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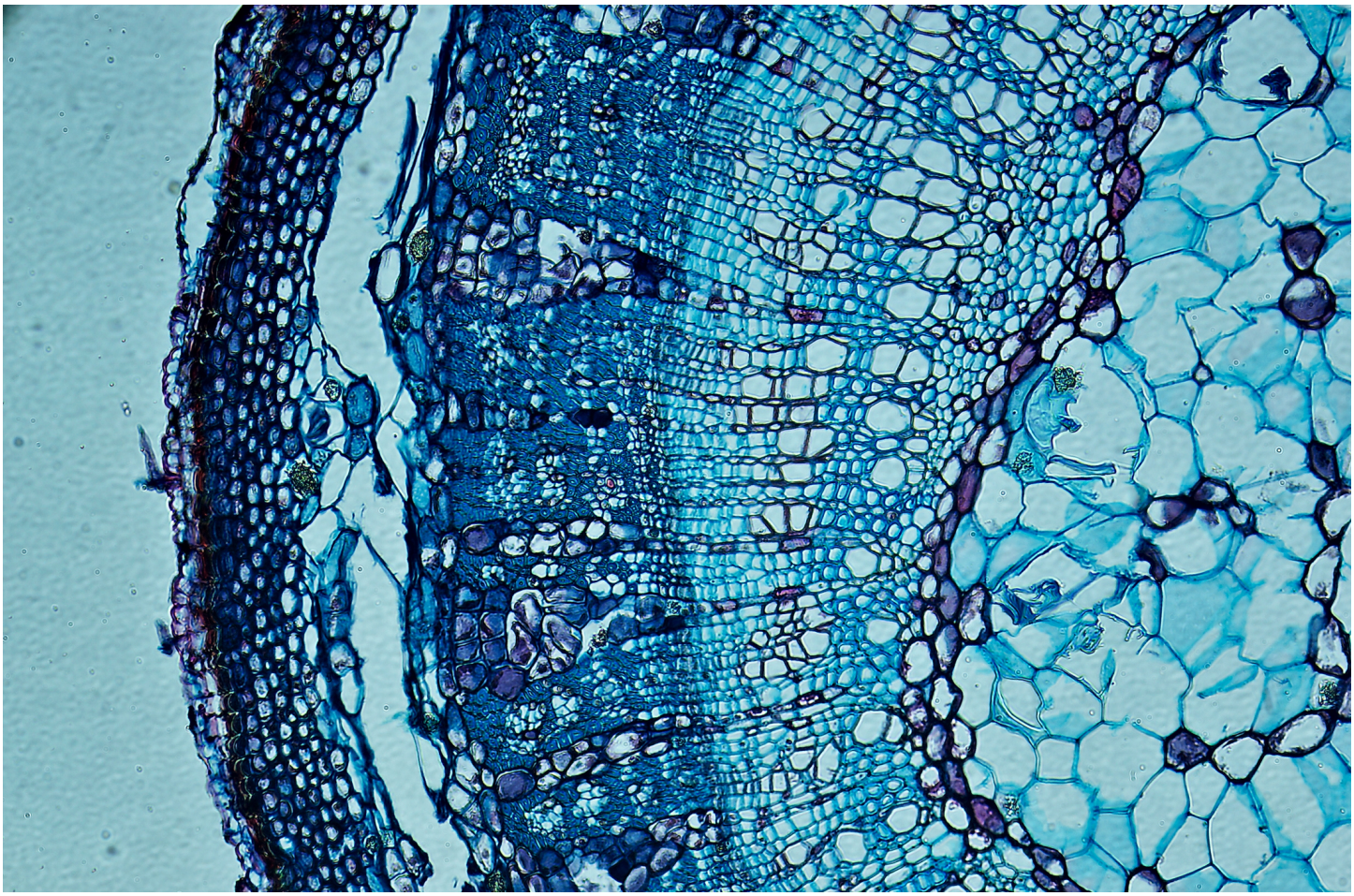
Fact Sheet
KNOWLEDGE • RESOURCES • TRAINING

Clinical Laboratory Fee Schedule



What's Changed?

- Added manual reference for CLFS specimen collections fees and travel allowance (page 3)
- Added link to CLFS webpage for revised and delayed data reporting requirements (page 3)
- Add link to CLFS webpage for data collection period information (page 4)
- Added link to CLFS webpage for delayed reporting requirements and phase-in of payment reductions (page 5)

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

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.

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.

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

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 tests and 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 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. The CLFS webpage has information on revised and delayed data reporting requirements.

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

You can find information on data collection periods on the CLFS 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 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

The CLFS Reporting webpage has information about the delayed reporting requirements and phase-in of payment reductions under the CLFS. 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 Meetings
- PFS Federal Regulation Notices
- Medicare Claims Processing Manual, Chapter 16
- SSA Section 1833 & SSA Section 1861
- Infectious diseases