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

MLN Matters Number: MM12737  Related Change Request (CR) Number: 12737
Related CR Release Date: May 4, 2022  Effective Date: July 1, 2022
Related CR Transmittal Number: R11398CP  Implementation Date: July 5, 2022

Provider Types Affected

This MLN Matters Article is for laboratory physicians, suppliers, and other providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

Make sure your billing staff knows about these changes:

- Where to find updates pertaining to Advanced Diagnostic Laboratory Tests (ADLTs)
- Delays in the next CLFS data reporting period for clinical diagnostic laboratory tests
- New codes, effective July 1, 2022

Background

CR 12737 provides instructions for the quarterly update of the CLFS.

ADLTs

Visit the [ADLT page](#) for more information regarding appropriate tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests (CDLTs) – DELAYED

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. On December 10, 2021, the [Protecting Medicare and American Farmers from Sequester Cuts Act (S. 610)](https://www.congress.gov/bill/117th-congress/senate-bill/610) delayed the reporting requirement and the application of the 15% phase-in reduction.
Under the CLFS final rule, reporting entities must give CMS certain private payor rate information for their component applicable laboratories. The data collection period was from January 1, 2019 - June 30, 2019. The data collection period is where applicable information for a laboratory is obtained from claims for which the laboratory got final payment during the period.

We’ve made the following revisions to the reporting period:

- Based the next data reporting period of January 1, 2023 - March 31, 2023, on the original data collection period of January 1, 2019 - June 30, 2019. After the next data reporting period, there’s a 3-year data reporting cycle for CDLTs that aren’t ADLTs (2026, 2029, and so on).

- Extended the statutory phase-in of payment reductions resulting from private payor rate implementation through Calendar Year (CY) 2025. There’s a 0.0% reduction for CY 2021 and CY 2022, and we won’t reduce payment by more than 15% for CYs 2023-2025.

**CLFS Beginning January 1, 2018**

- Effective January 1, 2018, we base CLFS rates on weighted median private payor rates as PAMA requires
- The Medicare Part B deductible and coinsurance don’t apply for services paid under the CLFS
- Read the PAMA Regulations for more details
- **Access to Data File**: Interested parties, such as Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may get the CLFS files, when available. They’re in multiple formats, including Excel, text, and comma delimited.

- **Pricing Information**: The CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). We set the fees in accordance with section 1833(h)(4)(B) of the Social Security Act. **Note**: Additional specimen collection codes may be listed during the COVID-19 Public Health Emergency (PHE).

**New Codes Effective July 1, 2022**

**Proprietary Laboratory Analysis (PLAs)**

See the New Codes tab in the table attached to CR 12737 titled, New Codes Effective July 1, 2022. We added the listed new codes to the national HCPCS file with an effective date of July 1, 2022. Your MAC will price these new codes (where applicable) until they’re nationally priced and undergo the CLFS annual payment determination process in accordance with sections 1833(h)(8), 1834A(c), and 1834(A)(f) of the Act. MACs will only price PLA codes for laboratories within their jurisdiction.
More Information

We issued CR 12737 to your MAC as the official instruction for this change.

For more information, find your MAC’s website.

Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>May 5, 2022</td>
<td>Initial article released.</td>
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