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

MLN Matters Number: MM12435  Related Change Request (CR) Number: 12435
Related CR Release Date: September 10, 2021  Effective Date: October 1, 2021
Related CR Transmittal Number: R10988CP  Implementation Date: October 4, 2021

Provider Types Affected

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

Provider Action Needed

This Article tells you about the quarterly update to the CLFS, effective October 1, 2021. Make sure your billing staff knows about these changes.

Background

Advanced Diagnostic Laboratory Tests (ADLTs)

Refer to the CMS ADLT website for more information about these tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests

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. CMS published the CLFS final rule, Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, in the Federal Register on June 23, 2016.

Under the CLFS final rule, reporting entities must give us certain private payor rate information for their component applicable laboratories. The data collection period was from January 1, 2019, through June 30, 2019.
The revisions to the reporting period are:

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

**CLFS Beginning January 1, 2018**

Since January 1, 2018, we base CLFS rates on weighted median private payor rates. Part B deductible and coinsurance don’t apply for services we pay under the CLFS. The [PAMA Regulations](#) give more details.

We’ll make the quarterly CLFS available. Other interested parties, such as Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may want to download the quarterly CLFS. It will be available in these formats:

- Excel®
- Text
- Comma delimited

The CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615).

**New Codes Effective October 1, 2021 – Proprietary Laboratory Analysis (PLAs)**

See the table in CR 12435. We added the listed new codes in this table to the national HCPCS file with an effective date of October 1, 2021. These new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process. MACs will only price PLA codes for laboratories within their jurisdiction. The table includes the laboratory, long descriptor, short descriptor, and Type of Service of each new code.

**More Information**

We issued [CR 12435](#) to your MAC as the official instruction for this change.

For more information, contact your [MAC](#).
Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 10, 2021</td>
<td>Initial article released.</td>
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