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

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Implementation Date: April 6, 2020

PROVIDER TYPES AFFECTED

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

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

Protecting Access to Medicare Act of 2014 (PAMA) Updates

Next CLFS Data Reporting Period—DELAYED to January 2021

- Section 1834A of the Social Security Act (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 the Centers for Medicare & Medicaid Services (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.

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- 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 3-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).

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.

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 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: therascreen® 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: therascreen® 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/regulations-and-guidanceguidancetransmittals2020-transmittals/document/r4541cp.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
March 13, 2020	Initial article released.

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