	NEW	Gapfill
0394U	NEW	Crosswalk to G0482
82166	NEW	Crosswalk to 82024
0404U	NEW	Crosswalk to 0058U
0376U	NEW	Crosswalk to 0220U
0414U	NEW	Crosswalk to 0220U
0418U	NEW	Crosswalk to 0220U

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0406U	NEW	Crosswalk to 0021U
0359U	NEW	Crosswalk to 81539
0360U	NEW	Crosswalk to 81490
0365U	NEW	Crosswalk to 81503
0366U	NEW	Crosswalk to 81503
0367U	NEW	Crosswalk to 81503 + 82570
0375U	NEW	Crosswalk to 81503
0384U	NEW	Crosswalk to 0247U
0385U	NEW	Crosswalk to 0308U
0095U	REVISED	Crosswalk to 0095U

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0390U	NEW	Crosswalk to 0243U
81517	NEW	Crosswalk to 0014M
0019M	NEW	Gapfill
0407U	NEW	Crosswalk to 0105U
0415U	NEW	Crosswalk to 0309U
0387U	NEW	Crosswalk to 0067U * .5
0389U	NEW	Gapfill
0398U	NEW	Gapfill
0348U	RECONSIDERATION	Crosswalk to 0029U
0350U	RECONSIDERATION	Crosswalk to 0175U

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0355U	NEW	Crosswalk to 81401
0356U	NEW	Gapfill
0378U	NEW	Crosswalk to 81401
0403U	NEW	Crosswalk to 0011M
0413U	NEW	Crosswalk to 0260U
0324U	RECONSIDERATION	Crosswalk to 81535+(81536*3)
0369U	NEW	Crosswalk to 87507
0370U	NEW	Crosswalk to 87633
0371U	NEW	Crosswalk to 87633
0372U	NEW	Crosswalk to 87633

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0373U	NEW	Crosswalk to 87633
0374U	NEW	Crosswalk to 87633
87467	RECONSIDERATION	Gapfill
87523	NEW	Crosswalk to 87522
0402U	NEW	Crosswalk to 87631
0408U	NEW	Gapfill
0416U	NEW	Crosswalk to 87633
0380U	NEW	Crosswalk to 87633
0022U	REVISED	Gapfill
0388U	NEW	Gapfill

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0392U	NEW	Crosswalk to 0345U
0395U	NEW	Gapfill
0401U	NEW	Gapfill
0411U	NEW	Crosswalk to 0345U
0419U	NEW	Crosswalk to 0345U
0379U	NEW	Gapfill
0329U	RECONSIDERATION	Gapfill
0334U	RECONSIDERATION	Gapfill
0400U	NEW	Gapfill
81457	NEW	Gapfill

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
81458	NEW	Gapfill
81459	NEW	Gapfill
0409U	NEW	Crosswalk to 81455
0417U	NEW	Gapfill
0358U	NEW	Crosswalk to 81500
0361U	NEW	Gapfill
0393U	NEW	Crosswalk to 0035U
0399U	NEW	Gapfill
86041	NEW	Crosswalk to 83519
86042	NEW	Crosswalk to 83519

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
86043	NEW	Crosswalk to 86255
86366	NEW	Crosswalk to 83519
0412U	NEW	Gapfill
0396U	NEW	Gapfill
0410U	NEW	Crosswalk to 81349
0326U	RECONSIDERATION	Crosswalk to 0242U
0362U	NEW	Crosswalk to 0287U
0363U	NEW	Crosswalk to 0012M
0364U	NEW	Gapfill
0368U	NEW	Gapfill

Calendar Year (CY) 2024 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type <i>(new, revised, reconsidered, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column C, "Rate".	Rate
0405U	NEW	Crosswalk to 0318U
0391U	NEW	Crosswalk to 0287U
81462	NEW	Gapfill
81463	NEW	Gapfill
81464	NEW	Gapfill

Laboratory Cost:

Code Category

Blood Products

Transfusion Medicine

Reproductive Medicine Procedures

s Subject to Reasonable Charge Payment in CY 2024

Codes

P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033
P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9044 P9050 P9051 P9052 P9053 P9054
P9055 P9056 P9057 P9058 P9059 P9060 P9070 P9071 P9073 P9100

Also, payment for the following codes should be applied to the blood deductible as instructed in Publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 3, Section 20.5 through 20.5.4:

P9010 P9016 P9021 P9022 P9038 P9039 P9040 P9051 P9054 P9056 P9057 P9058

NOTE: Biologic products not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for codes P9041, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.

86850 86860 86870 86880 86885 86886 86890 86891 86900 86901 86902 86904 86905
86906 86920 86921 86922 86923 86927 86930 86931 86932 86945 86950 86960 86965
86970 86971 86972 86975 86976 86977 86978 86985

89250 89251 89253 89254 89255 89257 89258 89259 89260 89261 89264 89268 89272
89280 89281 89290 89291 89335 89337 89342 89343 89344 89346 89352 89353 89354
89356

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national I- (where applicable) until they are nationally priced and under MACs shall only price PLA codes for laboratories within thei

Laboratory	CPT Code
Cxbladder Detect+, Pacific Edge Diagnostics USA LTD, Pacific Edge Diagnostics USA LTD	0420U
Colosense™, Geneoscopy, Inc, Geneoscopy, Inc	0421U
Guardant360 Response™, Guardant Health, Inc, Guardant Health, Inc	0422U
Genomind® Pharmacogenetics Report – Full, Genomind®, Inc, Genomind®, Inc	0423U
miR Sentinel™ Prostate Cancer Test, miR Scientific®, LLC, miR Scientific®, LLC	0424U
RCIGM Rapid Whole Genome Sequencing, Comparator Genome, Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	0425U
RCIGM Ultra-Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	0426U
Early Sepsis Indicator, Beckman Coulter, Inc	0427U

Epic Sciences ctDNA Metastatic Breast Cancer Panel, Epic Sciences, Inc, Epic Sciences, Inc	0428U
Omnipathology Oropharyngeal HPV PCR Test, OmniPathology Solutions, Medical Corporation, OmniPathology Solutions, Medical Corporation	0429U
Malabsorption Evaluation Panel, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	0430U
Glycine Receptor Alpha1 IgG, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	0431U
Kelch-Like Protein 11 Antibody, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	0432U
EpiSwitch® Prostate Screening Test (PSE), Oxford BioDynamics Inc, Oxford BioDynamics PLC	0433U
RightMed® Gene Test Exclude F2 and F5, OneOme® LLC, OneOme® LLC	0434U
Chemoid®, Chemoid® Lab, Cordgenics, LLC	0435U
PROphet® NSCLC Test, OncoHost, Inc, OncoHost, Inc	0436U
MindX One™ Blood Test – Anxiety, MindX Sciences, MindX Sciences	0437U
EffectiveRX™ Comprehensive Panel, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	0438U

Additional Codes

The following new code has been added to the national HCIP and will be required to be used by providers starting in 2023 and undergo the CLFS annual payment determination process.

Laboratory	CPT Code

New Codes Effective January 1, 2024

HCPCS file with an effective date of January 1, 2024 and do not need to be manually added to the HCPCS files before the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1862(b)(7)(C) in their jurisdiction.

Long Descriptor
Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of MDK, HOXA13, CDC2, IGFBP5, and CXCR2 in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma
Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, GLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk
Oncology (pan-solid tumor), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate
Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition
Oncology (prostate), exosomebased analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RTqPCR), urine, reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cancer
Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)
Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis
Monocyte distribution width, whole blood (List separately in addition to code for primary procedure) (Use 0427U in conjunction with 85004, 85025)

Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden

Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)

Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative

Glycine receptor alpha1 IgG, serum or cerebrospinal fluid (CSF), live cell-binding assay (LCBA), qualitative

Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative

Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer

Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes

Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations

Oncology (lung), plasma analysis of 388 proteins, using aptamerbased proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy

Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score

Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted genedrug interactions

PCS file and does not need to be manually added to the HCPCS files by the MACs. However, this new code is class in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

Long Descriptor

y the MACs. However, these new codes are contractor-priced 1834A(c) and § 1834(A)(f).

Short Descriptor	TOS	Effective Date
ONC URTHL MRNA XPRSN 6 SNP	5	01/01/24
ONC CLRCT SCR SGL AMP 8 RNA	5	01/01/24
ONC PAN SOLID TUM ALYS DNA	5	01/01/24
PSYC GENOMIC ALYS PNL 26 GEN	5	01/01/24
ONC PRST8 XOM ALYS 53 SNCRNA	5	01/01/24
GENOM RPD SEQ ALYS EA CMPRTR	5	01/01/24
GENOME ULTRA-RAPID SEQ ALYS	5	01/01/24
MONOCYTE DSTREBJ WDTN WHL BLD	5	01/01/24

ONC BRST CTDNA ALYS 56/> GEN	5	01/01/24
HPV OROP SWAB 14 HIRISK TYP	5	01/01/24
GI MALABS AAT CALPRO PNCRTC	5	01/01/24
GLY RCPTR ALPHA1 IGG SRM/CSF	5	01/01/24
KLHL11 ANTB SR/CSF ASY QUAL	5	01/01/24
ONC PRST8 5 DNA REG MRK PCR	5	01/01/24
RX METAB ADVRS VRNT ALYS 25	5	01/01/24
ONC CHEMO RX CYTOX CSC 14 RX	5	01/01/24
ONC LNG PLSM ALYS 388 PRTN	5	01/01/24
PSYC ANXIETY DO MRNA 15 BMRK	5	01/01/24
RX METAB ADVRS VRNT ALYS 33	5	01/01/24

contractor-priced (where applicable) until they are nationally priced

Short Descriptor	TOS	Effective Date

The following codes are

CPT Code

0014M

Deleted Codes Effective January 1, 2024

e being deleted with a deletion date of January 1, 2024.

Long Descriptor

Liver disease, analysis of 3 biomarkers (hyaluronic acid [ha], procollagen iii amino terminal peptide [piiinp], tissue inhibitor of metalloproteinase 1 [timp-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years

Delete Date
01/01/2024