



Clinical Laboratory Fee Schedule



What's Changed?

CMS changed Medicare payment rules to pay independent labs for specimen collection from homebound patients and inpatients, page 3

You'll find substantive content updates in dark red font.

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](#) made changes to 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.
- CMS doesn't make geographic adjustments to CLFS payment amounts.

Material Types Examined

Clinical laboratories examine materials from the human body that provide 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 covers diagnostic clinical lab tests that meet the 1988 Clinical Laboratory Improvement Amendments (CLIA). Human laboratory specimen testing must meet quality standards in the CLIA. 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.

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

The CLFS pays a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses (generally referred to as the travel allowance) for trained personnel to collect specimens from homebound patients and inpatients (except hospital inpatients). Medicare pays the travel allowance only when the nominal specimen collection fee is also payable.

To make diagnostic testing available to Medicare patients during the COVID-19 public health emergency (PHE), we changed Medicare payment rules to pay independent labs for specimen collection from homebound patients and inpatients (not in a hospital) for COVID-19 CDLTs under certain circumstances and increased payments from \$3-\$5 to \$23-\$25. The increased fees will end at the termination of the COVID-19 PHE.

Medicare doesn't 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 for their component applicable laboratories. In general, the CLFS test payment paid on or after January 1, 2018, equals the weighted median of private payor rates for the test, based on the applicable information collected and reported. The data collection, reporting, and payment updates generally happen every 3 years.

SSA Section 1834A and CMS regulations at [42 CFR Section 414.507\(d\)](#) limit the CLFS rate reduction amounts for most CDLTs compared to the payment rates for the preceding year. For the first 3 years after the rate reduction started (calendar year [CY] 2018 through CY 2020), CMS reduced payments no more than 10% per year. For CYs 2021 and 2022, there are no reductions and CMS won't reduce payments more than 15% for CYs 2023-2025.

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

When you report applicable information, use your Tax Identification Number (TIN), not your National Provider Identifier (NPI).

Remember:

- 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 its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold

For the January 1, 2023-March 31, 2023, (formerly 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 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 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 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:

- U.S. FDA clears or approves the test
- The test meets all the following criteria:
 - Provides an analysis of multiple DNA, RNA, or protein biomarkers

- 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, when joined with a unique, empirically derived algorithm
- Gives new clinical diagnostic information unavailable from any other test or combination of tests
- Includes other assays

Generally, Medicare pays ADLTs using the same methods based on the weighted median of private payor rates as they pay other CDLTs. 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, Medicare determines payment based on crosswalking or gapfilling methods.

- Generally, reporting entities must report CDLTs to CMS every 3 years (not ADLTs)
- Reporting entities must report ADLTs applicable information annually
- Reporting entities must report ADLTs in an initial data collection period that ends the second quarter of the new ADLT initial period
- You must apply to CMS and ask for ADLT status for a CLFS CDLT

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](#).

Resources

- [CLFS](#)
- [CLFS Updates](#)
- [Clinical Labs Center](#)
- [CMS CLFS Annual Public Meeting](#)
- [CY 2022 PFS Final Rule](#)
- [Medicare Claims Processing Manual, Chapter 16](#)
- [SSA Section 1833 & SSA Section 1861](#)
- [2020 IFCs](#)

[Medicare Learning Network® Content Disclaimer, Product Disclaimer, and Department of Health & Human Services Disclosure](#)

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).