CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4326	Date: June 28 ,2019
	Change Request 11280

Transmittal 4296, dated May 3, 2019, is being rescinded and replaced by Transmittal 4326, dated, June 28, 2019 to update the policy section with additional information regarding Advanced Diagnostic Laboratory Tests (ADLTs). All other information remains the same.

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: July 1, 2019
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: July 1, 2019

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: 4326	Date: June 28, 2019	Change Request: 11280

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

EFFECTIVE DATE: July 1, 2019
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: July 1, 2019

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: 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 July 1, 2019

Proprietary Laboratory Analysis (PLAs)

The following new codes may need to be manually added to the HCPCS file by the MACs with an effective date of July 1, 2019. These new codes are also contractor-priced until they appear on the January 1, 2020 CLFS as applicable.

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

CPT Code: 0084U

Long Descriptor: Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens

Short descriptor: RBC DNA GNOTYP 10 BLD GROUPS

Laboratory: BLOODchip®ID CORE XT™, Grifols Diagnostic Solutions Inc

TOS: 5

CPT Code: 0085U

Long Descriptor: Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)

Short Descriptor: CDTB&VINCULIN IGG ANTB IA

Laboratory: Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc

TOS: 5

CPT Code: 0086U

Long Descriptor: Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility

Short Descriptor: NFCT DS BACT&FNG ORG ID 6+

Laboratory: Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc

TOS: 5

CPT Code: 0087U

Long Descriptor: Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score

Short Descriptor: CRD HRT TRNSPL MRNA 1283 GEN

Laboratory: Molecular Microscope® MMDx—Heart, Kashi Clinical Laboratories

TOS: 5

CPT Code: 0088U

Long Descriptor: Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for

rejection

Short Descriptor: TRNSPLJ KDN ALGRFT REJ 1494

Laboratory: Molecular Microscope® MMDx—Kidney, Kashi Clinical Laboratories

TOS: 5

CPT Code: 0089U

Long Descriptor: Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)

Short Descriptor: ONC MLNMA PRAME & LINC00518

Laboratory: Pigmented Lesion Assay (PLA), DermTech

TOS: 5

CPT Code: 0090U

Long Descriptor: Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)

Short Descriptor: ONC CUTAN MLNMA MRNA 23 GENE

Laboratory: myPath® Melanoma, Myriad Genetic Laboratories

TOS: 5

CPT Code: 0092U

Long Descriptor: Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy

Short Descriptor: ONC LNG 3 PRTN BMRK PLSM ALG

Laboratory: REVEAL Lung Nodule Characterization, MagArray, Inc

TOS: 5

CPT Code: 0093U

Long Descriptor: Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected

Short Descriptor: RX MNTR 65 COM DRUGS URINE

Laboratory: ComplyRX, Claro Labs

TOS: 5

CPT Code: 0094U

Long Descriptor: Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis

Short Descriptor: GENOME RAPID SEQUENCE ALYS

Laboratory: RCIGM Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine (RCIGM)

TOS: 5

CPT Code: 0095U

Long Descriptor: Inflammation (eosinophilic esophagitis), ELISA analysis of eotaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), specimen obtained by swallowed nylon string, algorithm reported as predictive probability index for active eosinophilic esophagitis

Short Descriptor: INFLM EE ELISA ALYS ALG

Laboratory: Esophageal String Test™ (EST), Cambridge Biomedical, Inc

TOS: 5

CPT Code: 0096U

Long Descriptor: Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine

Short Descriptor: HPV HI RISK TYPES MALE URINE

Laboratory: HPV, High-Risk, Male Urine, Molecular Testing Labs

TOS: 5

CPT Code: 0097U

Long Descriptor: Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V])

Short Descriptor: GI PATHOGEN 22 TARGETS

Laboratory: BioFire® FilmArray® Gastrointestinal (GI) Panel, BioFire® Diagnostics

TOS: 5

CPT Code: 0098U

Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae)

Short Descriptor: RESPIR PATHOGEN 14 TARGETS

Laboratory: BioFire® FilmArray® Respiratory Panel (RP) EZ, BioFire® Diagnostics

TOS: 5

CPT Code: 0099U

Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)

Short Descriptor: RESPIR PATHOGEN 20 TARGETS

Laboratory: BioFire® FilmArray® Respiratory Panel (RP), BioFire® Diagnostics

TOS: 5

CPT Code: 0100U

Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)

Short Descriptor: RESPIR PATHOGEN 21 TARGETS

Laboratory: BioFire® FilmArray® Respiratory Panel 2 (RP2), BioFire® Diagnostics

TOS: 5

CPT Code: 0101U

Long Descriptor: Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])

Short Descriptor: HERED COLON CA DO 15 GENES

Laboratory: ColoNext®, Ambry Genetics®, Ambry Genetics®

TOS: 5

CPT Code: 0102U

Long Descriptor: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])

Short Descriptor: HERED BRST CA RLTD DO 17 GEN

Laboratory: BreastNext®, Ambry Genetics®, Ambry Genetics®

TOS: 5

CPT Code: 0103U

Long Descriptor: Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])

Short Descriptor: HERED OVA CA PNL 24 GENES

Laboratory: OvaNext®, Ambry Genetics®, Ambry Genetics®

TOS: 5

CPT Code: 0104U

Long Descriptor: Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])

Short Descriptor: HERED PAN CA PNL 32 GENES

Laboratory: CancerNext®, Ambry Genetics®, Ambry Genetics®

TOS: 5

Deleted Codes Effective July 1, 2019

Existing code 0057U is being deleted.

Advanced Diagnostic Laboratory Tests (ADLTs) Effective July 1, 2019

CMS approved three 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.

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	
11280.1	Contractors shall be aware that the CLFS will be released quarterly, as needed, beginning in July 2019 and establish hours to accommodate retrieval and implementation of the quarterly CLFS data file.	X	X							VDC
11280.1.1	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
11280.2	Contractors shall retrieve and load for testing and claims processing purposes the July 2019 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
11280.2.1	Contractors shall note that the CLFS data file name will be in the following format: MU00.@BF12394.CLAB.V2019Q3 Note: The naming convention of the file is such that "yyyy" equals the calendar year and "r" equals the release number with January = 1, April = 2, July = 3, and October = 4	X	X							VDC
11280.2.2	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
11280.2.3	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
11280.3	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							
11280.4	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are	X								

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared-System Maintainers				Other	
		A	B	H H H	M A C	F I S S	M C S	V M S	C W F		
	performed for hospital-based renal dialysis facility patients (**NOTE** - This requirement is applicable to the January quarterly release CR only).										
11280.5	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		
11280.5.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly 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								
11280.6	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			D M E	C E D I
		A	B	H H H	M A C	
11280.7	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: 0