CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4541	**Date: March 6, 2020**
	Change Request 11681

SUBJECT: Quarterly 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 quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: April 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 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: 4541	Date: March 6, 2020	Change Request: 11681

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

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

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

B. Policy: <u>Protecting Access to Medicare Act of 2014 (PAMA) Updates</u>

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests—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.
- Under section 105 (a) of the Further Consolidated Appropriations Act of 2020 (FCAA), for CDLTs that are not Advanced Diagnostic Laboratory Tests (ADLTs), the data reporting period is delayed by one year. Applicable information that was required to be reported to CMS between January 1, 2020 and March 31, 2020, must now be reported between January 1, 2021, and March 31, 2021. Applicable laboratories must report applicable information 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, with the next data reporting period taking place in 2024. (Section 105(a)(1) of the FCAA).
- In addition, the FCAA updated the statutory phase-in provisions for the CLFS. 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).

<u>Advanced Diagnostic Laboratory Tests (ADLTs)</u>

- 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.

Fee Schedule Beginning January 1, 2018

Effective January 1, 2018, CLFS rates will be based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. For more details, visit PAMA Regulations, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

Access to Data File

The quarterly clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Under normal circumstances, CMS will make the updated CLFS data file available to A/B MAC contractors approximately 6 weeks prior to the beginning of each quarter. For example, the updated file will typically be made available for download and testing on or before approximately February 15th for the April 1st release. Internet access to the quarterly clinical laboratory fee schedule data file shall be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, shall use the Internet to retrieve the quarterly clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

Pricing Information

The clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees are established in accordance with Section 1833(h)(4)(B) of the Act.

New Codes Effective February 4, 2020

Medicare covers medically necessary and reasonable clinical diagnostic laboratory tests when ordered by a physician or non-physician practitioner who is treating the patient. The following codes will be added to the national HCPCS file with an effective date of February 4, 2020 and therefore do not need to be manually added to the HCPCS files by the MACs. 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 it was received after the 2019 public meeting.

Code: U0001

Short Descriptor: 2019 –nCoV diagnostic P

Long Descriptor: CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

TOS: 5

Code: U0002

Short Descriptor: COVID-19 lab test non-CDC

Long Descriptor: 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC

TOS: 5

New Codes Effective April 1, 2020

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2020 CLFS Quarterly Updates**", Tab "**New Codes Effective 4-1-2020**". The listed new codes have been added to the national HCPCS file with an effective date of April 1, 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 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.

The table includes the laboratory, long descriptor, short descriptor, and TOS of each new code.

Revised Codes Effective April 1, 2020

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2020 CLFS Quarterly Updates**", Tab "**Revised Codes Eff. 4-1-2020**". The listed revised codes have been added to the national HCPCS file with an effective date of April 1, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these revised codes are contractor-priced (where applicable) 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.

The table includes the laboratory, long descriptor, short descriptor, and TOS of each revised code.

Deleted Codes Effective April 1, 2020

Existing code 0006U is being deleted.

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	
11681.1	Contractors shall be aware that the CLFS will be released quarterly, as needed, and establish hours to accommodate retrieval and implementation of the quarterly CLFS data file.	X	X							VDC
11681.1.1	CMS shall notify contractors by email approximately six weeks prior to the beginning of the quarter when the Clinical Laboratory Fee Schedule (CLFS) data file is ready for download. CMS shall provide the file name.									CMS
11681.2	Contractors shall retrieve and load for testing and claims processing purposes the April 2020 quarterly	X	X							VDC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.									
11681.2.1	Contractors shall note that the CLFS data file name will be in the following format: MU00.@BF12394.CLAB.V2020Q2 Note: The naming convention of the file is such that "yyyy" equals the calendar year (for example, V2020) and "r" equals the release number (for example, Q2 reflects Quarter 2 or April release) with January = 1, April = 2, July = 3, and October = 4	X	X							VDC
11681.2.2	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., SSM or A/B MAC Part B name and number).	X	X							VDC
11681.2.3	Contractors shall address any questions/concerns regarding the content of the files and/or specific HCPCS codes contained within by emailing CLFS_Inquiries@cms.hhs.gov.	X	X							VDC
11681.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This requirement is applicable to the January quarterly release CR only).		X							
11681.4	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 (**NOTE** - This requirement is applicable to the January quarterly release CR only).	X								
11681.5	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	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11681.5.1	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							
11681.6	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							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11681.7	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 Arthur, 410-786-3434 or rasheeda.johnson1@cms.hhs.gov , Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov

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

VI. FUNDING

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

ATTACHMENTS: 1

New Codes Effective April 1, 2020

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of April 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
BeScreened™-CRC, Beacon Biomedical Inc, Beacon Biomedical Inc	0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	ONC CLRCT SCR 3 PRTN ALG	5	April 1, 2020
ibs-smart™, Gemelli Biotech, Gemelli Biotech	0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	GI IBS IA ANTI-CDTB&VINCULIN	5	April 1, 2020
VeriMAP Peanut Dx – Bead-based Epitope Assay, AllerGenis, AllerGenis	0165U	Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and interpretation	PEANUT ALLG SPEC ASMT 64 EPI	5	April 1, 2020
LiverFASt™, Fibronostics, Fibronostics	0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	LIVER DS 10 BIOCHEM ASY SRM	5	April 1, 2020
ADEXUSDx hCG Test, NOWDiagnostics, NOWDiagnostics	0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	CHORNC GONADOTROPIN HCG IA	5	April 1, 2020
Vanadis® NIPT, PerkinElmer, Inc, PerkinElmer Genomics	0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	FTL ANEUPLOIDY DNA SEQ ALYS	5	April 1, 2020
NT (NUDT15 and TPMT) genotyping panel, RPRD Diagnostics	0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	NUDT15&TPMT GENE COM VRNT	5	April 1, 2020
Clarifi™, Quadrant Biosciences, Inc, Quadrant Biosciences, Inc	0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	NEURO ASD RNA NEXT GEN SEQ	5	April 1, 2020
MyMRD® NGS Panel, Laboratory for Personalized Molecular Medicine, Laboratory for Personalized Molecular Medicine	0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	TRGT GEN SEQ ALYS PNL DNA 23	5	April 1, 2020

Revised Codes Effective April 1, 2020

Proprietary Laboratory Analysis (PLAs)

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

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
therascreen® FGFR RGQ RT-PCR Kit, QIAGEN, QIAGEN GmbH	0154U	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the 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) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status	ONC URTHL CA RNA FGFR3 GENE	5	April 1, 2020
therascreen® PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH	0155U	Oncology (breast cancer), DNA, 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), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status	ONC BRST CA DNA PIK3CA GENE	5	April 1, 2020