CLINICAL LABORATORY FEE SCHEDULE

Target Audience: Medicare Fee-For-Service Providers

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 materials examination
- Clinical laboratory services coverage
- CLFS Updates
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Background

Sections 1833 and 1861 of the Social Security Act (the Act) provide clinical laboratory services payment information under the Medicare Part B clinical lab fee schedule for services furnished through December 31, 2017. Payment for services furnished through December 31, 2017, are made on a Medicare Part B Physician Fee Schedule (PFS). To be eligible to receive payment for furnished services, you had to be a participating Medicare laboratory prior to furnishing the services, and a treating physician or qualified nonphysician practitioner had to order the patient's laboratory services.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) added Section 1834A of the Act, which significantly revises the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the CLFS. Effective January 1, 2018, Medicare uses certain private payor rate information reported by applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the CLFS.

Types of Materials Examination

Clinical laboratory services involve examining materials derived from the human body that provide patient information for diagnosis, prevention, or disease treatment, or to assess a medical condition:

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

Clinical Laboratory Services Coverage

Medicare may cover diagnostic clinical lab tests that meet the 1988 Clinical Laboratory Improvement Amendments (CLIA). CLIA establishes quality standards for all human-derived specimen laboratory testing. The Secretary of HHS must certify the laboratories that perform the clinical tests. Medicare covers medically necessary and reasonable diagnostic clinical laboratory services to diagnose or treat 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 screenings (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 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
- Other diseases

For more information about covered screenings and preventive services, refer to the Preventive Services Provider Resources webpage.

CLFS Updates: Payments for Services Furnished On and After January 1, 2018

PAMA establishes that the Medicare payment amount for a test on the CLFS generally is equal to the weighted median of the private payor rates determined for the test, based on the data that is collected during a data collection period and is reported to the Centers for Medicare & Medicaid Services (CMS) during a data reporting period. The statute also provides for a phase-in of payment rate reductions for the first 6 years of the revised payment system. Specifically, for the first 3 years after implementation (Calendar Year [CY] 2018 through CY 2020), payment rate reductions for most CLFS tests cannot be more than 10 percent per year and, for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. There are no geographic payment adjustments under the new CLFS.

Through notice and comment rulemaking, CMS established the requirements for a laboratory to be an "applicable laboratory," which is a laboratory that must collect applicable information for reporting to CMS. To be an "applicable laboratory," a laboratory must meet the CLIA definition of a laboratory in the Code of Federal Regulations (CFR) at 42 CFR 493.2 and, by its own billing National Provider Identifier (NPI), must meet the "majority of Medicare revenues" threshold (that is, receive more than 50 percent of its total Medicare revenues from the CLFS and/or PFS) and low expenditure threshold (that is, receive at least $12,500 in Medicare revenues for CLFS services) during a data collection period.

The determination of "applicable laboratory" is made at the NPI level but the reporting of applicable information is done at the Tax Identification Number (TIN) level (by the "reporting entity"). In the CY 2019 PFS final rule, CMS made two revisions to the regulatory definition of applicable laboratory: 1) Effective January 1, 2019, Medicare Advantage plan revenues are excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold); and 2) Effective January 1, 2019, hospitals that bill for their non-patient laboratory services may use Medicare revenues from the Form CMS 1450 14X Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

PAMA statute also creates a new subcategory of clinical diagnostic laboratory tests (CDLTs) called advanced diagnostic laboratory tests (ADLTs) that meet certain criteria. The test must be covered under Medicare Part B, be offered and furnished only by a single laboratory, and not sold for use by another laboratory except the single laboratory (or a successor owner). Additionally, ADLTs must meet one of the following criteria:

- The test is cleared or approved by the Food and Drug Administration
- The test meets all of the following criteria:
  - Is an analysis of multiple biomarkers of DNA, RNA, or proteins (statutory)
  - When combined with a unique, empirically derived algorithm, 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 (statutory and regulatory)
  - Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests (regulatory)
  - May include other assays (regulatory)

If CMS receives no applicable information for an ADLT or a CDLT that is assigned a new or substantially revised HCPCS code on or after the date of enactment of PAMA (that is, April 1, 2014), and which is not a new ADLT, the statute specifies that payment for the test will be determined on the basis of a crosswalking methodology or a gapfilling process:

- **Crosswalking:** Payment is based on an existing test or test combinations with similar methodology and resources
- **Gapfilling:** Medicare Administrative Contractors (MACs) determine payment when there are no other tests with similar methodology and resources

For more information about the new payer rates, refer to the Medicare Learning Network® (MLN) MLN Matters® Article, CY 2019 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment and the Medicare Clinical Diagnostic Laboratory Tests Payment System final rule.

Resources

Table 1. 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
CLFS Updates	CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html
Laboratory Services in the Medicare Claims Processing Manual	CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf
Latest Updates on CLFS (annual laboratory public meetings)	CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html
Medicare Learning Network® Catalog	CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MLNCatalog.pdf
New Requirements for Collecting and Reporting Data Under CLFS, MLN Matters® Article SE1619	CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1619.pdf

Table 2. Hyperlink Table

Embedded Hyperlink	Complete URL
42 CFR 493.2	https://www.ecfr.gov/cgi-bin/text-idx?SID=56bbde913ecf3ba972ede535304137f6&mc=true&node=se42.5.493_12&rgn=div8
1833	https://www.ssa.gov/OP_Home/ssact/title18/1833.htm
1834A	https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm
1861	https://www.ssa.gov/OP_Home/ssact/title18/1861.htm
CLIA	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
CY 2019 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11076.pdf
Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule	https://www.federalregister.gov/d/2016-14531
Preventive Services Provider Resources	https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/ProviderResources.html