

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13514	Date: December 5, 2025
	Change Request 14312

SUBJECT: Calendar Year (CY) 2026 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 2026 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, 2026

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

IMPLEMENTATION DATE: January 5, 2026

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:13514	Date: December 5, 2025	Change Request: 14312
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II. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2026 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

On November 12, 2025, Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 was passed and delayed data reporting requirements for clinical diagnostic laboratory tests (CDLTs) that aren’t advanced diagnostic laboratory tests (ADLTs). 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 February 1, 2026 – April 30, 2026 and based on the original data collection period of January 1, 2019 through June 30, 2019.
- A 0% payment reduction will be applied until January 30, 2026 so that a CDLT that isn’t an ADLT may not be reduced compared to the payment amount for that test in CY 2024. From January 31, 2026 -2028, payment may not be reduced by more than 15%-percent per year compared to the payment amount established for a test the preceding year.

- Please refer to the following CMS website for additional information regarding CLFS data reporting: <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-reporting>

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 2026** national minimum payment amount is **\$18.54** (This value reflects the **CY 2025** national minimum payment with a **1.9 percent** increase or **\$18.19 times 1.019**). 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 less the multi-factor productivity (MFP) adjustment percentage points(s), which for **CY 2026 is calculated to equal 2.7 (CPI-U) minus 0.8 (MFP) or 1.9 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 2026 CLFS data file shall be retrieved and downloaded through the CMS cloud fee file API on or after January 1, 2026.

The January 1, 2026, CY 2026 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 27, 2025, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2025 and new CY 2026 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the **Federal Register** on April 21, 2025 (CMS-1837-N). Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted proposed payment determinations on the website 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 9, 2025. CMS also posted a summary of the public comments and the rationale for the final payment determinations at the same CMS website identified in the previous sentence.

Pricing Information

The CY 2026 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 2026, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2026 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 "CY2026 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 2026

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 2026 is **2.7 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 "CY2026 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 "CY2026 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 "CY2026 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 "CY2026 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment," Tab **"C. New Codes Eff. 1-1-2026."**

The listed new codes have been added to the national HCPCS file with an effective date of January 1, 2026 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, 2026

Please see table attached to the Transmittal entitled "CY2026 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment," Tab "D. Deleted Codes Eff. 1-1-2026."

III. 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	
14312.1	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	
14312.1.1	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							
14312.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	claims if they are brought to their attention.									
14312.3	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 January 1, 2026.	X	X							
14312.4	The A/B MACs shall retrieve the CY 2026 Clinical Laboratory Fee Schedule from the CMS cloud on or after January 1, 2026.	X	X							Hybrid Cloud Data Center (HCDC)
14312.5	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
14312.6	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2024 through June 30, 2025 CPI-U, for CY 2026 of 2.7 percent.		X							
14312.7	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								

IV. PROVIDER EDUCATION

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.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

V. 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

VI. CONTACTS

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

VII. 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) 2026 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2025 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 (new, revised, reconsidered, or existing) New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
81195	RECONSIDERED	Crosswalk to 0331U
87513	RECONSIDERED	Crosswalk to 87150
0420U	RECONSIDERED	Gapfill
0423U	RECONSIDERED	Crosswalk to 0476U
0521U	NEW	Crosswalk to 86200 x 4
0522U	NEW	Crosswalk to 0358U
0523U	NEW	Crosswalk to 0022U-81449
0524U	NEW	Crosswalk to 0482U
0525U	NEW	Crosswalk to 0248U
0526U	NEW	Gapfill

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0527U	NEW	Crosswalk to 87631
0528U	NEW	Crosswalk to 0321U
0529U	NEW	Gapfill
0530U	NEW	Crosswalk to 81455
0531U	NEW	Gapfill
0532U	NEW	Crosswalk to 81425
0533U	NEW	Crosswalk to 0516U
0534U	NEW	Gapfill
0535U	NEW	Crosswalk to 80307
0536U	NEW	Crosswalk to 0453U

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0538U	NEW	Crosswalk to 81459
0539U	NEW	Crosswalk to 81464
0540U	NEW	Crosswalk to 0493U
0541U	NEW	Gapfill
0542U	NEW	Gapfill
0543U	NEW	Crosswalk to 81459
0544U	NEW	Gapfill
0545U	NEW	Crosswalk to 86363
0546U	NEW	Crosswalk to 86363
0547U	NEW	Crosswalk to 0361U

Calendar Year (CY) 2026 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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0548U	NEW	Crosswalk to 0361U
0549U	NEW	Crosswalk to 0012M
0550U	NEW	Crosswalk to 0160U
0551U	NEW	Gapfill
0552U	NEW	Gapfill
0553U	NEW	Crosswalk to 0254U
0554U	NEW	Crosswalk to 0254U
0555U	NEW	Crosswalk to 0254U
0556U	NEW	Crosswalk to 81513
0557U	NEW	Crosswalk to 81514

Calendar Year (CY) 2026 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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0558U	NEW	Crosswalk to 86316
0559U	NEW	Crosswalk to 86316
0560U	NEW	Crosswalk to 0306U
0561U	NEW	Crosswalk to 0307U
0562U	NEW	Crosswalk to 81445
0563U	NEW	Crosswalk to 87633
0564U	NEW	Crosswalk to 87633
0565U	NEW	Crosswalk to 0410U
0566U	NEW	Crosswalk to 0368U
0567U	NEW	Crosswalk to 81425

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0568U	NEW	Crosswalk to 81503
0569U	NEW	Gapfill
0570U	NEW	Crosswalk to 0358U
0571U	NEW	Crosswalk to 81455
0572U	NEW	Gapfill
0573U	NEW	Gapfill
0574U	NEW	Gapfill
87183	NEW	Crosswalk to 87150
87182	NEW	Gapfill
81524	NEW	Gapfill

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CPT Code #	Code Type (new, revised, reconsidered, or existing) New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
87494	NEW	Crosswalk to 87491+87591
81354	NEW	Crosswalk to 0260U
87627	NEW	Crosswalk to 0505U
87812	NEW	Crosswalk to 87811 + (87804x2)
G0567	NEW	Crosswalk to 87521
0575U	NEW	Crosswalk to 0069U
0576U	NEW	Crosswalk to 81558
0589U	NEW	Crosswalk to 0457U
0577U	NEW	Crosswalk to 0051U
0584U	NEW	Crosswalk to 0035U

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CPT Code #	Code Type (new, revised, reconsidered, or existing) New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
0578U	NEW	Crosswalk to 0497U
0579U	NEW	Crosswalk to 0385U
0580U	NEW	Crosswalk to 0042U
0582U	NEW	Crosswalk to 0094U
0583U	NEW	Crosswalk to 0094x0.5
0585U	NEW	Crosswalk to 81455
0587U	NEW	Crosswalk to 0328U
0588U	NEW	Crosswalk to 0203U
0586U	NEW	Crosswalk to 81456
0590U	NEW	Gapfill

Calendar Year (CY) 2026 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

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CPT Code #	Code Type (new, revised, reconsidered, or existing) New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
0591U	NEW	Crosswalk to 81539
0592U	NEW	Crosswalk to 81455
0593U	NEW	Crosswalk to 0321U
0581U	NEW	Crosswalk to 86833
0594U	NEW	Gapfill
0595U	NEW	Crosswalk to 87506
0596U	NEW	Gapfill
0597U	NEW	Gapfill
0598U	NEW	0399U
0599U	NEW	Crosswalk to 81503

Laboratory Costs Subject to Reasonable Charge Payment in CY 2026	
Code Category	Codes
Blood Products	P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9027 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.
Transfusion Medicine	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
Reproductive Medicine Procedures	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

New Codes Effective January 1, 2026					
<i>Proprietary Laboratory Analysis (PLAs)</i>					
The following new codes have been added to the national HCPCS file with an effective date of January 1, 2026 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
FidaLab Molecular Wound Infection Test, FidaLab LLC, FidaLab LLC	0600U	Infectious disease (wound infection), identification of 65 organisms and 30 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism	NFCT DS WND INFCTJ 65ORGS&30	5	01/01/26
Synovasure® Comprehensive PJI Test Panel with SynTuitionTM, CD Laboratories, Inc, a division of Zimmer Biomet, CD Diagnostics, Inc, a division of Zimmer Biomet	0601U	Infectious disease (periprosthetic joint infection), analysis of 11 biomarkers (alpha defensins 1–3, C-reactive protein, microbial antigens for Staphylococcus [SPA, SPB], Enterococcus, Candida, and C. acnes, total nucleated cell count, percent neutrophils, RBC count, and absorbance at 280 nm) using immunoassays, hematology, clinical chemistry, synovial fluid, and diagnostic algorithm reported as a probability score	NFCT DS PJI ALYS 11 BMRKS IA	5	01/01/26
Kihealth Inc® Diabetes Risk Test, Kihealth Inc® Laboratory	0602U	Endocrinology (diabetes), insulin (INS) gene methylation using digital droplet PCR, insulin, and C-peptide immunoassay, serum, Hemoglobin A1c immunoassay, whole blood, algorithm reported as diabetes-risk score	ENDOCRIN DM INS GEN MTHYLTN	5	01/01/26
SLL Comprehensive Drug Analysis, Soft Landing Labs, Soft Landing Labs	0603U	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS), results reported as positive or negative	RX ASY PRSMV 77RX/METABLT UR	5	01/01/26
Bradykinin, Quantitative, by LC-MS/MS, Virant Diagnostics, Inc	0604U	Allergy and immunology (chronic recurrent angioedema), 4 bradykinin peptides, liquid chromatography and tandem mass spectrometry (LC-MS/ MS), whole blood, quantitative	ALL&IMMUNOLOGY CRAE 4BK PEP	5	01/01/26
Tryptase Gene Copy Number Analysis by dPCR, Virant Diagnostics, Inc	0605U	Allergy and immunology (hereditary alpha tryptasemia), DNA, analysis of TPSAB1 gene copy number variation using digital PCR, whole blood, results reported with genotype-specific interpretation of alpha-tryptase copy number and algorithmic classification as normal or abnormal	ALL&IMMUNOLOGY HAT TPSAB1	5	01/01/26
Osmotic Gradient Ektacytometry, Cincinnati Children’s Clinical Laboratories, RR Mechatronics	0606U	Hematology (red cell membrane disorders), RBCs, osmotic gradient ektacytometry, whole blood, quantitative	HEM RED CLL MEMB DO RBC OGE	5	01/01/26
EMMA (Endometrial Microbiome Metagenomic Analysis), Igenomix®, Igenomix® USA	0607U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 31 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations	REPRDTVE MED EMA RTPCR 31BCT	5	01/01/26
ALICE (Analysis of Infectious Chronic Endometritis), Igenomix®, Igenomix® USA	0608U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 10 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations (Do not report 0608U in conjunction with 0607U)	REPRDTVE MED EMA RTPCR 10BCT	5	01/01/26
ClarityDX Prostate, Protean BioDiagnostics, Nanostics Inc	0609U	Oncology (prostate), immunoassay for total prostate-specific antigen (PSA) and free PSA, serum or plasma, combined with clinical features, algorithm reported as a probability score for clinically significant prostate cancer	ONC PROSTATE IA TOT&FREE PSA	5	01/01/26
LifeScale Gram Negative Kit (LSGN) with the LifeScale AST system, Affinity Biosensors, LLC, Affinity Biosensors, LLC	0610U	Infectious disease (antimicrobial susceptibility), phenotypic antimicrobial susceptibility testing of positive blood culture using microfluidic sensor technology to quantify bacterial growth response to multiple antibiotic types, reporting categorical susceptibility (susceptible, susceptible dose dependent, intermediate, resistant), minimum inhibitory concentration, and interpretive comments	NFCT DS ANTMCR SC PHENOTYPIC	5	01/01/26
HelioHCCTM Strat, Helio Genomics®, Helio Genomics®	0611U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0612U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	ONC LVR ALYS >1000 MR CFDNA	5	01/01/26

HelioHCCTM Trace, Helio Genomics®, Helio Genomics®	0612U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0611U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	ONC LVR ALYS >1000 MR CFDNA	5	01/01/26
AssureMDxTM, Vesica Health® Inc	0613U	Oncology (urothelial carcinoma), DNA methylation and mutation analysis of 6 biomarkers (TWIST1, OTX1, ONECUT2, FGFR3, HRAS, TERT promoter region), methylation-specific PCR and targeted next-generation sequencing, urine, algorithm reported as a probability index for bladder cancer and upper tract urothelial carcinoma	ONC UC DNA MTHYLTN&MUT 6BMRK	5	01/01/26

Deleted Codes Effective January 1, 2026

The following codes are being deleted with a deletion date of January 1, 2026.

CPT Code	Long Descriptor	Delete Date
0033U	Htr2a (5-hydroxytryptamine receptor 2a), htr2c (5-hydroxytryptamine receptor 2c) (eg, citalopram metabolism) gene analysis, common variants (ie, htr2a rs7997012 [c.614-2211t>c], htr2c rs3813929 [c.-759c>t] and rs1414334 [c.551-3008c>g])	01/01/2026
0131U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mrna sequence analysis panel (13 genes) (list separately in addition to code for primary procedure)	01/01/2026
0132U	Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mrna sequence analysis panel (17 genes) (list separately in addition to code for primary procedure)	01/01/2026
0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mrna sequence analysis panel (12 genes) (list separately in addition to code for primary procedure)	01/01/2026
0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative	01/01/2026
0508U	Transplantation medicine, quantification of donor-derived cell-free dna using 40 singlenucleotide polymorphisms (snps), plasma, and urine, initial evaluation reported as percentage of donor-derived cellfree dna with risk for active rejection	01/01/2026
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	01/01/2026
0544U	Nephrology (transplant monitoring), 48 variants by digital pcr, using cell-free dna from plasma, donor-derived cell-free dna, percentage reported as risk for rejection	01/01/2026
0550U	Oncology (prostate), enzymelinked immunosorbent assays (elisa) for total prostatespecific antigen (psa) and free psa, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer	01/01/2026
0551U	Tau, phosphorylated, ptau217, by single-molecule array (ultrasensitive digital protein detection), using plasma	01/01/2026