CLINICAL LABORATORY SERVICES PAYMENT SYSTEM

*payment***basics**

Revised: October 2026

Clinical laboratory services are tests on specimens from the body (such as blood or urine) that are used to diagnose and treat patients. Under Part B, Medicare covers medically reasonable and necessary laboratory services that are ordered by a physician or a qualified nonphysician practitioner when they are provided in a laboratory that is certified by CMS. With a few exceptions, Medicare does not cover routine screening tests unless directed by law. Covered screening tests (with some restrictions) include those for cardiovascular disease and colorectal, prostate, and cervical cancer.

Clinical laboratory services are furnished by laboratories located in hospitals and physician offices, as well as by independent laboratories. Services may also be furnished by laboratories located in dialysis facilities, nursing facilities, and other institutions, but frequently these tests are paid under other Medicare payment systems.

The majority of laboratory services do not involve the work of a physician; these services are paid under the clinical laboratory fee schedule (CLFS), described in this document. Unlike most other Medicare services, there is no beneficiary cost sharing for CLFS services. In 2025, Medicare spending for laboratory services totaled $12.0 billion.[1] Laboratory services that include physician work, such as surgical pathology, are paid under the fee schedule for physicians and other health professionals and are described in a separate document—Physician and Other Health Professional Payment System in MedPAC's *Payment Basics* series.

The policies discussed in this document were current as of September 30, 2026. This document does not reflect proposed legislation or regulatory actions.

Defining the product Medicare buys

Medicare sets payment rates for more than 2,000 Healthcare Common Procedure Coding System (HCPCS) codes used in the CLFS. A single HCPCS code may identify more than one testing method for a given substance or more than one substance analyzed by a single method.

Setting the payment rates

Before 2018, CLFS payment rates were largely based on historical laboratory charge data that were capped and then inflated over time. In response to evidence suggesting that Medicare's CLFS payment rates were excessive, the Protecting Access to Medicare Act of 2014 (PAMA) required the CLFS to be based on private-payer rates.

Pursuant to PAMA, beginning in 2018, CMS sets CLFS rates based on the weighted median of private-payer rates. CMS establishes a weighted median for each HCPCS code based on private-payer rates and volume data reported by applicable laboratories. To be considered an applicable laboratory, an entity must meet the definition of a laboratory established by the Clinical Laboratory Improvement Amendments, bill Medicare Part B under its own national provider identifier (NPI), receive a majority of its Medicare revenues from the CLFS or the physician fee schedule, and meet the low-expenditure threshold.[2] For new laboratory tests and those for which CMS receives no private-payer information, CMS establishes payment rates using "crosswalking" or "gap-filling" methodologies. Under the crosswalking methodology, the payment rate for a laboratory service is established based on the rate of a similar service or combination of services. Gap-filling is used when no similar service exists and involves setting payment rates on information such as charges, discounts to charges, and resources required to perform the test.

In addition to changing the manner in which Medicare sets payment rates for laboratory services, PAMA established a new subcategory of laboratory services, referred to as advanced diagnostic laboratory tests (ADLTs), to which special

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payment rules apply. ADLTs are tests that are offered by only a single laboratory and meet other criteria, such as being an analysis of multiple biomarkers of DNA, RNA, or proteins that provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. The CLFS payment rate for a new ADLT is equal to the product's actual list charge for three calendar quarters. After this period, the payment rate for an ADLT is set at the weighted median of private-payer rates, but unlike the payment rates for other laboratory services, CMS collects new private-payer data and establishes a new payment rate for an ADLT every year instead of every three years.

Payment updates

Since 2018, CLFS payment rates are not updated annually based on inflation. Instead, for most services, payment rates are in effect for three years, after which CMS institutes revised payment rates based on new data collected from laboratories. For 2027, CLFS rates will be based on private-payer rates in effect from January 1, 2025, to June 30, 2025, reported by laboratories. ■

1 Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2026. *2026 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds*. Washington, DC: Boards of Trustees.

2 A laboratory meets the low-expenditure threshold if it receives at least $12,500 in Medicare revenues from the CLFS during the data-collection period. A hospital outreach laboratory does not need to bill under its own NPI to be considered an applicable laboratory. Instead, such laboratories can be identified based on their billings under the CMS–1450 14x type of bill.