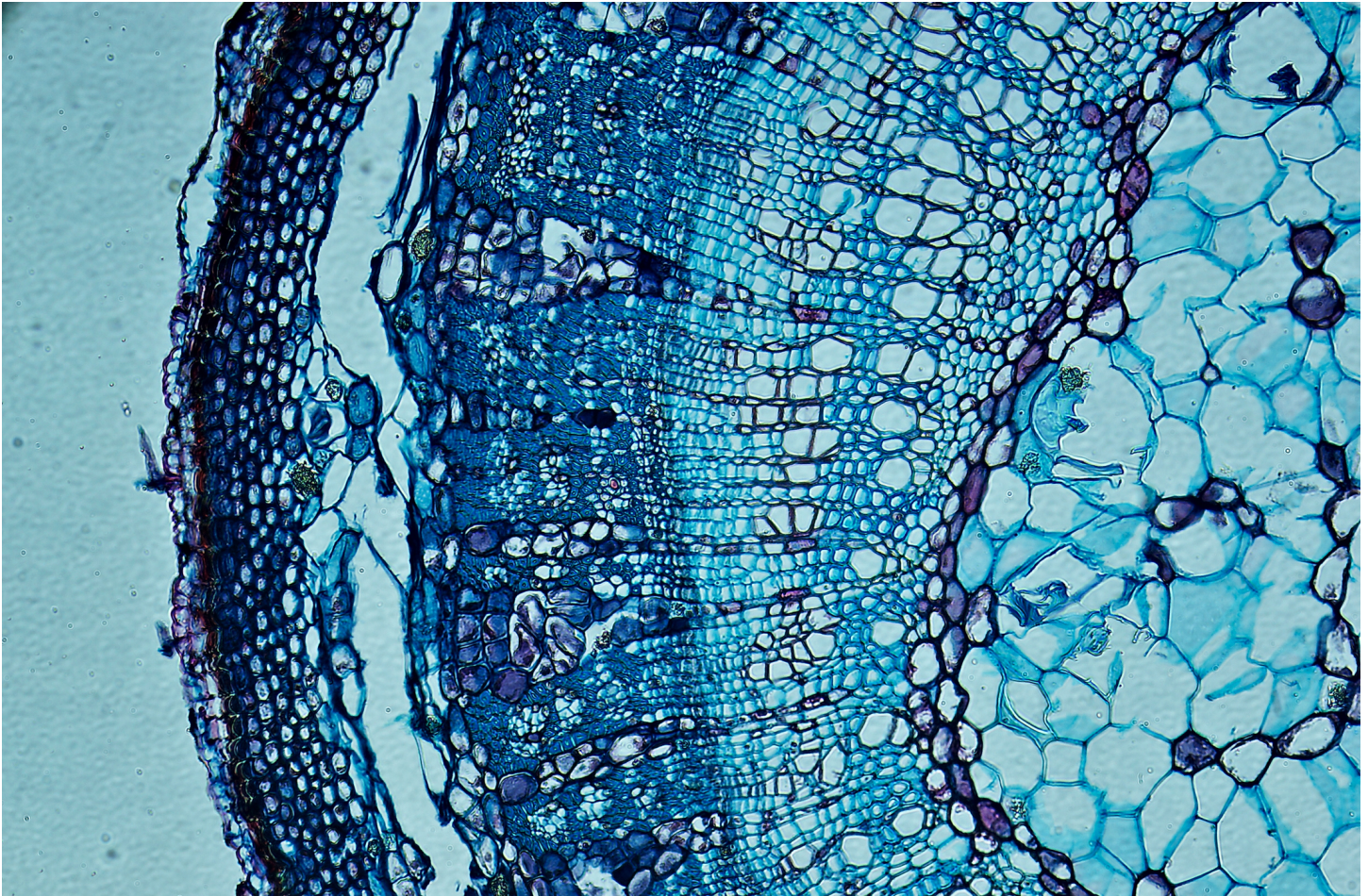




Clinical Laboratory Fee Schedule



What's Changed?

- CMS modified the specimen collection amounts for CY 2023 (page 3)
- CMS modified the flat-rate travel allowance for CY 2023 (page 3)

Substantive content changes are in dark red.

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 information for diagnosis, prevention, disease treatment, or to assess a medical condition, 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). 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.

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

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). We pay 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 for COVID-19 specimen collection ended for dates of service on or after May 12, 2023.

The COVID-19 public health emergency (PHE) ended on May 11, 2023. View [Infectious diseases](#) for a list of waivers and flexibilities that were in place during the PHE.

Additionally, beginning CY 2023, the specimen collection fee will increase from \$3 to \$8.57, and as required by the Protecting Access to Medicare Act of 2014 (PAMA), we will increase this amount by \$2 for those specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA, which will result in a \$10.57 specimen collection fee for those beneficiaries. The specimen collection fee will be updated annually by the Consumer Price Index for all Urban Consumers (CPI-U).

For CY 2023, we also finalized certain modifications and clarifications to the Medicare CLFS travel allowance policies, including changes to the travel allowance basis requirements and the travel allowance amount requirements. Details regarding these provisions are available in the [CY 2023 Physician Fee Schedule \(PFS\) Final Rule](#).

We don't cover clinical laboratory screenings (tests done on patients with no personal disease history and with no disease signs or symptoms), with some 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](#) webpage and choose the Resources menu in the list of preventive services.

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

Rate reduction occurred during CYs 2018-2020. We didn't reduce payments for CYs 2021 and 2022, and 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 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 their hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold

For the January 1, 2023-March 31, 2023, 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, we base 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:

- The 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 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, we pay 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, we determine payment based on crosswalking or gapfilling methods.

Generally, You must:

- Report CDLTs to CMS every 3 years (not ADLTs)
- 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 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 2023 PFS Final Rule](#)
- [Medicare Claims Processing Manual, Chapter 16](#)
- [SSA Section 1833](#) & [SSA Section 1861](#)
- [Infectious diseases](#)

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