

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11881	Date: February 28, 2023
	Change Request 13023

Transmittal 11733 issued December 08, 2022, is being rescinded and replaced by Transmittal 11881, dated, February 28, 2023, to remove CPT code 0245U from the CY 2023 CLFS Annual Updates attachment, this code is no longer a part of the gapfill process for 2023. All other information remains the same.

SUBJECT: Calendar Year (CY) 2023 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, 2023

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

IMPLEMENTATION DATE: January 3, 2023

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: 11881	Date: February 28, 2023	Change Request: 13023
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SUBJECT: Calendar Year (CY) 2023 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2023

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

IMPLEMENTATION DATE: January 3, 2023

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2023 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)

Calendar Year (CY) 2023 Medicare Physician Fee Schedule Final (PFS) Rule:

On November 1, 2022, the CMS issued a final rule that includes updates and policy changes for Medicare payments under the PFS, and other Medicare Part B issues, effective on or after January 1, 2023.

CLFS updates and policy changes are as follows:

- Revised Data Reporting Period and Phase-in of Payment Reductions
 - In accordance with section 4(b) of the Protecting Medicare and American Farmers from Sequester Cuts Act, we finalized certain conforming changes to the data reporting and payment requirements at 42 Code of Federal Regulations (CFR) part 414, subpart G. Specifically, we finalized revisions to Subsection (§) 414.502 to update the definitions of both the “data collection period” and “data reporting period,” specifying that for the data reporting period of January 1, 2023 through March 31, 2023, the data collection period is January 1, 2019 through June 30, 2019. We also finalized revisions to § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every three years beginning January 2023. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4(b) of this law. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0% as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15% as compared to the amount established for the preceding year.
- Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests
 - Specimen Collection Policy: We finalized an increase to the nominal fee for specimen collection based on the Consumer Price Index for all Urban Consumers (CPI-U). Therefore, for CY 2023, the general specimen collection fee will increase from \$3 to \$8.57 and as required by Protecting Access to Medicare Act of 2014 (PAMA), we will increase this amount by \$2 for those specimens collected from a Medicare beneficiary in a Skilled Nursing

Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA), which will result in a \$10.57 specimen collection fee for those beneficiaries. In addition, we finalized a policy to update this fee amount annually by the percent change in the CPI-U. We also finalized our proposals to codify and clarify various laboratory specimen collection fee policies in § 414.523(a)(1). This is because the policies implementing the statutory requirements under section 1833(h)(3)(A) of the Act for the laboratory specimen collection fee, which are currently described in the Medicare Claims Processing Manual publication 100-04, chapter 16, § 60.1, did not have corresponding regulations text and some of the manual guidance is no longer applicable.

- Travel Allowance Policy: We finalized as proposed to codify in our regulations, and make certain modifications and clarifications to, the Medicare CLFS travel allowance policies. We finalized the addition of § 414.523(a)(2) “Payment for travel allowance” to reflect the requirements for the travel allowance for specimen collection. Specifically, in accordance with section 1833(h)(3)(B) of the Act, we finalized to include in our regulations the following requirements for the travel allowance methodology: (1) a general requirement, (2) travel allowance basis requirements, and (3) travel allowance amount requirements.
- Please refer to the following CMS website for additional information regarding these policies: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched>

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations>

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 2023** national minimum payment amount is **\$17.31** (This value reflects the **CY 2022** national minimum payment with an **8.7 percent** increase or **\$15.92 times 1.087**). 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 2023 is 9.1 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 2023 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, 2022. Internet access to the CY 2023 CLFS data file shall be available after December 1, 2022, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. Other interested parties shall use the Internet to retrieve the CY 2023 CLFS. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 23, 2022, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2022 codes and new CY 2023 Current Procedural Terminology (CPT) codes. Notice of the meeting was

published in the **Federal Register** on April 18, 2022. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on the web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. Additional written comments from the public were accepted until October 24, 2022. 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 2023 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 2023, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2023 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 "CY2023 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 2023

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 2023 is **9.10 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 "CY2023 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 "CY2023 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 "CY2023 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 "CY2023 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment," Tab "C. New Codes Eff. 1-1-2023."

The listed new codes have been added to the national HCPCS file with an effective date of January 1, 2023 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, 2023

None for this update.

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				Othe r
		A	B	HH H		FIS S	MC S	VM S	CW F	
13023.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2023 Clinical Laboratory Fee Schedule data files (filenames: MU00.@BF12394.CLAB.V2023Q1.FULLREPL MU00.@BF12394.CLAB.V2023Q1.UPDTONLY) from the CMS mainframe on or after December 1, 2022. Please note that the two data files will have the same contents since all records will have an	X	X							

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	
	update.									
13023.1.1	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	
13023.1.2	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	
13023.2	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							
13023.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
13023.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2021 through June 30, 2022, updated by the inflation-index update for year CY 2023 of 9.1 percent.		X							
13023.5	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								
13023.6	CMS shall issue a separate instruction on the clinical laboratory travel fees, if there is a revision to the standard mileage rate for CY 2023.								CM S	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13023.7	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@cms.hhs.gov , Ariana Pitcher, Ariana.Pitcher@cms.hhs.gov , Sarah Harding, 410-786-4001 or Sarah.Harding@cms.hhs.gov , Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Calendar Year (CY) 2023 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 D, "Rate".	Rate
80220	Reconsidered	Crosswalk to 80299
81349	Reconsidered	Crosswalk to 81229
81418	NEW	Gapfill
81441	NEW	Crosswalk to 81443
81445	NEW	Crosswalk to 81445
81449	NEW	Crosswalk to 81445
81451	NEW	Crosswalk to 81450
81456	NEW	Crosswalk to 81455
83529	Reconsidered	Crosswalk to 83520
84433	NEW	Crosswalk to 82657

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86036	Reconsidered	Crosswalk to 86255
86037	Reconsidered	Crosswalk to 86256
86051	Reconsidered	Crosswalk to 83516
86052	Reconsidered	Crosswalk to 86255
86053	Reconsidered	Crosswalk to 86357
86231	Reconsidered	Crosswalk to 86038
86258	Reconsidered	Crosswalk to 86255
86362	Reconsidered	Crosswalk to 86255
86363	Reconsidered	Crosswalk to 86357
86364	Reconsidered	Crosswalk to 83516

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86409	Reconsidered	Gapfill
86413	Reconsidered	Gapfill
86596	Reconsidered	Crosswalk to 86255
87428	Reconsidered	Gapfill
87467	NEW	Crosswalk to 84702
87468	NEW	Crosswalk to 87476
87469	NEW	Crosswalk to 87476
87478	NEW	Crosswalk to 87476
87484	NEW	Crosswalk to 87476
87913	NEW	Crosswalk to 87910

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0022U	Reconsidered	Gapfill
0229U	Reconsidered	Crosswalk to 81327 x 2
0276U	Revised	Crosswalk to 81443
0285U	NEW	Gapfill
0286U	NEW	Crosswalk to 0030U
0287U	NEW	Crosswalk to 0026U
0288U	NEW	Crosswalk to 81522
0289U	NEW	Crosswalk to 0203U
0290U	NEW	Crosswalk to 0203U
0291U	NEW	Gapfill

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0292U	NEW	Gapfill
0293U	NEW	Crosswalk to 0203U
0294U	NEW	Crosswalk to 0203U
0295U	NEW	Crosswalk to 0067U
0296U	NEW	Crosswalk to 0170U
0297U	NEW	Gapfill
0298U	NEW	Crosswalk to 0204U
0299U	NEW	Gapfill
0300U	NEW	Gapfill
0301U	NEW	Gapfill

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0302U	NEW	Gapfill
0303U	NEW	Gapfill
0304U	NEW	Gapfill
0305U	NEW	Gapfill
0306U	NEW	Gapfill
0307U	NEW	Gapfill
0308U	NEW	Crosswalk to 0163U
0309U	NEW	Crosswalk to 0163U
0310U	NEW	Crosswalk to 0163U
0311U	NEW	Crosswalk to 87077

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0312U	NEW	Crosswalk to 81490
0313U	NEW	Crosswalk to 0026U
0314U	NEW	Gapfill
0315U	NEW	Gapfill
0316U	NEW	Crosswalk to 87449 + 87015
0317U	NEW	Crosswalk to 0053U
0318U	NEW	Gapfill
0319U	NEW	Gapfill
0320U	NEW	Gapfill
0321U	NEW	Crosswalk to 87633 + 87632

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0322U	NEW	Crosswalk to 0063U
0323U	NEW	Crosswalk to 0152U
0324U	NEW	Crosswalk to 81535 + 81536 x 3
0325U	NEW	Crosswalk to 81535 + 81536 x 3
0326U	NEW	Gapfill
0327U	NEW	Crosswalk to 81507
0328U	NEW	Crosswalk to 0143U
0329U	NEW	Gapfill
0330U	NEW	Crosswalk to 87633
0331U	NEW	Gapfill

Calendar Year (CY) 2023 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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0332U	NEW	Gapfill
0333U	NEW	Gapfill
0334U	NEW	Crosswalk to 81455
0335U	NEW	Crosswalk to 0214U
0336U	NEW	Crosswalk to 0215U
0337U	NEW	Gapfill
0338U	NEW	Gapfill
0339U	NEW	Crosswalk to 0005U
0341U	NEW	Gapfill
0342U	NEW	Crosswalk to 81503

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0343U	NEW	Crosswalk to 0005U
0344U	NEW	Gapfill
0345U	NEW	Crosswalk 0175U
0346U	NEW	Gapfill
0347U	NEW	Crosswalk to 0175U
0348U	NEW	Crosswalk to 0029U
0349U	NEW	Crosswalk to 0029U
0350U	NEW	Crosswalk to 0175U
0351U	NEW	Crosswalk to 81500
0352U	NEW	Crosswalk to 87631

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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 D, "Rate".	Rate
0353U	NEW	Crosswalk to 87491 + 87591
0354U	NEW	Crosswalk to 87624
86015	Reconsidered	Crosswalk to 86255

Laboratory Costs Subject to Reasonable Charge Payment in CY 2023

Code Category	Codes
Blood Products	<p>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</p> <p>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</p> <p>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.</p>
Transfusion Medicine	<p>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</p>
Reproductive Medicine Procedures	<p>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</p>

New Codes Effective January 1, 2023

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of January 1, 2023 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
Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping, Quest Diagnostics®, Quest Diagnostics®	0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)	APOL1 RISK VARIANTS	5	01/01/23
NavDx®, Naveris, Inc, Naveris, Inc	0356U	Oncology (oropharyngeal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence	ONC OROP 17 DNA DDPCR ALG	5	01/01/23
DAWN™ IO Melanoma, InterVenn Biosciences, InterVenn Biosciences	0357U	Oncology (melanoma), artificial intelligence (AI)-enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents	ONC MLNMA AI QUAN ALYS 142	5	01/01/23
Lumipulse® G βAmyloid Ratio (1-42/1-40) Test, Fujirebio Diagnostics, Inc, Fujirebio Diagnostics, Inc	0358U	Neurology (mild cognitive impairment), analysis of β-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative	NEURO ALYS β-AMYL 1-42&1-40	5	01/01/23
IsoPSA®, Cleveland Diagnostics, Inc, Cleveland Diagnostics, Inc	0359U	Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer	ONC PRST8 CA ALYS ALL PSA	5	01/01/23
Nodify CDT®, Bodesix, Inc, Bodesix, Inc	0360U	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy	ONC LUNG ELISA 7 AUTOANT ALG	5	01/01/23
Neurofilament Light Chain (NFL), Mayo Clinic, Mayo Clinic	0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative	NEURFLMNT LT CHN DIG IA QUAN	5	01/01/23
Thyroid GuidePx®, Protean BioDiagnostics, Protean BioDiagnostics	0362U	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes	ONC PAP THYR CA RNA 82&10	5	01/01/23
Cxbladder™ Triage, Pacific Edge Diagnostics USA, Ltd, Pacific Edge Diagnostics USA, Ltd	0363U	Oncology (urothelial), mRNA, geneexpression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma	ONC URTHL MRNA 5 GEN ALG	5	01/01/23