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

Medicare Learning Network®

Official CMS Information for
Medicare Fee-For-Service Providers

Clinical Laboratory Fee Schedule

PAYMENT SYSTEM FACT SHEET SERIES

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This publication provides the following information about the Clinical Laboratory Fee Schedule (CLFS):

- Background;
- Coverage of clinical laboratory services;
- How payment rates are set; and
- Resources.

Background

Under Sections 1833 and 1861 of the Social Security Act (the Act), outpatient clinical laboratory services are paid on a 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. You, as the laboratory, physician, or medical group, must accept assignment. Accepting assignment means that you will be paid the Medicare allowed amount as payment in full for your services.

Clinical laboratory services involve the following types of examination of materials derived from the human body for the purpose of providing 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; or
- Other examination of materials.

Coverage of Clinical Laboratory Services

Clinical laboratory services must 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. In addition, clinical laboratory services must be medically reasonable and necessary to the overall diagnosis and treatment of the patient's condition. Laboratories that perform clinical laboratory tests must be certified by the Secretary of the Department of Health & Human Services. For more information about the laboratory certification process, visit http://www.cms.gov/CertificationandComplianc/10_Labs.asp on the Centers for Medicare & Medicaid Services (CMS) website.

Covered clinical laboratory services are furnished in:

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

Medicare does not cover routine screening tests, with the exception of the following preventive screening services for beneficiaries who meet certain conditions:

- Cardiovascular disease screening blood tests;
- Screening Pap tests;
- Colorectal cancer screening tests;
- Prostate Specific Antigen screening blood tests;
- Diabetes screening tests;
- Human Immunodeficiency Virus infection screening tests; and

- Screening for chlamydia, gonorrhea, syphilis, and hepatitis B with the appropriate Food and Drug Administration (FDA) approved/cleared laboratory tests, used consistent with FDA approved labeling, in compliance with CLIA regulations, and ordered by the primary care physician or practitioner (for claims with dates of service on or after November 8, 2011).

For more information about preventive services, visit http://www.cms.gov/PrevntionGenInfo on the CMS website. For more information about CLIA regulations, visit http://www.cms.gov/CLIA/01_Overview.asp on the CMS website.

How Payment Rates Are Set

Each Medicare Administrative Contractor pays for services based on the local geographic area, and the 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; or
- A national limitation amount (NLA) for the Healthcare Common Procedure Coding System (HCPCS) code.

For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of all local FS amounts. For tests for which NLAs were first established on or after 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. Each year new laboratory test codes and corresponding fees are added to the FS. Fees may be updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U), as authorized by legislation. The table below shows the CLFS update for calendar years (CY) 2010 through 2012.

Calendar Year	Clinical Laboratory Fee Schedule Update
2010	-1.9 percent
2011	-1.75 percent
2012	0.65 percent

For CYs 2011 through 2015, Section 3401(l) of the Affordable Care Act requires that the CPI-U update is reduced by a multi-factor productivity (MFP) adjustment and by 1.75 percentage points. 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. The MFP for CY 2012 is 1.2 percent. The CPI-U update is adjusted by the MFP, resulting in a 2.4 percent update for CY 2012 (3.6 percent – 1.2 percent = 2.4 percent). Next, the 1.75 percent reduction is applied, resulting in a 0.65 percent CLFS update for CY 2012.

Section 3122 of the Affordable Care Act re-instituted reasonable cost payment for clinical laboratory tests performed by hospitals with fewer than 50 beds in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011.

A cervical or vaginal smear test (Pap smear) is paid the lesser of the local fee or the NLA, but not less than a national minimum payment amount. The national minimum payment amount for the cervical or vaginal smear in CY 2012 is $14.97, which includes the 0.65 percent annual update for CY 2012.

Resources

For more information about clinical laboratory services and the CLFS, visit http://www.cms.gov/center/clinical.asp and http://www.cms.gov/clinicallabfeesched on the CMS website. You may also refer to Chapter 16 of the "Medicare Claims Processing Manual" (Publication 100-04) located at http://www.cms.gov/Manuals/IOM/list.asp and the "Laboratory" section of the Medicare Learning Network® publication titled "MLN Guided Pathways to Medicare Resources Provider Specific" booklet at http://www.cms.gov/MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf on the CMS website. To find Medicare information for beneficiaries (e.g., Medicare basics, managing health, and resources), visit http://www.medicare.gov on the CMS website.

This fact sheet was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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