



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

MLN Matters Number: MM11681 **Revised**

Related Change Request (CR) Number: 11681

Related CR Release Date: **April 3, 2020**

Effective Date: April 1, 2020

Related CR Transmittal Number: **R10033CP**

Implementation Date: April 6, 2020

**Note: We revised this article on April 6, 2020, to reflect revisions to CR11681. The CR revisions added code 87635 to the HCPCS file, effective March 13, 2020, added two new COVID-19 test codes (G2023 and G2024), effective March 1, 2020, and removed the section on the delay of the CLFS reporting period. This revised article reflects these revisions. Also, in the article, we revised the CR release date, transmittal number and the web address of the CR. All other information remains the same.**

### PROVIDER TYPES AFFECTED

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This MLN Matters Article is for physicians, other providers, and suppliers submitting clinical laboratory claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

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CR 11681 informs MACs about the changes in the April 2020 quarterly update to the Clinical Laboratory Fee Schedule (CLFS). Make sure that your billing staffs are aware of these changes.

### BACKGROUND

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#### **Advanced Diagnostic Laboratory Tests (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](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, see the

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 CLFS.

### **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 the MACs 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 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, shall use the Internet to retrieve the quarterly CLFS. It will be available in multiple formats: Excel, text, and comma delimited.

### **Pricing Information**

The CLFS includes separately payable fees for certain specimen collection methods (Healthcare Common Procedure Coding System (HCPCS) codes 36415, P9612, and P9615). The fees are established in accordance with Section 1833(h)(4)(B) of the Act.

The initial pricing for the new codes U0001 and U0002 for the Center for Disease Control and Prevention (CDC) test will be about \$36 and non-CDC tests will be initially priced around \$51, respectively. These prices may vary slightly depending on the local Medicare Administrative Contractor (MAC). View the full price by MAC list at: <https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf>

### **New Codes Effective February 4, 2020**

The following new codes are added to the national HCPCS file with an effective date of February 4, 2020, and does not need to be manually added to the HCPCS files by the MACs. However, this new code is contractor-priced until it is 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
  - Type of Service (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 March 1, 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. As part of the Public Health Emergency for the COVID-19 pandemic and in efforts to be as expansive as possible within the current authorities to have testing available to Medicare beneficiaries who need it, the following codes are being priced under the CLFS per guidance provided in the interim final rule with comment (IFC) entitled, Medicare Program and Medicaid Program; Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC). The codes will be added to the national HCPCS file with an effective date of March 1, 2020.

- Code: G2023
  - Short Descriptor: Specimen collect COVID-19
  - Long Descriptor: specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
  - TOS: 5
- Code: G2024
  - Short Descriptor: Spec coll SNF/Lab COVID-19
  - Long Descriptor: specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source
  - TOS: 5

### **New Code Effective March 13, 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 code will be added to the national HCPCS file with an effective date of March 13, 2020. This new code is contractor-priced until it is 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: 87635
  - Short Descriptor: SARS-COV-2 COVID-19 AMP PRB
  - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
  - TOS: 5

**New Codes Effective April 1, 2020***Proprietary Laboratory Analysis (PLAs)*

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 will only price PLA codes for laboratories within their jurisdiction.

- CPT Code 0163U
  - Long Descriptor: 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
  - Short Descriptor: ONC CLRCT SCR 3 PRTN ALG
  - Laboratory: BeScreened™-CRC, Beacon Biomedical Inc, Beacon Biomedical Inc
  - TOS: 5
  
- CPT Code 0164U
  - Long Descriptor: Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
  - Short Descriptor: GI IBS IA ANTI-CDTB&VINCULIN
  - Laboratory: ibs-smart™, Gemelli Biotech, Gemelli Biotech
  - TOS: 5
  
- CPT Code 0165U
  - Long Descriptor: Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and interpretation
  - Short Descriptor: PEANUT ALLG SPEC ASMT 64 EPI
  - Laboratory: VeriMAP Peanut Dx – Bead-based Epitope Assay, AllerGenis, AllerGenis
  - TOS: 5
  
- CPT Code 0166U
  - Long Descriptor: 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
  - Short Descriptor: LIVER DS 10 BIOCHEM ASY SRM

- Laboratory: LiverFASt™, Fibronostics, Fibronostics
- TOS: 5
- CPT Code 0167U
  - Long Descriptor: Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood
  - Short Descriptor: CHORNC GONADOTROPIN HCG IA
  - Laboratory: ADEXUSDx hCG Test, NOWDiagnostics, NOWDiagnostics
  - TOS: 5
- CPT Code 0168U
  - Long Descriptor: 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
  - Short Descriptor: FTL ANEUPLOIDY DNA SEQ ALYS
  - Laboratory: Vanadis® NIPT, PerkinElmer, Inc, PerkinElmer Genomics
  - TOS: 5
- CPT Code 0169U
  - Long Descriptor: NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
  - Short Descriptor: NUDT15&TPMT GENE COM VRNT
  - Laboratory: NT (NUDT15 and TPMT) genotyping panel, RPRD Diagnostics
  - TOS: 5
- CPT Code 0170U
  - Long Descriptor: Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
  - Short Descriptor: NEURO ASD RNA NEXT GEN SEQ
  - Laboratory: Clarifi™, Quadrant Biosciences, Inc, Quadrant Biosciences, Inc
  - TOS: 5
- CPT Code 0171U
  - Long Descriptor: 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
  - Short Descriptor: TRGT GEN SEQ ALYS PNL DNA 23
  - Laboratory: MyMRD® NGS Panel, Laboratory for Personalized Molecular Medicine, Laboratory for Personalized Molecular Medicine
  - TOS: 5

**Revised Codes Effective April 1, 2020***Proprietary Laboratory Analysis (PLAs)*

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.

- CPT Code 0154U
  - Long Descriptor: 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
  - Short Descriptor: ONC URTHL CA RNA FGFR3 GENE
  - Laboratory: theascreen® FGFR RGQ RT-PCR Kit, QIAGEN, QIAGEN GmbH
  - TOS: 5
  
- CPT Code 0155U
  - Long Descriptor: 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
  - Short Descriptor: ONC BRST CA DNA PIK3CA GENE
  - Laboratory: theascreen® PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH
  - TOS: 5

**Deleted Codes Effective April 1, 2020**

Existing code 0006U is being deleted.

**ADDITIONAL INFORMATION**

The official instruction, CR 11681, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10033cp.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
April 6, 2020	We revised this article to reflect revisions to CR11681. The CR revisions added code 87635 to the HCPCS file, effective March 13, 2020, and added two new COVID-19 test codes (G2023 and G2024), effective March 1, 2020, and removed the section on the delay of the CLFS reporting period. This revised article reflects these revisions. Also, in the article, we revised the CR release date, transmittal number and the web address of the CR. All other information remains the same.
March 13, 2020	Initial article released.

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