

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4347	Date: August 2, 2019
	Change Request 11406

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: October 1, 2019

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

IMPLEMENTATION DATE: October 7, 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

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

EFFECTIVE DATE: October 1, 2019

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

IMPLEMENTATION DATE: October 7, 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.

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.

New Codes Effective October 1, 2019

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	was received (e.g., SSM or A/B MAC Part B name and number).										
11406.2.3	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
11406.3	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								
11406.4	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									
11406.5	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	
11406.5.1	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								
11406.6	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 D I	C M E D I
		A	B	H H H		
11406.7	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 October 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 October 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.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
KidneyIntelX™, RenalytixAI, RenalytixAI	0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (<i>TNFR1</i> , <i>TNFR2</i>), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including <i>APOL1</i> genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)	NEPH CKD MULT ECLIA TUM NEC	5	October 1, 2019
13C-Spirulina Gastric Emptying Breath Test (GEBT), Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC, Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC	0106U	Gastric emptying, serial collection of 7 timed breath specimens, non-radioisotope carbon-13 (¹³ C) spirulina substrate, analysis of each specimen by gas isotope ratio mass spectrometry, reported as rate of ¹³ CO ₂ excretion	GSTR EMPTG 7 TIMED BRTH SPEC	5	October 1, 2019
Singulex Clarity C.diff toxins A/B assay, Singulex	0107U	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method	C DIFF TOX AG DETCJ IA STOOL	5	October 1, 2019

TissueCypher® Barrett's Esophagus Assay, Cernostics, Cernostics	0108U	Gastroenterology (Barrett's esophagus), whole slide—digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer	GI BARRETT ESOPH 9 PRTN BMRK	5	October 1, 2019
MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories, Inc/MycoDART, Inc	0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (<i>A. fumigatus</i> , <i>A. terreus</i> , <i>A. niger</i> , and <i>A. flavus</i>), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	ID ASPERGILLUS DNA 4 SPECIES	5	October 1, 2019
Oral OncolyticAssuranceRX, Firstox Laboratories, LLC, Firstox Laboratories, LLC	0110U	Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed drug(s) when detected	RX MNTR 1+ORAL ONC RX&SBSTS	5	October 1, 2019
Praxis™ Extended RAS Panel, Illumina, Illumina	0111U	Oncology (colon cancer), targeted <i>KRAS</i> (codons 12, 13, and 61) and <i>NRAS</i> (codons 12, 13, and 61) gene analysis utilizing formalin-fixed paraffin-embedded tissue	ONC COLON CA KRAS&NRAS ALYS	5	October 1, 2019
MicroGenDX qPCR & NGS For Infection, MicroGenDX, MicroGenDX	0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	IADI 16S&18S RRNA GENES	5	October 1, 2019
MiPS (Mi-Prostate Score), MLabs, MLabs	0113U	Oncology (prostate), measurement of <i>PCA3</i> and <i>TMPRSS2-ERG</i> in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score	ONC PRST8 PCA3&TMPRSS2-ERG	5	October 1, 2019

EsoGuard™, Lucid Diagnostics, Lucid Diagnostics	0114U	Gastroenterology (Barrett's esophagus), <i>VIM</i> and <i>CCNA1</i> methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	GI BARRETTS ESOPH VIM&CCNA1	5	October 1, 2019
ePlex Respiratory Pathogen (RP) Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	RESPIR IADNA 18 VIRAL&2 BACT	5	October 1, 2019
Snapshot Oral Fluid Compliance, Ethos Laboratories	0116U	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications	RX MNTR NZM IA 35+ORAL FLU	5	October 1, 2019
Foundation PIS™, Ethos Laboratories	0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain	PAIN MGMT 11 ENDOGENOUS ANAL	5	October 1, 2019
Viracor TRAC™ dd-cfDNA, Viracor Eurofins, Viracor Eurofins	0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA	TRNSPLJ DON-DRV CLL-FR DNA	5	October 1, 2019

MI-HEART Ceramides, Plasma, Mayo Clinic, Laboratory Developed Test	0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events	CRD CERAMIDES LIQ CHROM PLSM	5	October 1, 2019
Lymph3Cx Lymphoma Molecular Subtyping Assay, Mayo Clinic, Laboratory Developed Test	0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter	ONC B CLL LYMPHM MRNA 58 GEN	5	October 1, 2019
Flow Adhesion of Whole Blood on VCAM-1 (FAB-V), Functional Fluidics, Functional Fluidics	0121U	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood	SC DIS VCAM-1 WHOLE BLOOD	5	October 1, 2019
Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL), Functional Fluidics, Functional Fluidics	0122U	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood	SC DIS P-SELECTIN WHL BLOOD	5	October 1, 2019
Mechanical Fragility, RBC by shear stress profiling and spectral analysis, Functional Fluidics, Functional Fluidics	0123U	Mechanical fragility, RBC, shear stress and spectral analysis profiling	MCHNL FRAGILITY RBC PRFLG	5	October 1, 2019

First Trimester Screen Fβ SM , Eurofins NTD, LLC, Eurofins NTD, LLC	0124U	Fetal congenital abnormalities, biochemical assays of 3 analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried-blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21	FTL CGEN ABNOR 3 ANALYTES	5	October 1, 2019
Maternal Fetal Screen T1 SM , Eurofins NTD, LLC, Eurofins NTD, LLC	0125U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, maternal serum, algorithm reported as risk scores for fetal trisomies 13/18, 21, and preeclampsia	FTL CGEN ABNOR PRNT COMP 5	5	October 1, 2019
Maternal Fetal Screen T1 + Y Chromosome SM , Eurofins NTD, LLC, Eurofins NTD, LLC	0126U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for fetal trisomies 13/18, 21, and preeclampsia	FTL CGEN ABNOR PRNT COMP 5 Y	5	October 1, 2019
Preeclampsia Screen T1 SM , Eurofins NTD, LLC, Eurofins NTD, LLC	0127U	Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	OB PE 3 ANALYTES	5	October 1, 2019
Preeclampsia Screen T1 + Y Chromosome SM , Eurofins NTD, LLC, Eurofins NTD, LLC	0128U	Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for preeclampsia	OB PE 3 ANALYTES Y CHRMSM	5	October 1, 2019

BRCPlus, Ambry Genetics	0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (<i>ATM</i> , <i>BRCA1</i> , <i>BRCA2</i> , <i>CDH1</i> , <i>CHEK2</i> , <i>PALB2</i> , <i>PTEN</i> , and <i>TP53</i>)	HERED BRST CA RLTD DO PANEL	5	October 1, 2019
+RNAinsight™ for ColoNext®, Ambry Genetics	0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (<i>APC</i> , <i>CDH1</i> , <i>CHEK2</i> , <i>MLH1</i> , <i>MSH2</i> , <i>MSH6</i> , <i>MUTYH</i> , <i>PMS2</i> , <i>PTEN</i> , and <i>TP53</i>)	HERED COLON CA DO MRNA PNL	5	October 1, 2019
+RNAinsight™ for BreastNext®, Ambry Genetics	0131U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes)	HERED BRST CA RLTD DO PNL 13	5	October 1, 2019
+RNAinsight™ for OvaNext®, Ambry Genetics	0132U	Hereditary ovarian cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes)	HERED OVA CA RLTD DO PNL 17	5	October 1, 2019
+RNAinsight™ for ProstateNext®, Ambry Genetics	0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes)	HERED PRST8 CA RLTD DO 11	5	October 1, 2019

+RNAinsight™ for CancerNext®, Ambry Genetics	0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes)	HERED PAN CA MRNA PNL 18 GEN	5	October 1, 2019
+RNAinsight™ for GYNPlus®, Ambry Genetics	0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes)	HERED GYN CA MRNA PNL 12 GEN	5	October 1, 2019
+RNAinsight™ for ATM, Ambry Genetics	0136U	<i>ATM (ataxia telangiectasia mutated)</i> (eg, ataxia telangiectasia) mRNA sequence analysis	ATM MRNA SEQ ALYS	5	October 1, 2019
+RNAinsight™ for PALB2, Ambry Genetics	0137U	<i>PALB2 (partner and localizer of BRCA2)</i> (eg, breast and pancreatic cancer) mRNA sequence analysis	PALB2 MRNA SEQ ALYS	5	October 1, 2019
+RNAinsight™ for BRCA1/2, Ambry Genetics	0138U	<i>BRCA1 (BRCA1, DNA repair associated)</i> , <i>BRCA2 (BRCA2, DNA repair associated)</i> (eg, hereditary breast and ovarian cancer) mRNA sequence analysis	BRCA1 BRCA2 MRNA SEQ ALYS	5	October 1, 2019