CLINICAL LABORATORY FEE SCHEDULE

The Hyperlink Table, at the end of this document, gives the complete URL for each hyperlink.

Updates

Note: No substantive content updates.

Clinical Laboratory Fee Schedule (CLFS) topics:

- Background
- Material types examined
- Clinical laboratory services coverage
- Private payor rate-based CLFS summary
- Advanced diagnostic laboratory tests (ADLTs)
- Key takeaways
- Resources

Background

Effective January 1, 2018:

- SSA Section 1834A, as required by the Protecting Access to Medicare Act (PAMA) of 2014, made changes to how Medicare pays CLFS Clinical Diagnostic Laboratory Tests (CDLTs).
- The CLFS payment amount for most tests is equal to the weighted median of private payor rates. CMS generally updates the CLFS private payor payment rates every 3 years.
- CMS does not subject CLFS payment amounts to any geographic adjustments.

Material Types Examined

Clinical laboratories examine materials from the human body that give patient information for diagnosis, prevention, disease treatment, or to assess a medical condition, and include:

- Biological
- Microbiological
- Serological
- Chemical
- Immunohematological
- Hematological
- Biophysical
- Cytological
- Pathological
- Other materials examination

Clinical Laboratory Services Coverage

Medicare **may cover** diagnostic clinical lab tests that meet the 1988 Clinical Laboratory Improvement Amendments (CLIA). CLIA requires that human laboratory specimen testing meet quality standards. The HHS Secretary must certify the laboratories performing clinical tests. Medicare covers medically necessary and reasonable diagnostic clinical laboratory services to diagnose or treat an illness or injury.

Medicare covers diagnostic clinical laboratory services provided in:

- Hospital laboratories (for outpatient or non-hospital patients)
- Physician office laboratories
- Independent laboratories
- Dialysis facility laboratories
- Nursing facility laboratories
- Other institutions

Medicare **does not cover** clinical laboratory screenings (tests done on patients with no personal disease history and with no disease signs or symptoms), with certain exceptions.

Covered preventive services include clinical laboratory screenings for:

- Cardiovascular disease
- Diabetes
- Cervical cancer
- Colorectal cancer
- Prostate cancer
- Human immunodeficiency virus (HIV) infection
- Chlamydia, gonorrhea, syphilis, hepatitis B, and hepatitis C

For more information about covered screenings and preventive services, refer to the Preventive Services Provider Resources webpage.

Private Payor Rate-Based CLFS Summary

Under the private payor rate-based CLFS, reporting entities must report to CMS certain private payor rate information (applicable information) for their component “applicable laboratories.” In general, the CLFS test payment amount provided on or after January 1, 2018, equals the weighted median of private payor rates determined for the test, based on the applicable information collected and reported to CMS during a data collection period. The data collection, reporting, and payment updates generally happen every 3 years.

SSA Section 1834A and CMS regulations at 42 CFR Section 414.507(d) limits the CLFS rate reduction amounts for most CDLTs compared to the payment rates for the preceding year. For the first 3 years after implementation (calendar year [CY] 2018 through CY 2020), the reduction cannot be more than 10% per year. There is a 0.0% reduction for CY 2021, and payment may not be reduced by more than 15% for CYs 2022–2024.

For a lab to be "applicable," it must do the following by its own National Provider Identifier (NPI) during a data collection period:

- Meet the CLIA definition of a laboratory at 42 CFR Section 493.2
- Meet the "majority of Medicare revenues" threshold (more than 50% of its total Medicare revenues from the CLFS and/or PFS)
- Meet the low expenditure threshold (at least $12,500 in Medicare CLFS services revenues)

When you report applicable information, be sure to use your Tax Identification Number (TIN), not your NPI.

In the CY 2019 PFS final rule, CMS made two revisions to the regulatory definition of an applicable laboratory:

1. CMS does not include Medicare Advantage plan revenues in the majority of Medicare revenues threshold calculation.
2. Hospitals that bill non-patient laboratory services use Form CMS 1450 14X Type of Bill (TOB) Medicare revenues to determine if its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

For the January 1, 2022–March 31, 2022, (previously January 1, 2020–March 31, 2020) data reporting period, CMS will allow reporting entities to combine certain applicable information at the TIN level, instead of reporting each "applicable laboratory" at the NPI level.

For new or substantially revised laboratory test codes and laboratory test codes that CMS gets no applicable information on during a data reporting period, they base the payment rate on "crosswalking" or "gapfilling" methods until private payor rate data becomes available for the next update. Under **crosswalking**, Medicare bases the payment amount on an existing test or combination of tests with similar methods and resources. Use **gapfilling** when there's no other test with similar methods and resources. In this case, MACs develop a payment amount for the test. For more information, refer to the Clinical Laboratory Fee Schedule Annual Payment Determination Process educational tool.

Advanced Diagnostic Laboratory Tests

SSA Section 1834A created a new CDLTs sub-category called advanced diagnostic laboratory tests (ADLTs). To qualify as an ADLT, the test must:

- Be Medicare Part B covered
- Be offered and provided only by a single laboratory
- Not be sold for use by another laboratory except the single laboratory (or a successor owner)

ADLTs must also meet one of the following criteria:

- U.S. FDA clears or approves the test
- The test meets all the following criteria:
  - Is an analysis of multiple DNA, RNA, or protein biomarkers
  - When combined with a unique, empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies
  - Gives new clinical diagnostic information unavailable from any other test or combination of tests
  - May include other assays

Generally, Medicare pays ADLTs on the CLFS using the same methods based on the weighted median of private payor rates as other CDLTs. However, Medicare pays new ADLTs at a rate equal to their actual list charge during a new ADLT initial period of 3 calendar quarters. Once the new ADLT initial period ends, Medicare pays new ADLTs based on the weighted median of private payor rates as other CDLTs. If no applicable ADLT information is available during a data reporting period, Medicare determines payment based on crosswalking or gapfilling methods.

CMS generally requires CDLTs reporting every 3 years (not ADLTs). Reporting entities must report ADLTs applicable information annually, except ADLTs in an initial data collection period (in this case, a reporting entity reports by the end of the second quarter of the new ADLT initial period).

For CMS to approve a CLFS CDLT as an ADLT, you must submit an application to request ADLT status for the test to CMS. For more information on ADLTs, refer to the PAMA Regulations.

For more information about the CLFS, refer to the Medicare Learning Network® (MLN) MLN Matters® Article SE19006.

Key Takeaways

- The CLFS payment amount for most tests is equal to the weighted median of private payor rates. CMS generally updates CLFS every 3 years.
- Under the private payor rate-based CLFS, reporting entities must report to CMS certain private payor rate information (applicable information) for their component "applicable laboratories."

Resources

- CLFS
- CLFS Updates
- Clinical Labs Center
- CMS CLFS Annual Public Meeting
- Medicare Claims Processing Manual, Chapter 16
- SSA Section 1833
- SSA Section 1861