CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4498	**Date: January 22, 2020**
	Change Request 11598

Transmittal 4476, dated December 13, 2019, is being rescinded and replaced by Transmittal 4498, dated, January 22, 2020 to revise the policy section. All other information remains the same.

SUBJECT: Calendar Year (CY) 2020 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 2020 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, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

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: 4498	Date: January 22, 2020	Change Request: 11598

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SUBJECT: Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2020 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:
Protecting Access to Medicare Act of 2014 (PAMA) Updates

- Next CLFS Data Reporting Period—DELAYED to January 2021

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.

- **For Clinical Diagnostic Laboratory Tests (CDLTs) that are not Advanced Diagnostic Laboratory Tests (ADLTs), the data reporting is delayed by one year**. CDLT data that was supposed to be reported between January 1, 2020 and March 31, 2020, must now be reported between **January 1, 2021, and March 31, 2021**. Labs must report data from the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will then resume on a three-year cycle, beginning in 2024. (Section 105(a)(1) of the Further Consolidated Appropriations Act of 2020 (FCAA)).
- In addition, the statutory phase-in provisions are updated. For 2020, the rates for CDLTs that are not ADLTs or new CLDTs may not be reduced by more than 10% of the rates for 2019. There will be a 15% reduction cap for each of 2021, 2022, and 2023. (Section 105(a)(2) of FCAA).

- Reminder: Revisions to the Definition of Applicable Laboratory

The Physician Fee Schedule (PFS) final rule entitled "Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019" (CMS-1693-F) was displayed in the **Federal Register** on November 1, 2018 and was published on November 23, 2018. In the CY 2019 PFS final rule, CMS made two revisions to the regulatory definition of applicable laboratory: 1) Effective January 1, 2019, Medicare Advantage plan revenues were excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold); and (2) Effective January 1, 2019, hospitals that bill for their non-patient laboratory services may use Medicare revenues from the Form CMS 1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

The regulatory definition of an applicable laboratory, which was effective January 1, 2019 is summarized below (revisions are annotated by italics font).

Applicable laboratory means an entity that:

(1) Is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (42 C.F.R. § 493.2);

(2) The laboratory bills Medicare under its own National Provider Identifier (NPI) *or*

(i) For hospital outreach laboratories --bills Medicare Part B on the Form CMS 1450 under bill type 14x;

(3) The laboratory must meet a "majority of Medicare revenues" threshold, where it receives more than 50 percent of its total Medicare revenues from one or a combination of the CLFS or the PFS in a data collection period.

For purposes of determining whether a laboratory meets the "majority of Medicare revenues" threshold, total Medicare revenues includes: fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance. ***As a reminder, effective January 1, 2019, total Medicare revenues no longer includes Medicare Advantage payments under Medicare Part C.***

(4) The laboratory must meet a "low expenditure" threshold, where it receives at least $12,500 of its Medicare revenues from the CLFS in a data collection period.

As noted above, the CLFS data collection period was January 1, 2019 through June 30, 2019. All hospital outreach laboratories that bill for non-patient laboratory services using the Form CMS 1450 14x TOB, were required to determine applicable laboratory status from their final paid Medicare claims received during the next data collection period. Hospital outreach laboratories that met the definition of an applicable laboratory will be required to report applicable information to CMS during the next data reporting period, which is January 1, 2021 through March 31, 2021. Additional sub regulatory guidance will be made available on the CLFS website under the PAMA regulations tab: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.

- Advanced Diagnostic Laboratory Tests (ADLTs) Effective January 1, 2020

1. The ADLT DecisionDx-Uveal Melanoma owned and furnished by Castle Bioscience was assigned PLA code 0081U effective 1/1/2019. This code is being deleted effective 12/31/2019 and replaced by CPT code 81552, effective 1/1/2020.

CPT Code: 81552

Long Descriptor: Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin embedded tissue, algorithm reported as risk of metastasis

Short Descriptor: ONC UVEAL MLNMA MRNA 15 GENE

2. Existing code 81538 is an ADLT and is priced at its median private payor rate.

3. Please refer to the following CMS website for additional information regarding other ADLTS: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests.

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 2020** is 0.**90** percent. Beginning **January 1, 2020,** 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 2020** national minimum payment amount is **$15.12** (This value reflects the **CY 2019**national minimum payment with a **0.9 percent** increase or **$14.99 times 1.0090)**. 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 2020 is 1.6 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 2020 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, 2019. Internet access to the CY 2020 CLFS data file shall be available after December 1, 2019, 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 2020 CLFS. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 24, 2019, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2019 codes and new CY 2020 CPT codes. Notice of the meeting was published in the **Federal Register** on

April 1, 2019. 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 27, 2019. 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 2020 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 2020, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2020 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 "CY2020 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 2020

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 2020 is **1.60 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 "**CY2020 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment**", Tab "**B. Reasonable Charge**".

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

Please see table attached to the Transmittal entitled "**CY2020 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 "**CY2020 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment**", Tab "**B. Reasonable Charge**".

New Codes Effective January 1, 2020

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2020 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment**", Tab "**C. New Codes Eff. 1-1-2020**". The listed new codes have been added to the national HCPCS file with an effective date of January 1, 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 2020 as they were received after the 2019 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			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11598.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2020 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.V2020Q1) from the CMS mainframe on or after December 1, 2019.	X	X							
11598.1.1	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
11598.1.2	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
11598.2	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							
11598.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
11598.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2018 through June 30, 2019, updated by the inflation-index update for year CY 2020 of 1.6 percent.		X							
11598.5	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								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11598.6	If there is a revision to the standard mileage rate for CY 2020, CMS shall issue a separate instruction on the clinical laboratory travel fees.									CMS

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11598.7	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) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0064U	New	**86780 PLUS 86318**
0065U	New	**86318**
0068U	New	**87631**
0086U	New	**Gapfill**
0096U	New	**87624**
0097U	New	**Gapfill**
0098U	New	**Gapfill**
0099U	New	**Gapfill**
0100U	New	**Gapfill**
87563	New	**87491**
0109U	New	**87631**
0115U	New	**Gapfill**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0084U	New	**0001U**
0121U	New	**Gapfill**
0122U	New	**Gapfill**
0123U	New	**Gapfill**
0062U	New	**Gapfill**
0063U	New	Gapfill
0066U	New	**87808**
0067U	New	**Gapfill**
0077U	New	**Gapfill**
0082U	New	**0006U**
0092U	New	**Gapfill**
0093U	New	**80307**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0095U	New	**Gapfill**
80145	New	**80155**
80230	New	**80155**
80235	New	**80199**
80187	New	**80199**
80280	New	**80155**
80285	New	**80199**
0105U	New	**0003U**
0106U	New	**Gapfill**
0107U	New	**87803**
0108U	New	**Gapfill**
0110U	New	**80199**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0116U	New	**0006U**
0117U	New	**Gapfill**
0119U	New	**Gapfill**
0124U	New	**81510**
0125U	New	**81512**
0126U	New	**81512**
0127U	New	**81510**
0128U	New	**81510**
81307	New	**81406**
81308	New	**81405**
81309	New	**81404**
0069U	New	**0005U TIMES 0.50**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0078U	New	**81226**
0089U	New	**0005U**
81522	New	**81518**
81542	New	**Gapfill**
0111U	New	**81275 PLUS 81276 PLUS 81311**
0112U	New	**Gapfill**
0113U	New	**0005U**
0114U	New	**Gapfill**
0120U	New	**81520**
0129U	New	**81432 PLUS 81433**
0130U	New	**81435**
0131U	New	**Gapfill**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0132U	New	**Gapfill**
0133U	New	**Gapfill**
0134U	New	**Gapfill**
0135U	New	**Gapfill**
0136U	New	**Gapfill**
0137U	New	**Gapfill**
0138U	New	**Gapfill**
0094U	New	**Gapfill**
0101U	New	**81435 PLUS 81436**
0102U	New	**81432 PLUS 81433**
0103U	New	**81432 PLUS 81433**
81163	Reconsidered	**81406 PLUS 81216**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
81165	Reconsidered	**81406**
0046U	Reconsidered	**Gapfill**
0049U	Reconsidered	**Gapfill**
0070U	New	**81226 TIMES 1.5**
0071U	New	**81405**
0072U	New	**81226**
0073U	New	**81226**
0074U	New	**81226**
0075U	New	**81226**
0076U	New	**81226**
0083U	New	**Gapfill**
0087U	New	**Gapfill**

Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information [1]

CPT Code #	**Code Type** *(new, revised, reconsiderd, or existing)* **New, revised and reconsidered codes are priced at the same rate as code (s) noted in column D, "Rate".**	**Rate**
0088U	New	**Gapfill**
0118U	New	**Gapfill**
81277	New	**81229**
0009M	Exisiting Code	**Delete**

Laboratory Costs Subject to Reasonable Charge Payment in CY 2020	
Code Category	**Codes**
Blood Products	P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033 P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9044 P9050 P9051 P9052 P9053 P9054 P9055 P9056 P9057 P9058 P9059 P9060 P9070 P9071 P9073 P9100 Also, payment for the following codes should be applied to the blood deductible as instructed in Publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 3, Section 20.5 through 20.5.4: P9010 P9016 P9021 P9022 P9038 P9039 P9040 P9051 P9054 P9056 P9057 P9058 NOTE: Biologic products not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for codes P9041, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.
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, 2020

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of January 1, 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 2020 as they were received after the 2019 public meeting.

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

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
NPDX ASD Energy Metabolism, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc	0139U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	NEURO AUSTM MEAS 6 C METABLT	5	January 1, 2020
ePlex® BCID Fungal Pathogens Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	0140U	Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected	NFCT DS FUNGI DNA 15 TRGT	5	January 1, 2020
ePlex® BCID GramPositive Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	0141U	Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected	NFCT DS BACT&FNG GRAM POS	5	January 1, 2020
ePlex® BCID GramNegative Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	0142U	Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected	NFCT DS BACT&FNG GRAM NEG	5	January 1, 2020
CareViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 120+ RX/METABLT	5	January 1, 2020
CareViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 160+ RX/METABLT	5	January 1, 2020
PainViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 65+ RX/METABLT	5	January 1, 2020
PainViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 80+ RX/METABLT	5	January 1, 2020
RiskViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 85+ RX/METABLT	5	January 1, 2020
RiskViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 100+ RX/METABLT	5	January 1, 2020
PsychViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 60+ RX/METABLT	5	January 1, 2020
PsychViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service	DRUG ASSAY 120+ RX/METABLT	5	January 1, 2020
BioFire® FilmArray® Pneumonia Panel, BioFire® Diagnostics, BioFire® Diagnostics	0151U	Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results	NFCT BCT/VIR RESP NFCTJ 33	5	January 1, 2020
Karius® Test, Karius Inc, Karius Inc	0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens	NFCT BCT FNG PRST DNA >1000	5	January 1, 2020
Insight TNBCtype™, Insight Molecular Labs	0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement	ONC BREAST MRNA 101 GENES	5	January 1, 2020
therascreen® FGFR RGQ RT-PCR Kit, QIAGEN, QIAGEN GmbH	0154U	FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3)	FGFR3 GENE ANALYSIS	5	January 1, 2020
therascreen PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH	0155U	PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y)	PIK3CA GENE ANALYSIS	5	January 1, 2020
SMASH™, New York Genome Center, Marvel Genomics™	0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis	COPY NUMBER SEQUENCE ALYS	5	January 1, 2020
CustomNext + RNA: APC, Ambry Genetics®, Ambry Genetics®	0157U	APC (APC regulator of WNT signaling pathway) (eg, familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0157U in conjunction with 81201)	APC MRNA SEQ ALYS	5	January 1, 2020

CustomNext + RNA: MLH1, Ambry Genetics®, Ambry Genetics®	0158U	MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0158U in conjunction with 81292)	MLH1 MRNA SEQ ALYS	5	January 1, 2020
CustomNext + RNA: MSH2, Ambry Genetics®, Ambry Genetics®	0159U	MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0159U in conjunction with 81295)	MSH2 MRNA SEQ ALYS	5	January 1, 2020
CustomNext + RNA: MSH6, Ambry Genetics®, Ambry Genetics®	0160U	MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0160U in conjunction with 81298)	MSH6 MRNA SEQ ALYS	5	January 1, 2020
CustomNext + RNA: PMS2, Ambry Genetics®, Ambry Genetics®	0161U	PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0161U in conjunction with 81317)	PMS2 MRNA SEQ ALYS	5	January 1, 2020
CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2), Ambry Genetics®, Ambry Genetics®	0162U	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure) *(Use 0162U in conjunction with 81292, 81295, 81298, 81317, 81435)	HERED COLON CA TRGT MRNA PNL	5	January 1, 2020