

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10575	Date: January 20, 2021
	Change Request 12080

Transmittal 10523, dated December 18, 2020, is being rescinded and replaced by Transmittal 10575, dated, January 20, 2021 to correct the attachment. Specifically, the payment determination for code 0177U crosswalk from 81310 to 81309. All other information remains the same.

SUBJECT: Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the CY 2021 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, 2021

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

IMPLEMENTATION DATE: January 4, 2021

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/revise 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: 10575	Date: January 20, 2021	Change Request: 12080
-------------	--------------------	------------------------	-----------------------

Transmittal 10523, dated December 18, 2020, is being rescinded and replaced by Transmittal 10575, dated, January 20, 2021 to correct the attachment. Specifically, the payment determination for code 0177U crosswalk from 81310 to 81309. All other information remains the same.

SUBJECT: Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2021

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

IMPLEMENTATION DATE: January 4, 2021

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2021 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

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.html#ADLT_tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests —DELAYED

- 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.
- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, revisions are as follows:
 - The next data reporting period of January 1, 2022 through March 31, 2022, will be based on the original data collection period of January 1, 2019 through June 30, 2019.

- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Coronavirus-19 (COVID-19) Policy Updates

- **Payment for High Throughput Technologies**

On October 15, 2020, The Centers for Medicare & Medicaid Services (CMS) issued ruling CMS-2020-1-R2 which amends CMS Ruling 2020-1-R, which articulated CMS’s policy concerning the designation and payment of certain clinical diagnostic laboratory tests (CDLTs) related to COVID-19 under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). CMS Ruling 2020-1-R defined certain highly sophisticated equipment called “high throughput technology,” and established a payment amount for molecular genomic CDLTs making use of high throughput technologies for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID-19 and that are administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (the Act). CMS Ruling 2020-2-R amends CMS Ruling 2020-1-R by modifying the payment amount established in that Ruling for such Clinical Diagnostic Laboratory Tests (CDLT) based on a re-evaluation of the resources necessary for the timely administration of these tests. The ruling establishes a revised payment amount for HCPCS codes U0003 and U0004 of \$75 per procedure (previously was \$100) and a new add-on payment amount of \$25 for HCPCS code U0005 which is to be used to indicate that the corresponding CDLT (U0003 or U0004) that makes use of high throughput technology for the detection of SARS–CoV–2 or diagnosis of the virus that causes COVID-19 is completed within 2 calendar days of the specimen being collected, and the laboratory completed a majority of these CDLTs (for all patients during the prior calendar month) in 2 calendar days or less from when the specimen was collected. For more information on this policy update, please refer to <https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf>.

Clinical Laboratory Fee Schedule Update to Fees

In accordance with Section 1833(h)(2)(A)(i) of the Act, the annual update to the local clinical laboratory fees for **CY 2021** is 0.20 percent. Beginning **January 1, 2021**, this update applies only to pap smear tests. 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 2021** national minimum payment amount is **\$15.15** (This value reflects the **CY 2020** national minimum payment with a **0.2 percent** increase or **\$15.12 times 1.0020**). 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 for **CY 2021** is **0.6 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 2021 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, 2020. Internet access to the CY 2021 CLFS data file shall be available after December 1, 2020, 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 2021 CLFS. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 22, 2020, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2020 codes and new CY 2021 CPT codes. Notice of the meeting was published in the **Federal Register** on May 4, 2020. 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 21, 2020. 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 2021 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). 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 2021, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2021 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 "CY2021 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 2021

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 2021 is **0.60 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 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 "**CY2021 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 "**CY2021 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 "**CY2021 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment**", Tab "**B. Reasonable Charge**".

New Codes Effective October 6, 2020

The listed new codes are on the national HCPCS file with an effective date of October 6, 2020 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 undergoes the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 87636

Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique

Short Descriptor: SARSCOV2 & INF A&B AMP PRB

TOS: 5

- Code: 87637

Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-

CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique

Short Descriptor: SARSCOV2&INF A&B&RSV AMP PRB

TOS: 5

- Code: 87811

Long Descriptor: Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

Short Descriptor: SARS-COV-2 COVID19 W/OPTIC

TOS: 5

Proprietary Laboratory Analysis (PLAs)

The listed new codes have been added to the national HCPCS file with an effective date of October 6, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2021 as they were received after the 2020 public meeting.

MACs shall only price PLA codes for laboratories within their jurisdiction.

- Code: 0240U

Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected

Short Descriptor: NFCT DS VIR RESP RNA 3 TRGT

Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (SARS-CoV-2 & Flu targets only), Cepheid

TOS: 5

- Code: 0241U

Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected

Short Descriptor: NFCT DS VIR RESP RNA 4 TRGT

Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets), Cepheid

TOS: 5

New Codes Effective November 10, 2020

The listed new code will be added to the national HCPCS file with an effective date of November 10, 2020 and does not need to be manually added to the HCPCS files by the MACs. However, the new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 87428

Long Descriptor: Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARSCoV-2 [COVID-19]) and influenza virus types A and B

Short Descriptor: SARSCOV & INF VIR A&B AG IA

TOS: 5

New Codes Effective January 1, 2021

Per the above discussion in the COVID-19 Policy Updates section, Payment for High Throughput Technologies, the listed new code was added to the national HCPCS file with an effective date of January 1, 2021 and does not need to be manually added to the HCPCS files by the MACs. Such test, as identified by U0005, in accordance with CMS Ruling CMS-2020-02-R, shall be paid at the rate of \$25.

This new code is listed below:

- Code: U0005

Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (List separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R2.

Short Descriptor: Infec agen detec ampli probe

TOS: 5

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2021 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment**", Tab "**C. New Codes Eff. 1-1-2021**". The listed new codes have been added to the national HCPCS file with an effective date of January 1, 2021 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2021 as they were received after the 2020 public meeting.

MACs shall only price PLA codes for laboratories within their jurisdiction.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C	Shared-System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
12080.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2021 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.V2021Q1) from the CMS mainframe on or after December 1, 2020.	X	X									
12080.1.1	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								VDCs	
12080.1.2	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									VDCs	
12080.2	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									
12080.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X									
12080.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2019 through June 30, 2020, updated by the inflation-index update for year CY 2021 of 0.6 percent.		X									
12080.5	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										
12080.6	If there is a revision to the standard mileage rate for CY 2021, CMS shall issue a separate instruction on the clinical laboratory travel fees.										CMS	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
12080.7	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Rasheeda Johnson, 410-786-3434 or Rasheeda.Johnson1@cms.hhs.gov , Laura Ashbaugh, 4107861113 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) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0141U	NEW	Gapfill
0142U	NEW	Gapfill
0151U	NEW	Gapfill
0202U	NEW	87633
0140U	NEW	Gapfill
0152U	NEW	Gapfill
0210U	NEW	[0065U PLUS (0065U TIMES 0.03)]
U0001	NEW	Gapfill
U0002	NEW	Gapfill
U0003	NEW	Gapfill

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
U0004	NEW	Gapfill
87635	NEW	Gapfill
86328	NEW	Gapfill
86769	NEW	Gapfill
0181U	NEW	81403
0182U	NEW	81405
0183U	NEW	81403
0184U	NEW	81403
0185U	NEW	81403
0186U	NEW	81403

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0187U	NEW	81404
0188U	NEW	81404
0189U	NEW	81404
0190U	NEW	81404
0191U	NEW	81404
0192U	NEW	81404
0193U	NEW	81406
0194U	NEW	81403
0196U	NEW	81403
0197U	NEW	81403

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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, reconsiderd, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
0198U	NEW	81406
0199U	NEW	81404
0200U	NEW	81404
0201U	NEW	81403
0221U	NEW	Gapfill
0222U	NEW	Gapfill
0180U	NEW	Gapfill
0143U	NEW	Gapfill
0144U	NEW	Gapfill
0145U	NEW	G0480

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0146U	NEW	G0480
0147U	NEW	G0480
0148U	NEW	G0480
0149U	NEW	G0480
0150U	NEW	G0480
80179	NEW	80299
80151	NEW	80299
80143	NEW	80299
82077	NEW	83520
80161	NEW	80299

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
80167	NEW	80299
80181	NEW	80299
80189	NEW	80187
80193	NEW	80230
80204	NEW	80230
80210	NEW	80199
0219U	NEW	Gapfill
81513	NEW	87631
81514	NEW	87506
81546	NEW	81545

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0208U	NEW	Gapfill
0014M	NEW	0003M*0.35
0166U	NEW	0003M
0139U	NEW	Gapfill
0170U	NEW	0090U
81554	NEW	This code was approved as an Advanced Diagnostic Laboratory Test (ADLT).
0164U	NEW	Gapfill
0168U	NEW	81420
0174U	NEW	Gapfill
0015M	NEW	Gapfill

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0016M	NEW	Gapfill
0163U	NEW	Gapfill
81307	Reconsideration	81317
0071U	Reconsideration	81238
0101U	Reconsideration	Gapfill
0102U	Reconsideration	Gapfill
0103U	Reconsideration	Gapfill
0129U	Reconsideration	Gapfill
81168	NEW	81315
81278	NEW	81315

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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, reconsiderd, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
81191	NEW	81315
81192	NEW	81315
81193	NEW	81315
0209U	NEW	Gapfill
81194	NEW	81315 TIMES 2.5
0153U	NEW	Gapfill
0155U	NEW	81309
0177U	NEW	81309
0157U	NEW	Gapfill
0158U	NEW	Gapfill

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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, reconsiderd, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
0159U	NEW	Gapfill
0160U	NEW	Gapfill
0161U	NEW	Gapfill
0162U	NEW	Gapfill
81279	NEW	81403
81338	NEW	81402
81339	NEW	81403
81347	NEW	81120
81348	NEW	81233
81357	NEW	81120

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
81360	NEW	81120
0171U	NEW	Gapfill
81351	NEW	81298
81353	NEW	81299
81352	NEW	81334
0154U	NEW	81309 PLUS 81315
0156U	NEW	Gapfill
0179U	NEW	Gapfill
0195U	NEW	81215
0169U	NEW	0034U

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0165U	NEW	Gapfill
0167U	NEW	84703
0178U	NEW	Gapfill
81419	NEW	81443
0173U	NEW	Gapfill
0175U	NEW	Gapfill
0203U	NEW	0011M
0204U	NEW	81455
0205U	NEW	81330
0211U	NEW	0019U PLUS 0036U

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0212U	NEW	Gapfill
0213U	NEW	Gapfill
0214U	NEW	Gapfill
0215U	NEW	Gapfill
0216U	NEW	Gapfill
0217U	NEW	Gapfill
0218U	NEW	81408 PLUS 81161
0176U	NEW	86828
0206U	NEW	Gapfill
0207U	NEW	Gapfill

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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 D, "Rate".	Rate
0220U	NEW	Gapfill
82681	NEW	82670
U0002QW	NEW	U0002
87635QW	NEW	87635
87426QW	NEW	87426
0006U	EXISTING CODE	DELETE
0124U	EXISTING CODE	DELETE
0125U	EXISTING CODE	DELETE
0126U	EXISTING CODE	DELETE
0127U	EXISTING CODE	DELETE

Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) Mapping Information ¹

¹CPT codes, descriptions and other data only are copyright 2020 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, reconsiderd, or existing)</i> New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".	Rate
0128U	EXISTING CODE	DELETE
87450	EXISTING CODE	DELETE

Laboratory Costs Subject to Reasonable Charge Payment in CY 2021

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, 2021

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of January 1, 2021 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2021 as they were received after the 2020 public meeting.

MACs shall only price PLA codes for laboratories within their jurisdiction.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
Comprehensive Screen, Aspent Health	0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation	RX ASY PRSMV 30+RX/METABLT	5	January 1, 2021
PanGIA Prostate, Genetics Institute of America, Entopsis, LLC	0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer	ONC PRST8 MA MOLEC PRFL ALG	5	January 1, 2021
Colvera®, Clinical Genomics Pathology Inc	0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	BCAT1 PROMOTER MTHYLTN ALYS	5	January 1, 2021
Genomic Unity® AR Analysis, Variantyx Inc, Variantyx Inc	0230U	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	AR FULL SEQUENCE ANALYSIS	5	January 1, 2021
Genomic Unity® CACNA1A Analysis, Variantyx Inc, Variantyx Inc	0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions	CACNA1A FULL GENE ANALYSIS	5	January 1, 2021
Genomic Unity® CSTB Analysis, Variantyx Inc, Variantyx Inc	0232U	CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	CSTB FULL GENE ANALYSIS	5	January 1, 2021
Genomic Unity® FXN Analysis, Variantyx Inc, Variantyx Inc	0233U	FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	FXN GENE ANALYSIS	5	January 1, 2021
Genomic Unity® MECP2 Analysis, Variantyx Inc, Variantyx Inc	0234U	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	MECP2 FULL GENE ANALYSIS	5	January 1, 2021
Genomic Unity® PTEN Analysis, Variantyx Inc, Variantyx Inc	0235U	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	PTEN FULL GENE ANALYSIS	5	January 1, 2021
Genomic Unity® SMN1/2 Analysis, Variantyx Inc, Variantyx Inc	0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions	SMN1&SMN2 FULL GENE ANALYSIS	5	January 1, 2021
Genomic Unity® Cardiac Ion Channelopathies Analysis, Variantyx Inc, Variantyx Inc	0237U	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	CAR ION CHNLPHTY GEN SEQ PNL	5	January 1, 2021
Genomic Unity® Lynch Syndrome Analysis, Variantyx Inc, Variantyx Inc	0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	ONC LNCH SYN GEN DNA SEQ ALY	5	January 1, 2021
FoundationOne® Liquid CDx, FOUNDATION MEDICINE, INC, FOUNDATION MEDICINE, INC	0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	TRGT GEN SEQ ALYS PNL 311+	5	January 1, 2021