

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



Clinical Laboratory Fee Schedule

Payment System Series



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Please note: The information in this publication applies only to the Medicare Fee-For-Service Program (also known as Original Medicare).

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

Learn about these Clinical Laboratory Fee Schedule (CLFS) topics:

- ❖ Background
- ❖ Types of examination of materials
- ❖ Coverage of clinical laboratory services
- ❖ How payment rates are set
- ❖ Updates to the CLFS
- ❖ Resources

Background

Under Sections 1833 and 1861 of the Social Security Act (the Act), outpatient clinical laboratory services furnished through December 31, 2017, are paid on a fee schedule (FS) under Medicare Part B when they are furnished in a Medicare-participating laboratory and ordered by a physician or qualified non-physician practitioner who is treating the patient.

Under Section 216 of the Protecting Access to Medicare Act of 2014, outpatient clinical diagnostic laboratory tests (CDLTs) furnished on and after January 1, 2018, will be paid on a private payor rate-based FS.

The statute also creates a new subcategory of CDLTs called advanced diagnostic laboratory tests (ADLTs) which are covered under Part B, offered and furnished by a single laboratory, and are only for use by the original developing laboratory (or successor owner). ADLTs must also meet one of these criteria:

- ❖ They are an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins combined with a unique algorithm to yield a single patient-specific result
- ❖ They are cleared or approved by the Food and Drug Administration
- ❖ They meet other similar criteria established by the Secretary of the Department of Health & Human Services (HHS)

Types of Examination of Materials

Clinical laboratory services involve these types of examination of materials derived from the human body to provide information for the diagnosis, prevention, or treatment of disease or for the assessment of a medical condition:

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





Coverage of Clinical Laboratory Services

Medicare may cover diagnostic tests performed by a clinical laboratory that meet all applicable requirements of the Clinical Laboratory Improvement Amendments (CLIA) of 1988, which established quality standards for all laboratory testing performed on specimens derived from humans. Laboratories that perform clinical laboratory tests must be certified by the Secretary of HHS. For more information about CLIA regulations, visit [CMS.gov/Regulations-and-Guidance/Legislation/CLIA](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA). For more information about the laboratory certification process, visit [CMS.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Labs.html](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Labs.html). In addition, Medicare covers diagnostic clinical laboratory services that are reasonable and necessary for the diagnosis or treatment of an illness or injury.

Covered diagnostic clinical laboratory services are furnished in:

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

Medicare does not cover clinical laboratory services for screening (tests performed on patients with no personal history of a disease and with no signs or symptoms of that disease) except in defined circumstances for individuals who meet certain conditions. Covered preventive services include screening clinical laboratory tests for:

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

For more information about covered screening tests and preventive services, visit [CMS.gov/Medicare/Prevention/PreventionGenInfo](https://www.cms.gov/Medicare/Prevention/PreventionGenInfo).

How Payment Rates Are Set

Payment Amounts for Services Furnished Through December 31, 2017

For clinical laboratory services furnished through December 31, 2017, each Medicare Administrative Contractor (MAC) pays for services based on the local geographic area, and fees are based on charges from laboratories in that geographic area. Payment is the lesser of:

- ❖ The amount billed
- ❖ The local fee for a geographic area
- ❖ A national limitation amount (NLA) for the Healthcare Common Procedure Coding System (HCPCS) code

The NLA is 74 percent of the median of all local FS amounts for tests for which the NLA was established before January 1, 2001. The NLA is 100 percent of the median of the local fees in accordance with Section 1833(h)(4)(B)(viii) of the Act for tests for which the NLA was first established on or after January 1, 2001.

Each year, new laboratory test codes and corresponding fees are added to the FS. Payment for new tests is established based on one of these methodologies:

- ❖ Crosswalking – An existing test or combination of tests with similar methodology and resources is used as a basis for the payment amount
- ❖ Gapfilling – Used when there is no other test with similar methodology and resources, and MACs develop a payment amount for the test

Payment Amounts for Services Furnished on and After January 1, 2018

Based on private payor rates from “applicable laboratories” reported to the Centers for Medicare & Medicaid Services (CMS) by “reporting entities,” the payment amount for a test on the new CLFS will be equal to the weighted median private payor rate for each test. An applicable laboratory must receive greater than 50 percent of its total Medicare revenues from the **CLFS and/or the Medicare Physician Fee Schedule** and at least \$12,500 in revenues from only the **CLFS** during a 6-month data collection period. The reporting entity with a tax identification number (TIN-level) will report private payor rate information to CMS for all of its components that are applicable laboratories. The weighted median private payor rate will be the new CLFS payment rate for most clinical laboratory services furnished on and after January 1, 2018. When no information for a given test is reported, crosswalking or gapfilling will be used to establish a payment amount for the test.

However, under the new CLFS, there will be no geographic adjustments to the payment amount. For more information about the new payor rates, refer to [Medicare Will Use Private Payor Prices to Set Payment Rates for Clinical Diagnostic Laboratory Tests Starting in 2018](#) and [Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule](#).

Updates to the Current CLFS

As authorized by legislation, prior to January 1, 2018, fees may be updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) and a multi-factor productivity (MFP) adjustment. The MFP adjustment will not apply in a year where the CPI-U is 0 or a percentage decrease for a year and may not result in an adjustment to the CLFS of less than 0 for a year. However, the application of the percentage adjustment may result in an adjustment to the CLFS of less than 0 for a year, and payment rates may be less than they were in the preceding year.

No Updates Under the New CLFS

Effective January 1, 2018, the CPI-U and MFP adjustment will no longer apply under the private payor rate-based CLFS.



Resources

This chart provides CLFS resource information.

Clinical Laboratory Fee Schedule Resources

For More Information About...	Resource
CLFS	CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched CMS.gov/Center/Provider-Type/Clinical-Labs-Center.html Chapter 16 of the Medicare Claims Processing Manual (Publication 100-04)
New Requirements for Collecting and Reporting Data Under CLFS	Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System
All Available Medicare Learning Network® (MLN) Products	MLN Catalog
Provider-Specific Medicare Information	MLN Guided Pathways: Provider Specific Medicare Resources
Medicare Information for Patients	Medicare.gov

Hyperlink Table

Embedded Hyperlink	Complete URL
Medicare Will Use Private Payor Prices to Set Payment Rates for Clinical Diagnostic Laboratory Tests Starting in 2018	https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-17.html
Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule	https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf
Chapter 16 of the Medicare Claims Processing Manual	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf
Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1619.pdf
MLN Catalog	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MLNCatalog.pdf
MLN Guided Pathways: Provider Specific Medicare Resources	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf



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