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

MLN Matters Number: MM12178
Related Change Request (CR) Number: 12178
Related CR Release Date: March 9, 2021
Effective Date: April 1, 2021
Related CR Transmittal Number: R10656CP
Implementation Date: April 5, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for laboratory services they provide to Medicare patients.

PROVIDER ACTION NEEDED

This article gives you details of the quarterly update to the Clinical Laboratory Fee Schedule (CLFS). Please be sure your billing staff is aware of these updates.

BACKGROUND

Here is a summary of the revisions for the April update:

Advanced Diagnostic Laboratory Tests (ADLTs)
Please refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests for additional information regarding these tests:

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests — DELAYED
The next CLFS data reporting period for Clinical Diagnostic Laboratory Tests (CDLTs) is delayed. Section 1834A of the Social Security (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 CDLTs under the CLFS. CMS published the CLFS final rule, Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F), 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 CMS certain private payor 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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Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that aren't ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS.

- The next data reporting period of January 1, 2022, through March 31, 2022, is based on the original data collection period of January 1, 2019, through June 30, 2019
- After the next data reporting period, there is a 3-year data reporting cycle for CDLTs that aren't ADLTs, (2025, 2028, and so on)
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended through CY 2024. **There is a 0.0% reduction for CY 2021,** and we won't reduce payment by more than 15% for s 2022-24.

CLFS Beginning January 1, 2018

- Effective January 1, 2018, we base CLFS rates on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014
- The Part B deductible and coinsurance don't apply for services paid under the CLFS
- For more details, visit PAMA Regulations
- **Access to Data File:** Internet access is available at the quarterly clinical laboratory fee
- Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, will use the Internet to retrieve the quarterly CLFS. It will be available in multiple formats, including Excel, text, and comma delimited.
- **Pricing Information:** The CLFS includes separately payable fees for certain specimen collection methods (CPT code 36415 and HCPCS codes P9612 and P9615). We established the fees in accordance with Section 1833(h)(4)(B) of the Act.
- Additional specimen collection codes may be listed below during the Public Health Emergency (PHE).

New Codes Effective April 1, 2021

Proprietary Laboratory Analysis (PLAs)

Table 1 lists new codes we added to the national HCPCS file with an effective date of April 1, 2021. These new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with Sections 1833(h)(8) and 1834(A)(c) of the Act. MACs will only price PLA codes for laboratories within their jurisdiction.

Table 1 – Codes Added to the National HCPCS File, Effective April 1, 2021

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS
Guardant360® CDx, Guardant Health Inc, Guardant Health Inc	0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	TRGT GEN SEQ ALYS PNL 55-74	5
PlGF Preeclampsia Screen, PerkinElmer Genetics, PerkinElmer Genetics, Inc	0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	OB PE BIOCHEM ASSAY PGF ALG	5
Oncotype MAP™ PanCancer Tissue Test, Paradigm Diagnostics, Inc, Paradigm Diagnostics, Inc	0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffinembedded tumor tissue	ONC SOLID ORGN DNA 257 GENES	5
ThyGeNEXT® Thyroid Oncogene Panel, Interpace Diagnostics, Interpace Diagnostics	0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	ONC THYR MUT ALYS 10 GEN&37	5
PrecisionBlood™, San Diego Blood Bank, San Diego Blood Bank	0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	RBC DNA GNOTYP 16 BLD GROUPS	5
PreTRM®, Sera Prognostics, Sera Prognostics, Inc®	0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone– binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	OB PRTRM BRTH IBP4 SHBG MEAS	5

Table 2 – Deleted Codes Effective April 1, 2021

CPT Code	Long Descriptor	Delete Date
0098U	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)	4/1/2021
0099U	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)	4/1/2021
0100U	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 pne	4/1/2021

ADDITIONAL INFORMATION

The official instruction, CR 12178, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10656cp.pdf.

Note: MACs won't search their files to either retract payment or retroactively pay claims, however, they will adjust claims you bring to their attention.

If you have questions, your MACs may have more information. Find their website via the CMS website.

DOCUMENT HISTORY

Date of Change	Description
March 9, 2021	Initial article released.