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

MLN Matters Number: MM11406
Related Change Request (CR) Number: 11406
Related CR Release Date: August 2, 2019
Effective Date: October 1, 2019
Related CR Transmittal Number: R4347CP
Implementation Date: October 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11406 provides instructions for the quarterly update to the Clinical Laboratory Fee Schedule (CLFS). Make sure your billing staffs are aware of these updates.

BACKGROUND

Effective January 1, 2018, CLFS rates are 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.

Note: Part B deductible and coinsurance do not apply for services paid under the CLFS.

Access to Data File
Under normal circumstances, CMS will make the updated CLFS data file available to MACs approximately six weeks prior to the beginning of each quarter. Internet access to the quarterly CLFS data file will 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, should use the Internet to retrieve the quarterly CLFS. It will be available in multiple formats: Excel, text, and comma delimited.

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Pricing Information
The CLFS 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 Social Security Act.

Advanced Diagnostic Laboratory Tests (ADLTs) Effective July 1, 2019
CMS approved three ADLTs. Please visit https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests for additional information regarding these tests.

New Codes Effective October 1, 2019
These following table shows the new codes effective October 1, 2019. All the codes have a Type of Service (TOS) code of 5. These codes are contractor-priced until they appear on the January 1, 2020 CLFS as applicable. MACs will only price Proprietary Laboratory Analysis (PLAs) codes for laboratories within their jurisdiction. Note that a more complete table that includes the name of the laboratories is attached to CR11406.

CPT Code	Long Descriptor	Short Descriptor
0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 *(TNFR1, TNFR2),* and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including *APOL1* 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
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
0107U	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method	C DIFF TOX AG DETCJ IA STOOL

CPT Code	Long Descriptor	Short Descriptor
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
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species *(A. fumigatus, A. terreus, A. niger,* and *A. flavus),* blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	ID ASPERGILLUS DNA 4 SPECIES
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
0111U	Oncology (colon cancer), targeted *KRAS* (codons 12, 13, and 61) and *NRAS* (codons 12, 13, and 61) gene analysis utilizing formalin-fixed paraffin-embedded tissue	ONC COLON CA KRAS&NRAS ALYS
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug- resistance gene	IADI 16S&18S RRNA GENES
0113U	Oncology (prostate), measurement of *PCA3* and *TMPRSS2-ERG* 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
0114U	Gastroenterology (Barrett's esophagus), *VIM* and *CCNA1* methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	GI BARRETTS ESOPH VIM&CCNA1
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

CPT Code	Long Descriptor	Short Descriptor
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
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
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
0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events	CRD CERAMIDES LIQ CHROM PLSM
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
0121U	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood	SC DIS VCAM-1 WHOLE BLOOD
0122U	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood	SC DIS P-SELECTIN WHL BLOOD
0123U	Mechanical fragility, RBC, shear stress and spectral analysis profiling	MCHNL FRAGILITY RBC PRFLG

CPT Code	Long Descriptor	Short Descriptor
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
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
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 scores for fetal trisomies 13/18, 21, and preeclampsia	FTL CGEN ABNOR PRNT COMP 5 Y
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
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
0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel *(ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN*, and *TP53)*	HERED BRST CA RLTD DO PANEL

CPT Code	Long Descriptor	Short Descriptor
0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel *(APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN,* and *TP53)*	HERED COLON CA DO MRNA PNL
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
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
0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes)	HERED PRST8 CA RLTD DO 11
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
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
0136U	*ATM (ataxia telangiectasia mutated)* (eg, ataxia telangiectasia) mRNA sequence analysis	ATM MRNA SEQ ALYS
0137U	*PALB2 (partner and localizer of BRCA2)* (eg, breast and pancreatic cancer) mRNA sequence analysis	PALB2 MRNA SEQ ALYS
0138U	*BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated)* (eg, hereditary breast and ovarian cancer) mRNA sequence analysis	BRCA1 BRCA2 MRNA SEQ ALYS

Deleted Codes Effective October 1, 2019

Existing code 0104U is being deleted.

ADDITIONAL INFORMATION

The official instruction, CR11406, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4347CP.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
August 2, 2019	Initial article released.