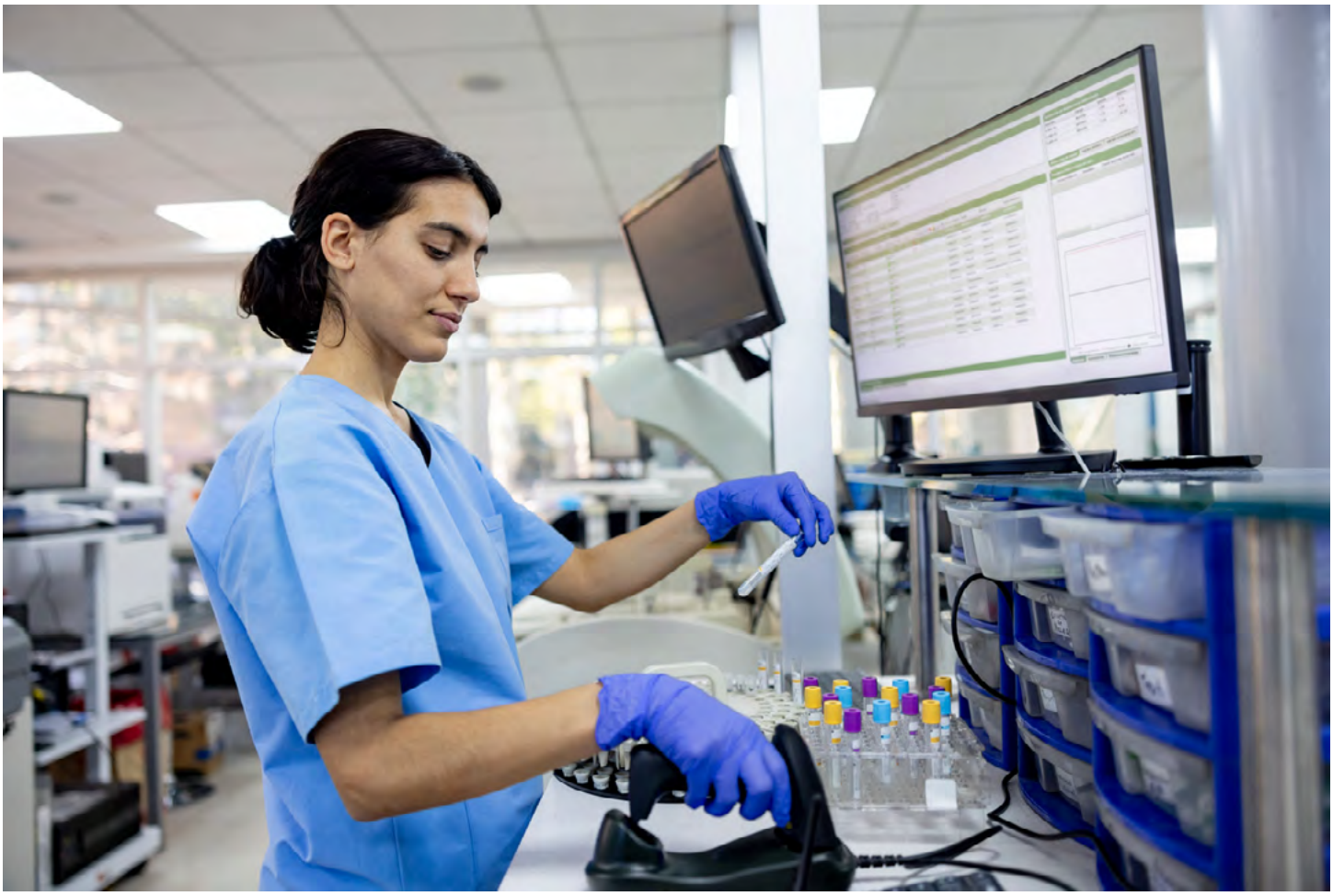
mln Fact Sheet
KNOWLEDGE • RESOURCES • TRAINING

Clinical Laboratory Fee Schedule



What's Changed?

- Section 221 of the 2025 Continuing Appropriations and Extensions Act delayed data reporting (page 2)

Substantive content changes are in dark red.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

This Medicare Learning Network® (MLN) fact sheet explains how Medicare pays for clinical diagnostic laboratory tests (CDLTs) and advanced diagnostic laboratory tests (ADLTs) under the Clinical Laboratory Fee Schedule (CLFS).

Effective January 1, 2018:

- The Social Security Act (SSA), Section 1834A changed how Medicare pays CLFS CDLTs.
- The CLFS payment amount for most tests equals the weighted median of private payor rates. CMS generally updates the CLFS private payor payment rates every 3 years.
- We don't make geographic adjustments to CLFS payment amounts.

Section 221 of the 2025 Continuing Appropriations and Extensions Act delayed data reporting requirements for CDLTs that aren't advanced diagnostic laboratory tests. It also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation. Refer to the Clinical Laboratory Fee Schedule webpage for more information.

Material Types Examined

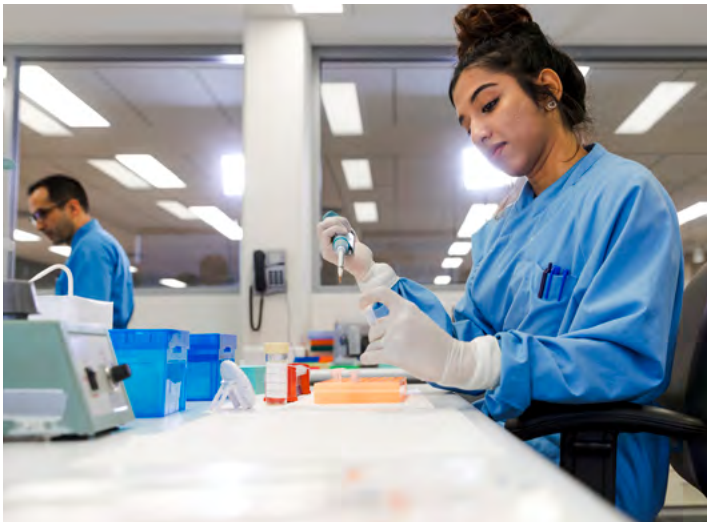
Clinical laboratories examine materials from the human body that provide information for diagnosis, prevention, treatment of any disease or impairment of, or the assessment of the health of human beings, including:

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

Clinical Laboratory Services Coverage

Medicare covers diagnostic clinical lab tests that meet the 1988 Clinical Laboratory Improvement Amendments (CLIA) requirements. Human laboratory specimen testing must meet the CLIA requirements for accurate and reliable testing. The HHS Secretary must certify the laboratories doing clinical tests.

Medicare covers medically necessary and reasonable diagnostic clinical laboratory services to diagnose or treat an illness or injury.



We cover 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

CLFS pays a nominal fee for specimen collection, transportation, and expenses for trained personnel to collect specimens from homebound patients and inpatients, except hospital inpatients. This is generally referred to as the travel allowance. We pay the travel allowance only when the nominal specimen collection fee is also payable.

For information on the specimen collection fees and travel allowance, review the Medicare Claims Processing Manual, Chapter 16, sections 60.1 and 60.2.

We don't cover clinical laboratory screenings or tests on patients with no personal disease history and no disease signs or symptoms, with some exceptions.

Covered preventive services include tests and screenings for:

- Cardiovascular disease
- Diabetes
- Cervical cancer
- Colorectal cancer
- Prostate cancer
- HIV infection
- Chlamydia, gonorrhea, syphilis, hepatitis B, and hepatitis C

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

Private Payor Rate-Based CLFS Summary

Applicable laboratories must report private payor rate information for its component applicable laboratories. In general, the CLFS test payment equals the weighted median of private payor rates for the test, based on the applicable information collected and reported.

Data collection, reporting, and payment updates generally happen every 3 years.

For a lab to meet applicable laboratory criteria, it must:

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

Remember:

- When you report applicable information, have both your Tax Identification Number (TIN) and NPI available
- CMS doesn't include Medicare Advantage plan revenues in the majority of Medicare revenues threshold calculation
- Hospitals that bill non-patient laboratory services use Form CMS-1450 Type of Bill (TOB) 14X Medicare revenues to decide if their hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold

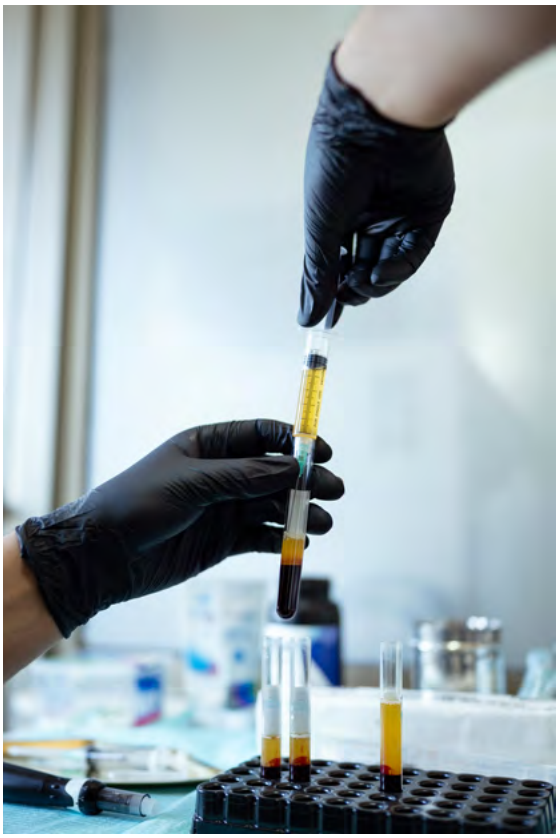
Find data reporting information and requirements on the Clinical Laboratory Fee Schedule webpage.

For new or revised laboratory test codes and laboratory test codes that CMS gets no applicable information on during a data reporting period, we base the payment rate on crosswalking or gapfilling until private payor rate data becomes available for the next update.

- Under **crosswalking**, we base the payment amount on an existing test or combination of tests with similar methods and resources.
- We 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 meet these criteria:

- Medicare Part B covers it
- A single laboratory offers and provides it
- The single laboratory, or a successor owner, sells it exclusively

ADLTs must also meet 1 of the following criteria:

- The FDA clears or approves the test
- The test:
  - Provides an analysis of multiple DNA, RNA, or protein biomarkers
  - Yields a result that predicts the probability a specific patient will develop a certain condition or conditions, or respond to a particular therapy or therapies, when joined with a unique, empirically derived algorithm
  - Provides new clinical diagnostic information unavailable from any other test or combination of tests
  - Includes other assays

Generally, we pay ADLTs using the same methods based on the weighted median of private payor rates. But we pay new ADLTs their actual list charge during a new ADLT initial period of 3 calendar quarters. Once the new ADLT initial period ends, we pay new ADLTs based on the weighted median of the private payor rates paid to the single laboratory and reported to CMS. If your ADLT has no applicable information available throughout a data reporting period, we determine payment based on crosswalking or gapfilling.

Generally, you must:

- Report CDLTs, but not ADLTs, to CMS every 3 years
- Report applicable ADLT information annually
- Report ADLTs in an initial data collection period that ends the second quarter of the new ADLT initial period
- Apply to CMS and ask for ADLT status for a CLFS CDLT

For more information about delayed reporting requirements and payment reductions under CLFS, review the CLFS Reporting webpage.

Resources

- CLFS Annual Public Meetings
- Clinical Laboratory Fee Schedule
- PFS Federal Regulation Notices
- SSA Section 1833 & SSA Section 1861

View the **Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure**.